Sunset 2028
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), & § 205.606
Spring 2026

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

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2026 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2026 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period 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 § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:

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

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

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

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

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

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

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

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

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. 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)).’’:

- Agar-agar
- Animal enzymes
- Calcium sulfate-mined
- Carrageenan
- Glucono delta-lactone
- Tartaric acid

§ 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)).’’:

- Cellulose

- Chlorine materials
    - (i) Calcium hypochlorite
    - (ii) Chlorine dioxide
    - (iii) Hypochlorous acid—generated from electrolyzed water
    - (iv) Sodium hypochlorite
- Potassium hydroxide
- Potassium lactate
- Silicon dioxide
- Sodium lactate

Agar-agar

Reference: § 205.605(a)(2)
Technical Report: 1995 TAP; 2011 TR; 2025 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Agar-agar has been used as a food additive for over 350 years. Current uses in food include stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. Agar-agar can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. A useful characteristic of agar-agar is its ability to withstand high temperatures. Since agar-agar is practically tasteless and does not require the addition of cations to form gels, it doesn't interfere with taste profiles. Agar-agar can be used in foods in combination with other thickening or gelling agents. Agar-agar is classified as generally recognized as safe (GRAS) by the FDA.

Manufacture
Agar-agar is a mixture of polysaccharides derived from the cell walls of red algae (seaweed) that live in marine environments, mainly from the cultivated genus *Gracilaria*. The amount and composition of agar-agar produced is highly variable within and across individuals, species, locations, and time of year [2025 TR, lines 169-170]. Specific manufacturing processes are generally confidential.

Algae are cultivated on floating rafts, bottom cultivation or in tanks or ponds. Algae that washes ashore may also be gathered. Algae are harvested, washed, and dried by sun or in ovens.

Prior to extraction, the *Gracilaria* species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution); others may receive mild acidic pretreatments. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides that produce agar-agar with increased gel strength. Without this pretreatment, the gels extracted from *Gracilaria* species would be too weak for most commercial production [2025 TR, lines 138-142]. Other algal species (*Gelidium* and *Pterocladia*) have a more active natural process that results in higher gel strength and lower gelling temperatures, but these species are much more difficult to cultivate; demand for the agar-agar from these species is high for use in pharmacology and microbiology applications, and shortages have occurred [2025 TR, lines 146-151].

After pretreatment, the agar-agar is extracted with boiling or hot water, followed by filtration. Water is removed from the gel through a freeze-thaw process or by mechanical pressure. The gel is then dried with hot air and may be shredded or milled, resulting in a finished product of flakes, strips, or powder.

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

- **Agar** is permitted as a soil amendment for use in initial mushroom spawn production (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).

- **Agar** is permitted. See Table 6.3 Extraction solvents and precipitation aids (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Microorganisms are permitted. Microbial preparations may contain substrates derived from agricultural or biological substances such as milk, lactose, soy, **agar**, etc. May also contain permitted carriers (see Table 6.3 & 6.4 Carriers). Includes starter and dairy cultures and other preparations of microorganisms normally used in product processing (Table 6.4 - Ingredients not classified as food additives, CAN/CGSB-32.311-2020).

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

- **Agar** is permitted in products of plant origin, milk-based products, and meat products (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- **Agar** is permitted in food of plant origin, although exclusions of the GSFA still apply. **Agar** is permitted in food of animal origin, although exclusions of the GSFA still apply (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Agar** is permitted as an additive (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Agar-agar** is not explicitly mentioned in the regulations.

Ancillary Substances

According to EU regulations, gel strength may be standardized by the addition of dextrose and maltodextrin or sucrose. Various materials may be used in the production process, but these steps are all followed by washing [2025 TR, 485-488]. After filtering of the crude gel, researchers mention the possible use of bleach or amylase, or precipitation with isopropanol, to remove algal residue [2025 TR, lines 490-491].

Human Health and Environmental Issues

Industrial agar-agar production requires large quantities of both alkali materials for pretreatment and energy to sustain high temperatures for several hours [2025 TR, lines 295-296]. The typical process takes 2-4 hours for extraction, consumes energy and water (15-20 times the weight of dry algae used, not including washing or freeze-thawing), and generates waste [2025 TR, lines 296-300]. These materials are costly in terms of waste disposal and exposure to employees and the environment.

Discussion

In 2011, the Handling Subcommittee voted unanimously to add agar-agar to the § 205.605(b) list of allowed synthetics, while retaining the nonsynthetic listing at § 205.605(a). However, based on public comments, the Subcommittee ultimately determined that the classification determination should be made after the Guidance NOP 5033-1, Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, was finalized. That Guidance has been completed, and the 2025 TR concludes that the most widely used form of agar-agar – alkali-extracted – is synthetic [2025 TR, line 472].

Given that current uses likely include synthetic agar-agar, the Handling Subcommittee is considering recommending the addition of synthetic agar-agar to the National List, while retaining the nonsynthetic listing as well, to align the regulation with practice.

Questions to our Stakeholders

1. What form(s) (nonsynthetic or synthetic) of agar-agar are currently in use in organic products?
2. Is agar-agar commonly used in organic products?

Animal enzymes

Reference: § 205.605(a)(3) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).
Technical Report: 2000 TAP; 2011 TR; 2015 Limited Scope TR (ancillary substances in enzymes)
Petition(s): N/A
Past NOSB Actions: 11/2000 meeting minutes and vote; 11/2007 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients [2011 TR, lines 140-142]. Animal enzymes, such as rennet, are used as a coagulant to curdle milk to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect.

Manufacture
Traditionally, the fourth stomach of calves or goat kids is dried, cleaned, and then sliced into pieces, before being stored in either whey or saltwater. Vinegar or wine can be added to lower the pH. After allowing the solution to sit for a few days, it is filtered repeatedly. A small amount of boric acid is added to the filtrate. In industrial production, the stomach is minced, and the pH adjusted by adding hydrochloric acid and sodium phosphate [2011 TR, lines 444-458].

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

- Enzymes are permitted as soil amendments and as production aids. Derived from plants, **animals** or microorganisms through the action of microorganisms are permitted (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Enzymes are permitted. Derived from plants, **animals** or microorganisms. Examples include, but are not limited to, bromelain, **bovine liver catalase**, ficin, **animal lipase**, malt, **pancreatin**, **pepsin**, **trypsin**, proteases and carbohydrases. **Animal-derived enzymes** shall be free of Specified Risk Material (SRM). This annotation will be reviewed at the next revision of the standard (Table 5.2 - Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- The following sources of enzymes are permitted: 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 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

- The following sources of enzymes are permitted: 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 - Processing aids, CAN/CGSB-32.311-2020).

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

- In the processing of food, the following products and substances may be used: (a) preparations of micro-organisms and **food enzymes** normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production (Processed food production rules, EC No. 2018/848).
- For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including **food enzymes** to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008 of the European Parliament and of the Council and, where applicable, in accordance with national provisions based on Union law (Food additives and processing aids, EC No. 2021/1165).
- **Enzymes** and micro-organisms are permitted silage additives, only authorised to ensure adequate fermentation (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).
- **Enzymes** and micro-organisms are permitted zootechnical additives (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).

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

- Specific criteria for additives and processing aids: a) binders, anti-caking agents, emulsifiers, stabilizers, thickeners, surfactants, coagulants: only natural sources are allowed; b) antioxidants: only natural sources are allowed; c) preservatives: only natural acids are allowed; d) colouring agents (including pigments), flavours and appetite stimulants: only natural sources are allowed; e) probiotics, **enzymes** and micro-organisms are allowed; f) antibiotics, coccidiostatics, medicinal substances, growth promoters or any other substance intended to stimulate growth or production shall not be used in animal feeding (Livestock and livestock products: Nutrition, CXG 32-1999).
- Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only: sea salt; coarse rock salt; yeasts; **enzymes**; whey; sugar; or sugar products such as molasses; honey; lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority (Livestock and livestock products: Nutrition, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Fodder preservatives such as the following may be used: a. bacteria, fungi and **enzymes**; b. natural products of food industry; c. plant based products; d. vitamins and minerals subject to 5.5.6. (Animal Nutrition, IFOAM NORMS 2014).
- Preparations of micro-organisms and **enzymes** commonly used in food processing may be used, with the exception of genetically engineered microorganisms and their products. Cultures that

are prepared or multiplied in-house shall comply with the requirements for the organic production of microorganisms (Ingredients, IFOAM NORMS 2014).

- Additives and processing aids from biological sources, such as fermentation cultures, **enzymes**, flavors, and gums must be derived from naturally occurring organisms by the use of biological, mechanical, and physical methods. Nonorganic forms are allowed in organic products only if there are no organic sources (Source and Manufacturing Process, IFOAM NORMS 2014).
- These may be used as ingredient or processing aids with approval from the control body: organic certified micro-organisms; preparations of micro-organisms; **enzymes and enzyme preparations** (Preparations of Micro-organisms and Enzymes for use in food processing, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Enzymes** are permitted (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Enzymes** are permitted (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Enzymes** are permitted (Table B.1 - Additives for alcohol beverages, JAS 1606 Organic Processed Foods).
- **Enzymes** are permitted (Table A.1 - Substances used in the preparation etc., JAS 1607 Organic Feed).
- Any feeds other than those (feeds) listed below must not be given **enzymes** or microorganisms (excluding those that have been produced using recombinant DNA technology) (Feeding, JAS 1608 Organic Livestock Products).

Ancillary Substances

Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients. In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation. 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. These additives must be generally recognized as safe (GRAS) or be FDA approved food additives for this use [2015 TR, lines 34-40].

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 [2015 TR, lines 54-59]. 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 [2015 TR, lines 72-81].

Ancillary Substances by Food Additive Functional Class

Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide, calcium stearate, magnesium silicate/talc, magnesium sulfate.

Carriers and fillers	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate, 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, purity gum (starch), saccharose, sorbitol, soy flour, sunflower oil, trehalose, vegetable oil, microcrystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	Sodium benzoate, potassium sorbate, ascorbic acid, 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	Maltodextrin, betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers	Acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Human Health and Environmental Issues

Producing or using animal enzymes does not negatively impact biodiversity or the environment. Since only small quantities are used, and the enzymes break down naturally, their release poses no environmental threat.

Discussion

There are no direct substitutes for animal-derived enzymes; an enzyme must be replaced with another that performs the same function. For example, one replacement for animal-sourced rennet in cheese production is genetically engineered chymosin, though its use is not compatible with organic food standards because of excluded methods involved in its creation [2011 TR, lines 809-812]. The 2000 TAP report indicated that animal enzymes could potentially be sourced from organic livestock.

During the comment period for the 2021 Spring meeting, most participants supported keeping animal enzymes on the National List. Comments highlighted the lack of organic animal enzymes, difficulties in establishing a consistent organic source, and cost concerns. Many noted that alternatives are insufficient for making certain varieties of cheese. Only one opposing comment called for further research into the necessity of catalase, animal lipase, pancreatin, pepsin, and trypsin.

Questions to our Stakeholders

1. What is the feasibility of producing animal enzymes from organic livestock? What would be barriers?
2. Are there any concerns regarding source materials from non-organic sources?
3. What challenges do certifiers encounter when verifying the origin and compliance of animal-derived enzymes?
4. What is the environmental impact of animal-derived enzymes vs. microbial/fermentation-based alternatives?
5. Are all of the animal enzymes listed necessary and being used in organic production?

Calcium sulfate-mined

Reference: § 205.605(a)(8)
Technical Report: 1996 TAP; 2001 TAP
Petition(s): 2000
Past NOSB Actions: 09/1996 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

- Coagulate in tofu manufacturing. Calcium sulfate is essential for traditional, soy-based tofu.
- Yeast food and dough conditioner, water conditioner.
- Firming agent (in canned foods).
- Jelling ingredient.
- Baking powder.
- Anticaking agent.

Manufacture
Calcium sulfate is produced either by mining naturally occurring mineral deposits or as a byproduct of industrial processes. The listing restricts calcium sulfate to mined sources, and mined gypsum is the primary source. After crude gypsum is mined in open-cast quarrying or via deep mining, it is ground and separated. It is normally sold in pure form but may contain impurities of calcium carbonate and natural occurring silica. These impurities are typically present at low levels and are reduced through physical processing such as crushing, screening, washing, or drying, but the material is not chemically synthesized or purified. Synthetic calcium sulfate can form as a by-product from many different processes, including from emissions from fossil fuel power stations. The material is generally recognized as safe (GRAS) by the FDA.

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

- Calcium is permitted with the following origin/usage conditions: calcium carbonate (calcitic limestone), calcium magnesium carbonate (dolomitic limestone), calcium silicate, and **calcium sulphate (gypsum), all from mined sources**. Other biological or mineral sources, such as shells from aquatic animals (for example, oyster shell flour), aragonite, eggshell meal and lime from sugar processing. Calcium chloride derived from naturally occurring brines and not chemically treated. Prohibited forms include slaked limestone (calcium hydroxide); quicklime (calcium oxide); **calcium sulphate produced using sulphuric acid and calcium products that have been used in controlled atmosphere storage** (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Calcium sulphate (gypsum)** is permitted as a soil amendment with the following origin/usage conditions: **from mined sources** are allowed; **calcium sulphate produced using sulphuric acid is prohibited**. To correct calcium and sulphur deficiencies and soil salinity problems (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Calcium sulphate (gypsum) from mined sources** is permitted; **calcium sulphate produced using sulphuric acid is prohibited** (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

- **Calcium sulphate (gypsum)** is permitted. Sulphates produced using sulphuric acid are prohibited. May be used: a) as a carrier for cakes and biscuits; b) for soybean products; and c) for bakers' yeast (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).

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

- **Calcium sulphate (gypsum)** is permitted in products of natural origin containing calcium sulphate at various degrees of hydration. Minimum content of nutrients (percentage per weight): 25% CaO; 35% SO_3. Calcium and sulphur expressed as total CaO + SO_3. Fineness of grind: at least 80% to pass through a sieve with a 2 mm mesh width; at least 99% to pass through a sieve with a 10 mm mesh width. From 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply (Annex II: Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- **Calcium sulphate** is permitted in products of plant origin as a carrier (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- **Calcium sulphate** is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- **Gypsum (calcium sulphate)** is permitted, only from natural sources/origin (Table 1 - Substances for use in soil fertilizing and conditioning, CXG 32-1999).
- **Calcium sulphate** is permitted in food of plant origin: soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10); cakes, cookies and pies (e.g. fruit-filled or custard type); yeast and like products; soybean protein products; fermented soybean products. **Calcium sulphate** is not permitted in food of animal origin (Table 3 - Ingredients of non-agricultural origin, CXG 32-1999).
- **Calcium sulphate** is permitted for plant products as a coagulation agent (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Calcium sulfate** is permitted as an additive for soybean products, confectionery, and in bakers' yeast (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- In the cases where it is difficult to obtain the spawns specified in (a)-(c), spawns [can be] cultured by using the following cultivation substances: 1) yeast extract, 2) malt extract, 3) sugar, 4) glucose, 5) calcium carbonate, 6) **calcium sulfate** (Spawns, JAS 1605 Organic Products of Plant Origin).
- Gypsum (calcium sulfate) is permitted with the following criteria: natural substances or substances derived from natural sources which have not undergone any chemical treatment (Table A.1 - Fertilizers and soil improvement substances, JAS 1605 Organic Products of Plant Origin).
- **Calcium sulfate** is permitted with the following criteria: limited to the use as a coagulant, or in confectionery, prepared legumes/beans, or baker's yeast (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Calcium sulfate** is permitted (Table B.1 - Additives for alcohol beverages, JAS 1606 Organic Processed Foods).

Ancillary Substances

None reported in the 2001 TAP.

Human Health and Environmental Issues
Calcium sulfate may be obtained from natural sources, with mined gypsum being the primary natural source. Gypsum is one of the most widely used minerals worldwide, and the United States is the largest producer. Gypsum is mined across many regions of the United States and Canada, with a significant share of production concentrated in a small group of leading states. Most deposits occur as gypsum in the dihydrate form, although anhydrite also occurs naturally. The mining of calcium sulfate involves quarrying or blasting and the use of heavy equipment, generating gypsum dust in the process. This dust can affect air quality and can be a potential exposure hazard to humans and other animals. There are no other known negative effects of toxicity and/or persistence in the environment caused by production of calcium sulfate from these methods, if standard regulations for proper mining activities are followed.

Discussion
In organic handling and processing, calcium sulfate is utilized because it is naturally derived and minimally processed with a long history of safe use. Its necessity is limited to specific applications, such as traditional tofu production, where few alternatives provide equivalent functionality without compromising product quality or organic principles. In past sunset reviews, manufacturers and trade associations have emphasized its use in tofu production. It was also noted that calcium sulfate was used in the brewing industry to adjust the mineral content of water. One interest group asked that its use be limited to coagulation of bean curd, noting evidence was not available for its use in other food applications. During the last sunset review in 2021, the Board agreed that this material satisfies the OFPA evaluation criteria and unanimously supported the relisting of calcium sulfate.

Questions to our Stakeholders
1. Are there any alternative coagulants or processing aids that could replace calcium sulfate without compromising quality or organic principles?
2. Are there specific applications where calcium sulfate is essential versus optional?
3. How would limiting or restricting its use impact your production processes or product offerings?

Carrageenan

Reference: § 205.605(a)(9)
Technical Report: 1995 TAP; 2011 TR; 2016 Limited Scope TR; 2026 Limited Scope TR

Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987 – misspelled as 'carageenan'); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Carrageenan is a food additive used as an emulsifier, thickener, and gelling compound primarily in meat and dairy products. It is often used as a vegan alternative to animal-sourced gelatin. Carrageenan provides a 'mouthfeel' similar to that of fatty foods and thus may be used in low fat or dairy replacement products (Zhang et al., 2024a). Carrageenan is listed as an FDA-approved food additive at 21 CFR 172.620, and is allowed for use as an emulsifier, stabilizer or thickener in foods in the amount necessary to have the

intended effect. In Europe, carrageenan is not allowed in infant formula, while China restricts the amount allowed in baby formula (Zhang et al. 2024a).

Manufacture

Carrageenan is made through three common methods of production: alcohol process, gel process, and semi-refined process. In all processing methods, the finished carrageenan is produced through a fairly simple process of heating edible red algae in a hot alkali solution, typically using potassium hydroxide. The cellulose from the plant is then removed through centrifugation and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder for addition to foods.

The three main kinds of carrageenan (kappa, iota, and lambda carrageenan) are extracted from different seaweed species (or are extracted from seaweed at different life stages) and are distinguished chemically by the number and position of ester sulphates on the carbohydrate units in the molecules. This information is relevant, as the different types have different properties and uses in the food industry, but are not distinguished in food labelling:

- Kappa-carrageenan – forms strong gels in combination with potassium ions and is used primarily in dairy products.
- Iota-carrageenan – forms soft gels in the presence of calcium ions.
- Lambda-carrageenan – does not gel and is used to thicken dairy products.

Historically, the seaweed used to make carrageenan grew in small patches along the coastline and required a large amount of labor to harvest (Langford, 2024a). Larger scale farming of seaweed was unsuccessful until 1974, when a location in the South Philippines had all the necessary components to allow for seaweed farms to thrive. About a decade later seaweed farming also became viable in Indonesia (Langford, 2024a). An innovation in processing reduced the cost of processing carrageenan in the 1990s (Langford, 2024a). This allowed seaweed farming to emerge in other tropical regions, but 92 percent of the supply still comes from the Philippines and Indonesia (Langford, 2024b). In 2021, Indonesian seaweed (carrageenan) production totalled 7.1 metric tons (Langford, 2024b). Processing plants are located in China, Philippines, and Indonesia (Zhang et al., 2024a). China is the top country in terms of carrageenan processing, both domestically and through heavy investment in processing facilities in Indonesia (Zhang et al., 2024b).

In 2018, the carrageenan industry was valued at $500 million, with production equal to 60,000 metric tons in China, Indonesia, and Philippines (Taylor, 2019). The volume of carrageenan used in dairy products and processed meats remained relatively stable between 2009 and 2019, while the amount used for bakery, confectionary, and beverages increased by a sizeable amount (Zhang et al., 2024a). The market for carrageenan is expected to increase 3.8 percent in volume and 5.4 percent in value between 2023 and 2030 (Zhang et al., 2024a).

International Acceptance

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

Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids. By exception, isopropyl alcohol may be used to derive carrageenan.

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

The EEC allows carrageenan as an additive to organic dairy foods, and its use is prohibited in all baby formula.

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

Permitted, although exclusions and limitations as specified by the GSFA still apply.

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM allows carrageenan as a food additive with no annotations.

Japan Agricultural Standard (JAS) for Organic Production
Limited to use in dairy products.

Ancillary Substances
The 2026 limited-scope TR indicates that manufacturers may include the following ancillary materials in food-grade carrageenan [2026 TR lines 578-595]:

- sugars for standardization purposes (e.g., dextrose or maltodextrin)
- sodium, potassium, or calcium salts to obtain specific gelling or thickening characteristics
- emulsifiers carried over from drum-drying processes (e.g., xanthan gum)

Food-grade refined carrageenan produced by alcohol precipitation contains approximately 90% anhydrous carrageenan, 8% moisture, and 2% inorganic salts (mainly chlorides). Food-grade refined carrageenan manufactured by the gel-press method contains about 77% anhydrous carrageenan, 8% moisture, and up to 15% inorganic salts (mainly chlorides). Additionally, both food-grade refined and semi-refined carrageenan may not contain more than 0.1% of methanol, ethanol, or propane-2-ol, singly or in combination.

Environmental Issues and Human Health Concerns
Seawood farming, specifically for the seaweed raised for carrageenan, has several environmental issues. Seaweed farms can be a lucrative business for small scale aquaculture as the overhead is low, requiring at the most basic level nylon strings or netting in shallow coastal waters. The turnover to harvest is quite short, at only 6 weeks. The harvested product is shelf-stable and can be stored for a relatively long period of time (Langford, 2024b) However, increased demand for seaweed has resulted in the establishment of some farms that involve first destroying important nearshore habitats like mangrove swamps or eelgrass beds to provide growing environments. Drifting mats from the established farms can also smother other nearby habitats, such as coral reefs. For example, when seaweed farming was introduced to India, to promote aquaculture for carrageenan, the seaweed rapidly invaded and smothered coral reefs in a nearby marine reserve (Baglar, 2008). Some coastal communities have improved their economic condition, but for some the economic gains were short lived due to environmental collapse (Langford, 2024b).

Research into the ecological effects of seaweed farming indicates that the diversity of fish is reduced in and around the seaweed farms. Proximity to seaweed farming reduces the size and growth rates of sea grass beds. A proposed environmental mitigation strategy is to move seaweed farming to deeper, sandy-bottomed areas and ensure that the farms are a safe distance from vulnerable habitats like coral reefs (Kelly et al.,2020).

The impacts of seaweed aquaculture can be positive. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, remove impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some effects of climate change (Duart et al., 2017). In addition, it is a food source that requires no freshwater or chemical inputs, making it an attractive alternative to terrestrial-based crops. Lastly, seaweed farming can provide a viable alternative to fishing in areas where overfishing has depleted fish populations.

Current scientific evidence on the human health impacts of food-grade carrageenan remains mixed and, in several areas, limited. Research continues to differentiate food-grade carrageenan from *degraded carrageenan* (including poligeenan), which is not used in food and is known to cause gastrointestinal ulceration and cancer in animal models. Although some low-molecular-weight fractions can arise during extraction or through microbial fermentation, the extent and relevance of in-vivo degradation of food-grade carrageenan remain uncertain.

Digestive Fate. Studies using simulated digestive systems indicate that carrageenan largely resists digestion in the stomach and small intestine but may undergo microbial fermentation in the colon. Recent work suggests that gut bacteria—particularly species within *Bacteroides*—may degrade carrageenan and produce metabolites capable of influencing inflammatory responses. However, the physiological significance of these interactions in humans has not been fully established.

Toxicology. Available toxicological data do not identify safety concerns for carrageenan consumed at typical levels found in food. Carrageenan shows low acute toxicity in mammals, and only two isolated human allergic reactions have been reported. Reviews, including by McKim et al. (2019), have found no evidence that food-grade carrageenan is carcinogenic, genotoxic, or tumor-promoting. Intake estimates vary widely among populations, and the ADI for carrageenan remains "not specified" due to limited data on exposure and long-term effects.

Impurities. Food-grade carrageenan may contain low levels of naturally occurring or process-related impurities such as formaldehyde or semi-carbazide. Regulatory evaluations, including the European Food Safety Authority (EFSA's), conclude that these impurities occur at levels far below those associated with health risks and do not pose a concern for consumers.

Inflammation and Ulceration. Evidence regarding carrageenan's role in intestinal inflammation is conflicting. In vitro studies suggest that carrageenan can contribute to inflammatory signaling under certain conditions, especially when inflammation is already present. Limited human data—including a small trial in ulcerative colitis patients—suggest that individuals with pre-existing inflammatory bowel disease may be more susceptible to adverse effects. Additional research indicates that inflammatory outcomes may depend on interactions between carrageenan, gut microbiota, and the integrity of the epithelial barrier.

Metabolic Effects. Findings related to metabolic outcomes are inconsistent. Some studies in animals and humans suggest that carrageenan may negatively affect glucose tolerance or insulin signaling, while others show potential lipid-lowering benefits or no adverse metabolic effect. Large-scale epidemiological data from France indicate a statistical association between carrageenan intake and increased risk of type 2 diabetes, though causal pathways remain unclear and limitations of self-reported dietary data apply.

Antiviral and Antibacterial Properties. Several studies demonstrate that specific forms of carrageenan—particularly iota-carrageenan—exhibit antiviral and antibacterial activity. Iota-carrageenan nasal sprays have shown clinical benefit in reducing common cold symptoms, and in vitro studies indicate potential inhibition of pathogens such as herpes simplex virus and *Chlamydia* species. These therapeutic findings remain separate from food uses.

Discussion

The relationship between carrageenan and the National Organic Standards Board (NOSB) has been marked by decades of evolving deliberation, reflecting shifting scientific perspectives, regulatory interpretations, and consumer expectations within organic food production. Notably the following:

At its 1995 meeting, the NOSB classified carrageenan as nonsynthetic, based on a TAP report outlining its manufacturing process. The decision was made without guidance from NOP 5033-1, which was published in 2016, and there was no clarification on which forms were considered nonsynthetic. Carrageenan is listed as nonsynthetic under 7 CFR 205.605(a), so certifiers generally treat it as such.

In 2012, the NOSB Handling Subcommittee suggested moving carrageenan to § 205.605(b) due to updated manufacturing information, recommending a review after new classification guidance from NOP. The full Board later proposed relisting carrageenan at § 205.605(a) with specific CAS numbers allowed and prohibiting use in infant formula; this recommendation was not implemented.

In 2016, the NOSB recommended removing carrageenan from § 205.605(a), but NOP did not act on these proposals noting that public comments suggested carrageenan remained necessary due to a lack of fully natural substitutes.

In 2021, NOSB voted against removing carrageenan from the list due to reaffirmed necessity.

Another point that should be taken up is the classification of carrageenan as a non-synthetic given Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016a) [2026 TR lines 486-562]. While it appears that all or virtually all carrageenan on the market is synthetically produced via alkaline extraction, stakeholder feedback on the feasibility of other extraction methods that avoid solvents would assist in further guiding this determination.

Some stakeholders in the past have questioned whether carrageenan remains truly necessary in organic processed foods, noting that while certain manufacturers consider it functionally useful, it is unclear whether its roles—such as gelling, stabilizing, or texturizing—lack feasible organic-compliant alternatives in all current applications.

Questions to our Stakeholders

1. Which organic products and uses currently rely on carrageenan?
2. What type of carrageenan (semi-refined / refined) and forms (kappa-, iota-, or lambda-) are being used in organic products?
3. Are carrageenan alternatives available to replace all uses?
4. Are there feasible methods to produce carrageenan as a non-synthetic (according to NOP 5033-1)?
5. Are there any concerns about ancillary ingredients used with carrageenan?
6. What restrictions or annotations might be appropriate for carrageenan? What new science on the safety or human health effects has emerged?

References:

Bagla, P. (2008) Seaweed invader elicits angst in India. Science. 320:1271.

Bixler, HJ (2017) The carrageenan controversy. Journal of Applied Phycology, 29:2201–2207.

Duarte CM., Wu J, Xiao X, Bruhn A, Krause-Jensen D (2017) Can seaweed farming play a role in climate change mitigation and adaptation? Frontiers in Marine Science 4.

Kelly EL, Cannon AL, Smith, JE (2020) Environmental impacts and implications of tropical carrageenophyte seaweed farming. Conservation Biology 34(2): 326-337.

Langford, Z. 2024a. Preface. *Globalisation and livelihood transformations in the Indonesian seaweed industry*. Taylor & Francis. Oxon and New York.

Langford, Z. 2024b. Introduction. *Globalisation and livelihood transformations in the Indonesian seaweed industry*. Taylor & Francis. Oxon and New York.

Taylor, A. 2019. Seaweed farming for food and fuels. Chemical and Engineering News, 97(34).

Tobacman JK, Bhattacharyya S, Borthakur A, Dudeja PK. (2008) The carrageenan diet: not recommended. Science 321(5892):1040-1041.

Zhang, J., Langford, Z. and Waldron, S., 2024a. The global carrageenan industry. In *Globalisation and livelihood transformations in the Indonesian Seaweed industry* (pp. 23-50). Routledge.

Zhang, J., Waldron, S., Langford, Z., Julianto, B. and Komarek, A.M., 2024b. China's growing influence in the global carrageenan industry and implications for Indonesia. *Journal of Applied Phycology*, *36*(2), pp.639-660.

Glucono delta-lactone

Reference: § 205.605(a)(14) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.
Technical Report: 2002 TAP; 2016 TR
Petition(s): 2002
Past NOSB Actions: 09/2002 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly silken tofu, and is generally thought to be the only material that can produce the physical and sensory components favored in that product. In tofu production, GDL serves as a coagulant. GDL can also be used as a curing or pickling agent, leavening agent, pH control agent and sequestrant. It is also used in feta cheese in place of lactic acid bacteria to reduce pH. Less tangy than citric acid, GDL slowly undergoes hydrolysis in water and converts to gluconic acid to produce a tangy flavor in food applications. GDL is generally recognized as safe (GRAS) by the FDA [2016 TR, lines 587-590, 597-599].

Manufacture
GDL is produced by crystallization from an aqueous solution of gluconic acid. There are a variety of ways gluconic acid can be produced. The most common method to produce gluconic acid is called the Blom process, where gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium

hydroxide or calcium carbonate is added to the fermentation process to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via fermentation and acid-base reactions [2016 TR, lines 500-525]. Other processes to make GDL involve oxidation of D-glucose with bromine water (which is not allowed by the National List annotation) and the use of purified enzymes [2016 TR, lines 281-282].

International Acceptance

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

- **Glucono delta lactone** is permitted with the following origin/usage conditions: production by the oxidation of D-glucose with bromine water is prohibited (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

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

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

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

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

Ancillary Substances

GDL is >99% pure and has no ancillary substances present. GDL is often sold in formulation with other additives specifically designed for the application. These substances should be reviewed separately as they are not ancillary substances.

The 2016 technical report (TR) states that there are many chemical methods of gluconic acid synthesis other than bromine water. It also states that some enzymes used in the production of GDL may be genetically engineered. Standard of purity for GDL is listed in the Food Chemicals Codex. It must be >99% pure. It can contain up to 4mg/kg of lead. Standards for other heavy metals are not listed. Up to 0.5% glucose contaminant is allowed. No reports of GDL contamination were found on the Internet or in CAB or Pub Med databases as of September 29, 2015 [2016 TR, lines 283-284, 646-649].

Human Health and Environmental Issues

The Handling Subcommittee was unable to document any environmental or human health issues associated with the production or consumption of GDL. Some sources have indicated it may cause minor bladder discomfort and/or back pain.

The 2016 technical report examined human health and environmental impacts of GDL use and production but found low to no risk. The TR did raise the question of classification, given the substance is produced via fermentation and acid-base reactions similar to the production of citric acid, which is also listed as nonsynthetic at § 205.605(a). The TR also raised concerns about the potential for GMO enzymes used in the production of GDL via the oxidation with enzymes production method (not the most common form of production).

Discussion

The original 2002 petition and primary use of GDL is for the coagulation of tofu. Other coagulants for tofu include magnesium chloride, calcium chloride, calcium sulfate, and magnesium sulfate [2016 TR, lines 256-257]. Acids such as citric or lactic acid can be used as well. Each of these substances produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu; sulfate salts produce soft tofu and GDL produces silken tofu. Citric and lactic acids produce acidified tofu that is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

For the 2021 sunset review, the Handling Subcommittee requested public comments regarding the use of GDL in organic processed foods other than tofu production. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic product. Further, the Handling Subcommittee asked if alternative tofu coagulants such as calcium and sulfate salt would be sufficient to produce all forms of tofu if GDL were removed from the National List. In response, companies commented that alternatives on the National List result in distinctly different and firmer tofu and that GDL is critical for silken, jelly-like tofu. Several tofu manufacturers commented in favor of retaining GDL. Lastly, the Subcommittee asked stakeholders whether GDL produced from enzymes should be prohibited or further restricted due to concerns about GMOs, an issue that is referenced in the 2002 TAP and noted as an issue for ongoing monitoring. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the Board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means; however, no information was presented on the commercial viability of this approach.

NOSB Review

At the Spring 2021 NOSB meeting, the Subcommittee received limited commentary from stakeholders about GDL. However, one commenter did indicate that the misalignment between the current annotation – which prohibits GDL made from bromine water and ensures only nonsynthetic GDL is used in organic – and the 2016 TR, which suggests GDL can be made from a variety of different chemical means, leaves the listing exposed to synthetic GDL production and some excluded methods. That comment suggests a clarification of the annotation may be needed.

The Handling Subcommittee heard from several certifiers about somewhat limited use of the material among their members. Although use was limited, support for relisting was clear. One non-profit stakeholder shared a concern flagged by the Subcommittee about potential negative impacts from mining for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only. Another stakeholder suggested GDL is nonessential, though several certifiers reported that a number of their members and clients are currently using GDL. Public comments at the last sunset review supported continued listing of GDL on the National List. Some public comments called for further review on the synthesis of gluconic acid to ensure only non-synthetic sources, potentially leading to further clarification of the annotation.

At this time, this material satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports the relisting of glucono delta-lactone.

Questions to our Stakeholders

1. How widespread is the use of GDL in organic applications?
2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?

4. Is the lack of international acceptance significant?
5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Tartaric acid

Reference: § 205.605(a)(28) Tartaric acid - made from grape wine.
Technical Report: 2011 TR
Petition(s): 2011 Petition to remove from § 205.605(b) - made from malic acid
Past NOSB Actions: NOSB meeting review 11/1995; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Tartaric acid naturally occurs in many plants, especially grapes, bananas, and tamarinds. It can also be produced synthetically from maleic acid, but the synthetic version was removed from the National List in 2013. Tartaric acid can be used to create several different salts, including tartar emetic (antimony potassium tartrate), cream of tartar (potassium hydrogen tartrate), and Rochelle salt (potassium sodium tartrate). The primary uses of tartaric acid are associated with its salts [2011 TR, lines 53-56].

Tartaric acid and its salts have a wide variety of uses. These include use as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. It has been used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks [2011 TR, lines 58-63].

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to rise without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties. Cream of tartar is used to make cake frosting and candies [2011 TR, lines 69-74].

Although tartaric acid is isolated from wines, it may also be used in winemaking to alter acidity. For non-grape wines, it may be added to increase acidity or to help prevent degradation of the flavor from unwanted microorganisms [2011 TR, lines 76-83].

Tartaric acid and its salts (i.e., potassium acid tartrate, sodium potassium tartrate acid) are classified by FDA as generally recognized as safe (GRAS).

Manufacture
The 2011 TR states that tartaric acid is an unwanted component present at the end of the winemaking process, and with the addition of calcium hydroxide and potassium hydroxide, it can be precipitated out as

a calcium or potassium tartrate salt [2011 TR, lines 151-155]. The salts can then be purified to tartaric acid. The TR details the most prevalent processes for production of tartaric acid [2011 TR, lines 221-234]:

> The nonsynthetic form of tartaric acid is isolated from the undesirable wastes created during the winemaking process. These unwanted materials include grape pomace, grape stalks, grape seeds, and vine, which naturally contain a significant amount of tartaric acid. An excess of tartaric acid is generally unwanted in winemaking because it creates a sour and undesirable taste. The available excess tartaric acid is precipitated using potassium hydroxide or calcium hydroxide in order to create a wine with the desired taste. Then the resulting waste mixture is evaporated. This process produces a powder containing calcium or potassium tartrate and additional substances including polyphenols and tannins. The powder is then sold to facilities that purify tartaric acid. The process for extracting tartaric acid from waste materials is similar to the processing of excess tartaric acid, in that potassium hydroxide is added to the waste mixture. Activated carbon is also added to remove unwanted pigmentation. The potassium tartrate is precipitated by adding saturated pure tartaric acid solution and then the precipitate is redissolved with acidic water at 70°C. Potassium and sulfate ions must be removed from the remaining solution, so cation exchanges are performed followed by evaporation. The solution is then crystallized at 4°C.

International Acceptance

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

- Tartaric acid from lees is permitted for beverages (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Tartaric acid from lees is permitted for beverages (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

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

- Tartaric acid (L(+)-) is permitted in products of plant origin and mead (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- Tartaric acid (L(+)-) is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- Tartaric acid is permitted in food of plant origin, although exclusions of the GSFA still apply. Tartaric acid is not permitted in food of animal origin (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Tartaric acid is permitted as an additive and a processing and post-harvest handling aid only for wine (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- L-Tartaric acid is limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

- L-Tartaric acid is permitted (Table B.1 – Additives for alcoholic beverages, JAS for Organic Processed Foods).

Ancillary Substances
None identified.

Human Health and Environmental Issues
If appropriate use patterns and disposal recommendations are followed, it is unlikely that tartaric acid would cause harm to the environment. The biodegradability of tartaric acid is 95% after 3 days and the substance is considered readily biodegradable. No bioaccumulation is to be expected [2011 TR, lines 390-391].

Discussion
Tartaric acid is a critical component in several areas of food handling. While baking powder can be replaced with baking soda, cream of tartar must be added to maintain the baking powder properties. While tartaric acid is made from grapes, it is also an important component in winemaking and there are no organic alternatives. Other natural components of grapes, such as malic acid, can be used to alter the acidity of wine and possess preservative characteristics, but they often impart a different taste than tartaric acid [2011 TR, lines 438-440].

Public comments submitted for the previous sunset review raised the possibility of increasing the supply of organic tartaric acid. However, in order for tartaric acid to be labeled "organic," sulfur dioxide could not be used in the winemaking process prior to extraction of the tartrate salts – i.e., it would have to be a byproduct of wine that will be labeled "organic" or the relevant byproducts would need to be separated from the wine made from organic grapes prior to addition of sulfur dioxide. Production of wine labeled "organic" remains low, relative to wine labeled "made with organic grapes" that has sulfur dioxide added, and it is not clear whether removal of the tartrate salts prior to use of sulfur dioxide is a viable pathway for production. Accordingly, it is unclear whether there is capacity for significant production of organic tartaric acid.

For pH adjustment, citric acid and malic acid can be used; however, they impart certain flavors to the product. If a grape flavor is needed, tartaric acid would be the first choice.

Due to low impacts on human health and the environment and the advantageous qualities that tartaric acid lends to baked goods, wines, and other products, tartaric acid is a good candidate for relisting.

Questions to our Stakeholders
1. Is organic tartaric acid available in significant quantities?
2. Can tartrate salts be removed from wine made from organic grapes prior to addition of sulfur dioxide?
3. Are there other barriers to production of organic tartaric acid that could be lowered?

Cellulose

Reference: § 205.605(b)(11) Cellulose (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.
Technical Report: 2001 TAP; 2016 TR
Petition(s): 2001

Past NOSB Actions: 10/2001 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Annotation change effective 12/27/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028
Subcommittee Review

Use
In the powdered form, cellulose is used as a processing aid for filtration of juices and an anti-caking agent ingredient for use in shredded cheese. Regenerated cellulose casings are used for peelable/non-edible hot dog and sausage casings. Some of these uses in organic handling have been around since before the enacting of OFPA, with cellulose allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture
Cellulose is available in several different forms, each with varying functional qualities used for multiple purposes in organic handling. There are two specific forms of cellulose currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing.

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth [2016 TR, lines 55-56]. Most commercially available cellulose (powdered) is produced from wood pulp or other plant sources, e.g., corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc. The plant material goes through a delignification process that results in a chemically changed synthetic substance. The original process for making regenerated cellulose casing, the viscose method, dates to the 1890's and converts cellulose fibers into regenerated fibers and films. With some minor changes to the process, it is still in use today. Cellulose is considered Generally Regarded as Safe GRAS under 21 CFR 121.101 [2016 TR, line 320].

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

- For collagen casings, collagen shall be derived from animal sources. If derived from cattle, collagen shall be guaranteed free of Specified Risk Material (SRM). Other ingredients (such as, but not limited to cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture that remain in the collagen casing when it is used shall respect the requirement provided in 1.4 a) of CAN/CGSB-32.310. Permitted for poultry sausage (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Cellulose is permitted as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings. The TCF (Totally Chlorine Free) method of bleaching is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

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

- Cellulose is permitted in gelatine (Authorized food additives and processing aids, EC No. 2021/1165).
- Cellulose is permitted in products of plant origin and gelatine (Processing aids and other products, EC No. 2021/1165).

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

- Cellulose is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Cellulose is permitted as a processing and post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Powdered cellulose is limited to the use as a filter aid in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

The 2016 TR referenced three sources of commercially available cellulose that do not include any ancillary substances [2016 TR, line 133], yet suggested that the inclusion of ancillary substances potentially increased functional efficacy. The 2016 TR provided additional information about the use of ancillary substances [2016 TR, lines 131-154]. Some examples are polymers and co-polymers that improve absorption, increase or decrease viscosity, and increase yield. Food grade filtering systems composed mainly of cellulose may also include various polymers or substances like fiberglass for ease of handling, or to increase throughput. Enzymes may improve the shelf life of grated cheeses that use cellulose as an anti-caking agent, although cellulose without additives is commercially available and clearly identified. Sausage casings, including those made from regenerated cellulose, may be lubricated with vegetable, animal or mineral oil in the shirring process. Synthetic sausage casings may be formulated with mineral oil, propylene glycol and lecithin. Regenerated cellulose sausage casings are commercially available without additives.

Ancillary items were discussed at the 2016 meeting in St. Louis, where the NOSB decided that a proposal on ancillary items was needed. The subcommittee prepared a January 3, 2017 proposal titled *Ancillary Substances Permitted in Cellulose*, which listed 6 functional classes of ancillary substances for cellulose: shirring aid, humectant, coating, coating with Ph control, peeling aid, and synthetic binder. The proposal states that any ancillary items in these classes would not need to be reviewed, while a new functional class of ancillary substances would need to be reviewed. At the 2017 Spring meeting, in Denver the proposal was sent back to subcommittee because it contained mistakes (e.g. vinyl chloride was listed as an ancillary substance). At the Fall 2017 meeting, the Handling subcommittee chair reported that work would not continue on this topic, and that it would be better to work on ancillary substances in cellulose after the NOP finishes their review of ancillary substances. At the previous sunset review, ancillary substances were not discussed. The 2024 Research Priorities of the NOSB included the following statement (page 157): *Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.*

Human Health and Environmental Issues

During previous reviews, public comment, as well as the 2016 TR, raised concerns regarding the use of wood pulp as a source for cellulose and the environmental impact that logging of primary forests and replacement with monoculture plantations may have. Concerns were also raised about environmental problems caused by waste cellulose generated from food processing. The 2016 TR states that conversion of cellulosic food wastes, as well as cellulose waste from filtration aids and/or spent casings, into useful products is the subject of research. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs, and governmental regulations [2016 TR, lines 396-401].

Discussion

Most of the discussion pertained to the text of the previous sunset review, where the ancillary substances were listed in a table by functional class. After a lengthy discussion, the subcommittee members agreed that the categorization was not included in the TR, leading us to track down the history of the ancillary substance use in cellulose. The question remains whether cellulose requires ancillary substances.

Questions to our Stakeholders

1. For which products, if any, is cellulose currently essential for organic handling?
2. Which ancillary substances are used with cellulose, for the three allowable uses in handling (filtration, anti-caking, and regenerative casings)?
3. Is it still necessary to allow cellulose with ancillary substances, given that versions with no ancillaries are available?

Chlorine materials – Calcium hypochlorite

Reference: § 205.605(b)(12)(i) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.
Calcium hypochlorite
Technical Report: 2006 TR (Chlorine materials- Handling); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Calcium hypochlorite is an Environmental Protection Agency (EPA)-registered pesticide (OPP Nos. 014701). Calcium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2) [2006 TR, lines 77-79].

Calcium hypochlorite is an "indirect" food additive approved by Food and Drug Administration (FDA). Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hypochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 117-122].

Manufacture
Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuum dried [2006 TR, lines 151-152].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- The following chlorine compounds are permitted: a) **calcium hypochlorite**; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) **calcium hypochlorite**; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- **Calcium hypochlorite** is not explicitly mentioned in the regulations.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
- **Calcium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production
- **Calcium hypochlorite** is not explicitly mentioned in the regulations.

Ancillary Substances
Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues
Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in a 2006, 2011, and 2025 Technical Reports (TR) (referenced above).

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders
1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Chlorine dioxide

Reference: § 205.605(b)(12)(ii) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(ii) Chlorine dioxide

Technical Report: 2006 TR (Chlorine materials); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments [2006 TR, lines 66-67]. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases [2011 TR, lines 149-150].

Manufacture
To form chlorine dioxide, sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid is reacted with methanol (CH_3OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate [2011 TR, lines 206-210].

International Acceptance

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

- Teat dips and udder wash are permitted. Substances, such as alcohol, iodine, hydrogen peroxide, **chlorine dioxide** and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations. Chlorhexidine can be used as a post-milking teat dip if alternative germicidal agents and physical barriers have lost their effectiveness (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted: a) calcium hypochlorite; b) **chlorine dioxide**; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) **chlorine dioxide**; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

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

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

[International Federation of Organic Agriculture Movements (IFOAM) Norms]

- **Chlorine dioxide** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

[Japan Agricultural Standard (JAS) for Organic Production]

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

Ancillary Substances

Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders

1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: § 205.605(b)(12)(iii) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iii) Hypochlorous acid - generated from electrolyzed water.

Technical Report: 2006 TR (Chlorine materials - Handling); 2011 TR - Crops; 2015 TR; 2025 TR (pending post)

Petition(s): 2015

Past NOSB Actions: 2016 NOSB Recommendation to add; 10/2021 recommendation

Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Hypochlorous acid is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SWDA) (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 118-122].

Manufacture
Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode but permits ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hypochlorite acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. [2006 TR lines 48-68].

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) **hypochlorous acid generated via electrolyzed water**; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) **hypochlorous acid generated via electrolyzed water**; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Hypochlorous acid** is not explicitly mentioned in the regulations.

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

- **Hypochlorous acid** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Hypochlorous acid** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Any substances other than **hypochlorous acid water** and sodium hypochlorite, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of **hypochlorous acid water** produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Hypochlorous acid water** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Ancillary Substances

Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues

Hypochlorous acid, generated from electrolyzed water, is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at § 205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above.).

As formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at a lower chlorine concentration and is likely safer for health and the environment than other currently listed chlorine sanitizers.

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food safety regulations under the Food

Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders

1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Sodium hypochlorite

Reference: § 205.605(b)(12)(iv) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iv) Sodium hypochlorite

Technical Report: 2006 TR (Chlorine materials); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Sodium hypochlorite is an EPA-registered pesticide (OPP No 014703). Sodium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

Sodium hypochlorite is an "indirect" food additive approved by FDA. Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). These hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 117-122].

Manufacture
Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na_2CO_3) [2006 TR, lines 156-159].

International Acceptance

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) **sodium hypochlorite**. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) **sodium hypochlorite** (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

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

- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Sodium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).
- **Sodium hypochlorite (e.g. as liquid bleach)** is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Any substances other than hypochlorous acid water and **sodium hypochlorite**, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite sodium chloride** is permitted with the following criteria: limited to those obtained by electrolyzing the salt solution (limited to those using salt containing no less than 99% sodium chloride) (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of hypochlorous acid water produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Ancillary Substances

Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above.).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders

1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Potassium hydroxide

Reference: § 205.605(b)(26) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.
Technical Report: 2001 TAP; 2016 TR
Petition(s): 2001 petition; 2011 petition to amend annotation
Past NOSB Actions: 10/1995 meeting minutes and vote; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to the National list 12/21/2000 (65 FR 80548); National List amended 11/03/2003 (68 FR 62215); National List amended 05/28/2013 (78 FR 31815); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base, and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent [2016 TR, lines 22-23].

Potassium hydroxide in poultry chill water increases the shelf life of broilers and other meat birds by killing various spoilage organisms, particularly when used in combination with lauric acid. To a limited extent, potassium hydroxide will also act as a preservative in the curing of certain foods, such as olives [2016 TR, lines 278-281].

Potassium hydroxide is also used in the lye peeling of fruits and vegetables. The annotation permits this use exclusively for peeling peaches. Peaches peeled for canning or pickling typically use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution - about 10% - and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and citric acid is used to neutralize the pH of the fruit [2016 TR, lines 88-92].

For certain grains and legumes, potassium hydroxide is used to remove tannins that interfere with nutrient uptake. For example, it increases the solubility of proteins in soybeans. It can also be used as a solvent to determine protein quality and total soluble protein in assays. Potassium hydroxide can be used as a substitute for the traditional calcium hydroxide (lime water) used to remove the pericarp of corn, a process known as nixtamalization - part of the process to make masa from corn. Furthermore, the removal of the pericarp or bran from corn, sorghum, and other grains increases the nutritional quality and digestibility of those grains [2016 TR, lines 296-306].

Manufacture
The 2016 technical report (TR) notes that the FDA specifies that food grade potassium hydroxide (KOH) is made by the electrolysis of potassium chloride (KCl) and water in the presence of a porous diaphragm [21 CFR 184.1631(a)]. Potassium chloride, also known as muriate of potash, is a naturally occurring mineral, with the main global source being Canada. Most U.S. production occurs in New Mexico and Utah. Potassium chloride is put into aqueous solution and is electrolyzed by various processes. Diaphragm cells will produce a liquor that contains 10-15% by weight of KOH and about 10% KCl. Most of the KCl crystallizes by evaporation and subsequent cooling during concentration. The concentrated KOH is about a 50% solution with about 0.6% KCl. Potassium hydroxide is regarded by the chemical industry as a by-product of the process for producing hydrochloric acid [2016 TR, lines 203-217].

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

- Aquatic plant products may be extracted by using the following substances in order of preference: a) substances in Table 4.2 Extractants; b) **potassium hydroxide**; c) sodium hydroxide provided the amount of solvent used does not exceed the amount necessary for extraction. The operator shall provide an affidavit from the manufacturer that proves the need to use sodium hydroxide. Sodium benzoate and potassium sorbate may be used as preservatives for water-extracted aquatic plant products. All other preservatives are prohibited unless listed in Table 4.2 (Column 1 or 2) with the exception that Formulants used in crop production aids are prohibited (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).

- Humates, humic acid and fulvic acid are permitted if mined; produced through microbial activity; extracted by physical processes; or with: a) Table 4.2 Extractants; or b) **potassium hydroxide**—**potassium hydroxide** levels used in the extraction process shall not exceed the amount required for extraction. Levels (mg/kg) of arsenic, cadmium, chromium, lead and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilising Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Plant extracts, oils and preparations are permitted as production aids with the following origin/usage conditions: permitted extractants include fats and oils (such as cocoa butter, lanolin and animal fats); alcohols; water; or substances listed on Table 4.2 (Column 2) other than Formulants used in crop production aids. Extraction with other solvents is prohibited except with, in order of preference: a) **potassium hydroxide**; or b) sodium hydroxide; provided the amount of solvent used does not exceed the amount necessary for extraction. The operator shall provide an affidavit from the manufacturer that proves the need to use sodium hydroxide. For control of pests (e.g., diseases, weeds and insects). Clove oil is permitted for sprout inhibition in potatoes (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Potassium hydroxide (caustic potash)** is permitted for pH adjustment. Prohibited for use in lye peeling of fruits and vegetables (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).
- **Potassium hydroxide (caustic potash)** is permitted (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Caustic potash** is permitted (Annex IV: Authorised products for cleaning and disinfection, EC No. 2021/1165).

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

- **Potassium hydroxide** is permitted for pH adjustment for sugar processing (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Seaweed and seaweed products are permitted with the following conditions for use: as far as obtained by (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or **potassium hydroxide** solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation (Appendix 2: Fertilizers and soil conditioners, IFOAM NORMS 2014).
- Algal preparations are permitted with the following conditions for use: as far as obtained by (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or **potassium hydroxide** solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).
- Caustic potash (**potassium hydroxide**) is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Potassium hydroxide** is permitted with the following criteria: limited to the use as a pH control agent in the processing of sugar (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).

- Sodium hydroxide and **potassium hydroxide** are permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS 1608 Organic Livestock Products).

Ancillary Substances
The TR did not identify any ancillary substances.

Human Health and Environmental Issues
The amount of fresh water used in the lye peeling process and the release of effluent that increases biological oxygen demand are two key environmental concerns about the lye peeling process. The release of potassium hydroxide in untreated or improperly treated wastewater will raise the pH and potassium levels of the body of water receiving it. Soap manufacturing can also threaten environmental health in the immediate vicinity of the soap manufacturing facility, as nutrient loading of potassium may result in algal blooms and eutrophication [2016 TR, lines 341-344, 353-355].

Human health toxicity mainly involves the risk of ingestion of concentrated potassium hydroxide. Ingestion of lye inevitably leads to esophagus damage, with over 90% of the cases also involving stomach damage [2016 TR, lines 376-377].

Discussion
In 1995, the NOSB approved the addition of potassium hydroxide to § 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read —prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process. The 2001 TAP review for that expansion noted that the stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances. The 2001 TAP review also noted that the environmental effects that had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step. Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Subcommittee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercial processing methods used for peaches, the NOSB favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Alternatives to potassium hydroxide include naturally occurring alkali substances such as sodium carbonate and sodium bicarbonate. The drawbacks of these natural materials are that they are less soluble than potassium hydroxide and they may not be effective in raising the pH. For fruit peeling, mechanical, steam, or hand peeling is an alternative. As noted above, while potassium hydroxide was not initially allowed for peeling in organic processing, subsequent petitions and NOSB decisions allowed for its limited use for the peeling of peaches.

Questions to our Stakeholders

1. For which organic products or processes do you currently use potassium hydroxide, and what functional role does it serve?
2. Are heat or mechanical methods not sufficient for peach peeling? Are there alternatives?

Potassium lactate

Reference: § 205.605(b)(27) Potassium lactate - for use as an antimicrobial agent and pH regulator only.
Technical Report: 2015 TR
Petition(s): 2004; 2014 NOP memo to NOSB
Past NOSB Actions: 04/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

Potassium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as generally recognized as safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas [2015 TR, lines 209-211].

Manufacture

Potassium lactate is generally produced from natural (fermented) lactic acid, which is then reacted with potassium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch [2015 TR, lines 102-103, 115-116].

International Acceptance

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Potassium lactate** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Potassium lactate** is not explicitly mentioned in the regulations.

Ancillary Substances
None reported in the 2015 TR.

Human Health and Environmental Issues
There does not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, the necessary precursor of potassium lactate. However, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment [2015 TR, lines 772-773].

Discussion
Many stakeholders view this listing as "enormously complicated," saying that it is the procedural history that is complicated and not the material itself. Potassium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the National List was based on the fact that both of the materials used to produce potassium lactate (lactic acid and potassium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Potassium lactate was added to the National List effective January 28, 2019. In past sunset reviews, the Handling Subcommittee found significant merit to keep potassium lactate on the National List at § 205.605(b) with the annotation: for use as an antimicrobial agent and pH regulator only.

In previous rounds of public comments, a majority of commenters were in support of relisting potassium lactate. A review of the use tables supplied by several associations indicate that potassium lactate is a widely used material. Some stakeholders asked why both potassium and sodium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as low sodium meat alternatives, that require potassium lactate specifically.

Questions to our Stakeholders

1. Are there any new technologies or ingredients that could replace the lactates?
2. What applications are Potassium and Sodium Lactate used in conjunction?

Silicon dioxide

Reference: § 205.605(b)(29) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.
Technical Report: 1996 TAP; 2010 TR, 2025 TR
Petition(s): 2010 petition to remove
Past NOSB Actions: 09/1996 minutes and vote; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL 12/21/2000 (65 FR 80548); National list amended 05/28/2013 (effective 11/03/2013) (78 FR 31815); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

Synthetic amorphous silica (SAS), the most common form of the chemical compound silicon dioxide used commercially, is used as a food additive for various functions including as:

- a flow agent in syrups, oligodextrines, fruit snacks and cheese powders
- an anticaking agent in foods, specifically spice blends and organic seed pellets
- a stabilizer in beer production (filtered out of the beer prior to final processing)
- an adsorbent in tableted foods
- a carrier
- a defoaming agent

Silicon dioxide is also available in the form of crystalline silica. The crystalline silica form is not used in food manufacturing.

Additionally diatomaceous earth (DE) is a nonsynthetic form silicon dioxide. DE has its own listing on the National List at § 205.605(a)(10). Its use is limited as a filtering aid only.

Manufacture

SAS can be manufactured by two main pathways.

1. Thermal process: The thermal process forms silicon dioxide through high-temperature fusion yielding pyrogenic silica, commonly known as fumed silica.
2. Wet process. The wet process forms silicon dioxide through silicic acid polymerization yielding precipitated silica, silica gel or colloidal silica.

The 2025 technical report (TR) provides an extensive explanation of both processes [2025 TR, lines 728-950]. Both the thermal and wet manufacturing processes result in a synthetic substance according to the decision tree [2025 TR, lines 979-997].

International Acceptance

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

Silicon dioxide (silica) is allowed with no restrictions on sources or uses except for maple syrup production, at CAN/CGSB-32.311 Permitted Substances List Table 6.3-Ingredients classified as food additives, and Table 6.5-Processing Aids. CAN/CGSB-32.310 7.2.12.6 allows silica powder in organic maple syrup production only for simple filtration with a filter press to remove suspended solids.

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

Silicon dioxide (E551) is permitted as outlined in Annex V, Section A1, which covers food additives, including carriers. It can be used in cocoa, herbs, spices in dried powdered form, flavorings, and propolis. However, there are specific conditions and limits for cocoa; it is only allowed for use in automated dispensing machines.

Annex V, Section A2 pertains to processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It also permits “silicon dioxide gel or colloidal solution,” albeit with a restriction on plant origin.

Furthermore, Annex V, Part D, concerning authorized products and substances for the production and conservation of organic grapevine products in the wine sector, allows “silicon dioxide gel or colloidal solution.”

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

Silicon dioxide (amorphous) is included as INS No. 551 and is listed under CODEX guidelines specifically in Annex 2, Table 3.1. This table lists additives permitted for use under specified conditions in certain organic food categories or individual food items. Amorphous silicon dioxide is allowed in “herbs, spices, seasonings, and condiments,” such as seasonings for instant noodles. However, it is not permitted in foods of animal origin under these guidelines. Additionally, silicon dioxide is permitted in the form of a gel or colloidal solution, as outlined in Table 4 of the CODEX guidelines. This table details processing aids that may be used in the preparation of products of agricultural origin, as specified in Section 3 of the guidelines, but their use is limited to plant products only.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Silicon dioxide (amorphous) is included as INS 551 and is listed under IFOAM guidelines Appendix 4–Table 1: Approved additives and processing/post-harvest handling aids. It is allowed without limitation.

Japan Agricultural Standard (JAS) for Organic Production

Silicon dioxide (INS Number 551) is permitted as outlined in Annex A, Table A.1, for additives in organic processed foods, excluding organic alcoholic beverages. Its use is limited to processed products derived from plant sources, where it can be utilized as a gel or colloidal solution.

Additionally, these standards allow silicon dioxide as listed in Appendix B, Table B.1, for additives in organic alcoholic beverages, with no specific annotations regarding its use.

Korea: Republic of Korea (ROK) Korean Organic Act

We were unable to access the specific ROK standards that detail the allowance of silicon dioxide in organic food handling.

Switzerland: Federal Office for Agriculture (FOAG), Switzerland Organic Ordinances, Organic Farming Ordinance (SR 910.18), EAER Ordinance on Organic Farming (SR 910.181), FOAG Ordinance on Organic Farming (SR 910.184)

Silicon dioxide (E551) is permitted in the form of a gel or colloidal solution, as outlined in Annex 3, Section A, which lists authorized food additives, including carriers. According to the specific restrictions set forth in these standards, silicon dioxide is allowed for products of plant origin, specifically dried powdered herbs, spices, and flavorings. For animal-origin products, it is only permitted for flavorings.

Additionally, silicon dioxide in gel or colloidal solutions is permitted in Annex 3, Section B, which covers directly used technical aids and other products that may be used to process organically produced agricultural ingredients, only for plant-origin products. Lastly, in Annex 7, Part B, which discusses feed additives for animals, colloidal silicon dioxide is also allowed as a binder and/or release agent, with no special conditions or restrictions.

Taiwan: Organic Agriculture Regulations

Silicon dioxide is permitted without specific conditions in Chapter 2, entitled "Substances Allowed for Production, Processing, Packaging, Distribution, and Sale," as shown in Table 3, which lists food additives permitted for use.

United Kingdom (Great Britain): Organic Products Regulations (2009), Retained Council Regulations (EC) (834/2007, 889/2008, and 1235/2008)

Silicon dioxide (E551) is permitted as detailed in Annex VIII, Section A, which pertains to food additives, including carriers. Specifically, it can be used for dried powdered herbs, spices, flavorings, and propolis. This standard also allows silicon dioxide to be included in preparations of foodstuffs derived from both plant and animal origins.

Additionally, Annex VIII, Section B covers processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It permits the use of silicon dioxide gel or colloidal solution solely in preparations of foodstuffs from plant origins without any specific conditions or restrictions.

Ancillary Substances

According to the 2016 NOSB Ancillary Substances Procedure, ancillary substances are intentionally added. The 2025 TR indicates that precipitated silica and silica gel may contain small amounts of sodium sulfate as an impurity. Since sodium sulfate appears to be residual from the acid-base reaction in the wet process and is not added intentionally, it appears that this does not meet the definition[2025 TR, Lines 1077-1083]

According to the 2025 TR, colloidal silica does contain stabilizing agents like aluminum oxide for the purpose of keeping SAS suspended in solution for up to six months. Certifiers should review stabilizing agents according to their ancillary substances policies[2025 TR, Lines 1085-1091].)

Human Health and Environmental Issues

<u>Human Health</u>

SAS toxicity is dependent on whether it is produced via wet processes (silica gel, precipitated silica, and colloidal silica) or thermal processes (fumed silica).

According to the 2025 TR, many recent studies have assessed the toxicity of food-grade SAS, including fumed silica and hydrated silica (such as precipitated silica, silica gel, and colloidal silica) and have not found conclusive evidence that SAS produces toxicity or harmful effects on human health when used as a food additive. Recent studies evaluating the oral toxicity of food-grade SAS in living animals have not shown adverse toxicological evidence. All studies published before 2022 indicate that oral exposure to SAS is safe.

Additionally, the 2025 TR notes recent concerns being raised by stakeholders in the food industry about the potential hazards and risks associated with SAS nanoparticles and their toxicity. The TR discusses several research studies that have been conducted. The following suggestions or results noted in the TR seem to indicate little to no impact on human health:

- SAS nanoparticles may not persist in living organisms after consumption because the material tends to form aggregates and agglomerates, or, in the case of colloidal silica, quickly polymerize.
- SAS nanoparticles may not be able to cross the mucus layer of the intestine.
- SAS nanoparticles were not internalized by the intestinal cells.
- Digested SAS nanoparticles did not induce any toxic effect on the intestinal barrier model.
- Overall absorption rates for SAS nanoparticles are relatively low and accumulation of these nanoparticles in tissue diminishes over time[2025 TR, Lines 1384-1404].

The TR did note one study that showed bioaccumulation of SAS particles in tissues—including the liver, placenta, and umbilical cord—can occur[2025 TR, Lines 1397-1399]. Also, there were some studies that discussed some specific toxicities. However, these studies are not all that relevant; in one case they used different forms of silicon dioxide (not SAS – which is used in food manufacturing) and in another case, the SAS particles were introduced intravenously (not ingested).

Lastly, the 2025 TR stated that inhalation of crystalline silica can cause silicosis. However, as stated earlier, crystalline silica form is not used in food manufacturing. The TR also noted that SAS exposure showed no evidence of adverse pulmonary effects, such as fibrosis of the lungs or any other permanent respiratory ailments.

Environmental
The 2025 TR states that while it is possible for SAS to negatively affect aquatic organisms, it is unlikely to have negative effects on the environment or biodiversity at the concentrations used in food processing [2025 TR, Lines 1178-1179].)

The SAS manufacturing processes (both thermal and wet), however, does pose some environmental concerns specifically regarding the precursors (silicon tetrachloride and sodium silicate). Silica sand, obtained through mining can lead to deforestation, biodiversity loss, soil erosion and acid drainage. However, the TR does state that most of the extracted sand is not used for SAS production but rather for hydraulic fracturing or well packing. [2025 TR, Lines 1276-1686].

Additionally, silicon tetrachloride production uses chlorine and carbon black. Chlorine contributes significantly to the environmental impact of fumed silica production due to the energy needed to obtain it via electrolysis and the aquatic implications of the chemicals used during its manufacture Carbon black is sometimes derived from petrochemical sources, significantly impacting the environment on multiple levels. [2025 TR, Lines, 1292-1300].

Lastly, sodium silicate uses large amounts of energy.

Discussion
Silicon dioxide was petitioned for removal in 2010 by RIBUS, the manufacturer of a commercially produced rice-based certified organic alternative to silicon dioxide. Data was presented in the petition claiming that a reformulation of the rice-based alternative could be substituted for silicon dioxide at a nearly 1:1 ratio. The Handling Subcommittee felt the data was limited, not published from a third-party source, and did not conclusively demonstrate its applicability in all products and processes; however, they wished to acknowledge the availability of a natural alternative. An annotation was proposed resulting in its current listing, which requires the use of organic rice hulls when commercially available.

In its last sunset review in 2021, public comments indicated that organic rice hulls are *not* a viable alternative for all current uses of silicon dioxide such as when used as:

- An anticaking agent in organic powders, including organic cheese powders, and spice and seasoning blends, where it was noted that rice hulls absorb excess moisture and clump. Additionally, it was noted that in order to achieve the desired technical effect, rice hulls must be used at a rate of 15-50% compared to 2% silicon dioxide to achieve the same effect.
- In organic dry flavors in which rice hulls have not adequately or evenly disbursed flavor actives and have taken up moisture. Additionally, increased rates render the flavor unsuitable for its intended use of flavoring.
- A flow agent for rice syrup solids.
- A clarifier in the production of beer.

Most stakeholders were in favor of relisting based on essentiality and seemed comfortable with the current annotation. However, there were a few comments that suggested NOSB should review the current annotation against the original annotation passed by the Board to ensure the intent of the original annotation is accurately conveyed.

The Handling Subcommittee reviewed the history regarding the annotation change. On the cover sheet that accompanied the Board's recommendation in 2011, the following was stated:

> "Motion to amend the annotation of the following substance: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetics allowed—Silicon

> dioxide—providing sufficient evidence showing non-synthetic alternatives are not commercially available for a specific product/process is presented.
>
> Correction made by NOP on 4/12/12: The motion as stated in the meeting transcript is: "Move to change the annotation of Silicon Dioxide on § 205.605 nonagricultural substances be synthetics allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available."

The cover sheet noted the original motion that was presented in the meeting packet. However, the Board did not vote on that motion. Rather, during the Fall 2011 meeting an alternative motion was drafted and voted on. This is the motion listed above as the correction made by NOP on 4/12/12.

The annotation was modified during the rulemaking process. NOP proposed to modify as follows: "permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available" to specify the specific alternative substance (e.g. organic rice hulls) the Board was considering at that time so that certifying agents can consistently verify that organic handlers are in compliance with the regulations as well as reduce the burden on organic handlers since they would not be required to demonstrate that all nonsynthetic alternatives to synthetic silicon dioxide were considered prior to its use.

There was also one commenter that suggested the Board limit the use of organic rice hulls when commercially available for products labels as "organic" and not for products labeled as "made with organic." This would more align with the yeast annotation. The Handling Subcommittee is seeking feedback on this idea.

The 2025 TR did evaluate alternatives to silicon dioxide. The TR explained that the silicon dioxide most commonly used in food handling cannot be obtained from nonsynthetic sources. As previously noted, the most common form used is SAS. The synthetic nature is right in the name of this substance. Natural forms, such as crystalline form or diatomaceous earth (a type of amorphous silica) are unsuitable for food applications[2025 TR, Lines 1487-1500]. The TR goes on to state that a single material that serves as a substitute for SAS in all applications was not able to be identified. Table 4 in the [2025 TR, line 1574] provides nonagricultural, nonsynthetic alternatives to silicon dioxide. The TR also notes some organic agricultural materials such as oat, barley and pelt hulls, rice and corn flours, and starches that could potentially be used for certain functionalities. As with the nonagricultural, nonsynthetic alternatives there is not one item that will work for all use cases, and these also are likely to have increased application rates similar to rice hulls, which would limit their viability[2025 TR, Lines 1637-1643].

Lastly, there has been some concern regarding whether silicon dioxide is an engineered nanomaterial. The TR authors state they were unable to classify SAS according to the definitions outlined in NOP Policy Memo 15-2 (i.e., "engineered nanomaterial"), based on the available analytical measurement data, as measurement estimates are limited in accuracy. The TR references one study whereby the researchers indicate that they do not understand SAS to be intentionally engineered under 100 nm for functional purposes. The TR references another study that states that particles between 1-100 nm are likely included in commercial products. However, in this second reference there isn't any indication that these are engineered nanomaterials, only that they are nano-sized[2025 TR Lines 1007-1069].

In reviewing the historical record (previous TRs and recommendations), there is no reference to "nanotechnology" or "nanomaterials." In the 2010 TR there is reference to the "submicron particle size" having unique physical and chemical properties[2010 TR, Lines 40-41]. Another place in the 2010 TR states that the most outstanding characteristics of amorphous silica, particularly synthetic amorphous silica, are their small particle size and high specific surface area, which determine their numerous applications [2010

TR, Lines 58-59]. It appears that previous Boards have recognized the small particle size and have not flagged these as engineered nanomaterials, which are prohibited from inclusion on the National List per NOP Policy Memo 15-2. The Handling Subcommittee is seeking feedback on this topic.

Questions to our Stakeholders

1. What is your understanding of the current listing of silicon dioxide in regards to engineered nanomaterials? Does the current listing allow silicon dioxide as an engineered nanomaterial since the substance is synthetic and their prohibition is not specified in the annotation? Or are they prohibited? Explain your rationale.
2. Should the Subcommittee consider annotating to:
    a. Only allowed synthetic amorphous silica (SAS)?
    b. Only require the use of organic rice hulls when commercially available for products labeled "organic" and not for products labeled as "made with organic?"
3. The 2025 TR lists several alternatives (both nonagricultural, nonsynthetic and organic agricultural). Do you have experience in using any of these alternatives to silicon dioxide? If so, please explain the alternative used and specific function.

Sodium lactate

Reference: § 205.605(b)(33) Sodium lactate - for use as an antimicrobial agent and pH regulator only.
Technical Report: 2015
Petition(s): 2004; 2014 NOP memo to NOSB
Past NOSB Actions: 04/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Sodium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as generally recognized as safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas [2015 TR, lines 203-204].

Manufacture
Sodium lactate is generally produced from natural (fermented) lactic acid, which is then reacted with sodium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch [2015 TR, lines 102-103, 115-116].

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

- **Sodium lactate** is not explicitly mentioned in the regulations.

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

- **Sodium lactate** is permitted in products of plant origin, milk-based products, and meat products (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).

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

- **Sodium lactate** is not explicitly mentioned in the regulations.

[**International Federation of Organic Agriculture Movements (IFOAM) Norms**]

- **Sodium lactate** is not explicitly mentioned in the regulations.

[**Japan Agricultural Standard (JAS) for Organic Production**]

- **Sodium lactate** is not explicitly mentioned in the regulations.

Ancillary Substances
None reported in the 2015 TR.

Human Health and Environmental Issues
There does not appear to be any human health concerns associated with sodium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid; however, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment [2015 TR, lines 772-773].

Discussion
Many stakeholders view this listing as "enormously complicated," saying that it is the procedural history that is complicated and not the material itself. Sodium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the National List was based on the fact that both of the materials used to produce sodium lactate (lactic acid and sodium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Sodium lactate was added to the National List effective January 28, 2019. In past sunset reviews, the Handling Subcommittee found significant merit to keep sodium lactate on the NL at § 205.605(b) with the annotation: for use as an antimicrobial agent and pH regulator only.

In previous rounds of public comments, a majority of comments were supportive of relisting sodium lactate. A review of the use tables supplied by several associations indicate that sodium lactate is a widely used material. Some stakeholders asked why both sodium and potassium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as low sodium meat alternatives, that require potassium lactate specifically.

Questions to our Stakeholders

1. Are there any new technologies or ingredients that could replace the lactates?
2. What applications are potassium and sodium lactate used in conjunction with?