Sunset 2028
Meeting 2 - Review
Handling Substances § 205.605(a), § 205.605(b)
Fall 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

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

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

- None

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 at § 205.605(b) of the National 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 document 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. In preparation for the Spring 2026 NOSB meeting, the Subcommittee asked stakeholders what form(s) of agar-agar are currently in use (synthetic v. nonsynthetic) and whether the material is commonly used in organic production.

Commenters noted that there are flaws in the Guidance NOP 5033-1 Decision Tree used to determine synthetic/nonsynthetic status and highlighted that there is a nonsynthetic process available. Commenters raised concerns about the environmental harms of seaweed production on aquatic environments, and one commenter stated that the version made from *Gracilaria* is synthetic and should be removed because of ecological impacts.

Commenters recommended aligning this listing with the 2020 NOSB recommendation on protecting marine ecosystems from harvest damage, which proposed adding the following annotation to the crop input marine microalgae listing:

> Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

The National Organic Program has previously stated that it does not plan to act on that recommendation.

Several certifiers stated that they certify operations that use agar-agar, and several others do not. One certifier noted that although they do not currently have clients using this substance, they have in the past and support keeping it available. One certifier noted that the Accredited Certifiers Association best practices advise that agar-agar as low risk and does not require active verification of nonsynthetic status.

Commenters noted that there are alternatives to agar-agar, including pectin and gums. However, a trade association noted that agar-agar has several unique qualities, including being less temperature sensitive than other alternatives, so it is useful for gels that remain firm at room temperature, and that being from seaweed allows for its use in foods that are halal, kosher, and vegan. That commenter also stated that there are not sufficient quantities of the nonsynthetic version available.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds agar-agar **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove agar-agar from the National List
Motioned by: Allison Johnson
Seconded by: Andrea Hatziyannis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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 the 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, highlighting the lack of organic animal enzymes, difficulties in establishing a consistent organic source, and cost concerns, with many noting 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.

Public comment received at the Spring 2026 meeting reflected broad support for continued listing. The input came primarily from accredited certifying agents reporting the extent of use among their certified operations and responding to the Subcommittee's questions, together with an organic policy coalition addressing sourcing. Reported use is modest and uneven across certifiers, and is purported to be obscured by the fact that many certifiers track "enzymes" generically and cannot readily separate animal-derived enzymes from microbial, fungal, or plant-derived ones. Where use was identifiable, rennet and animal lipase were clearly in active organic use—one certifier reported a single rennet product and four lipase inputs among its clients—while catalase, pancreatin, pepsin, and trypsin were not specifically identified in use this cycle, though generic tracking prevents a definitive per-enzyme conclusion. Consistent with prior reviews, the record indicates no available organic source and no direct organic-compliant substitute; the policy coalition encouraged the Board to continue the search for organic animal enzymes and, if a source is not available, to identify the barriers and how to overcome them.

On the feasibility of producing animal enzymes from organic livestock, direct comment was limited, and no commenter identified a currently available organic source. Barriers identified across the comments and prior record include the absence of a consistent commercial organic source, cost, and the structural point that the finished enzyme is itself a non-certified processing input, which complicates any requirement that its source material be organic. On concerns regarding nonorganic source materials, a certifier observed that nonorganic sources may be used in producing various § 205.605 nonsynthetic materials and cautioned that requiring only organic source materials would create significant challenges—since the final product is not itself certified—and would raise an unresolved question of whether ancillary ingredients would also need to be organic; notably, the Canadian standard requires that animal-derived enzymes be free of certain materials, which the Board may wish to note as a sourcing-integrity consideration.

Regarding verification, certifiers who addressed the question found it manageable and dependent on documentation rather than on any difficulty unique to animal enzymes. One certifier noted that the burden of collecting documentation typically falls on the operator, but that reviewing that documentation for compliance has not posed a challenge; another reported no challenges determining origin and compliance, verifying origin by email where it is not indicated on the spec sheet and requiring a Verification of Ingredient (VOI) form, absent which the input is deemed prohibited due to insufficient information. On the environmental impact of animal-derived enzymes versus microbial or fermentation-based alternatives, there was little direct comment and no comparative analysis. Finally, on whether all listed enzymes remain necessary and in use, the data confirm that rennet and animal lipase are actively used, while catalase, pancreatin, pepsin, and trypsin were not specifically reported this cycle—an inconclusive result given generic "enzyme" tracking—and, consistent with 2021, no commenter argued that any listed enzyme is unnecessary.

In sum, the comment record supports continued listing: no commenter sought removal, rennet and lipase remain in active use, no organic-compliant substitute exists, and certifiers report that origin and compliance can be verified through standard documentation. The open items are candidates for follow-up rather than obstacles to relisting—improving source-specific tracking so per-enzyme use can be confirmed, affirming SRM-free sourcing as a sourcing-integrity expectation, and determining whether the full list remains in active organic use—while the feasibility of an organic source and a formal environmental comparison remain unestablished and are best pursued through the work agenda or a limited-scope technical review.

Questions to our Stakeholders

1. Are all of the animal enzymes listed necessary and being used in organic production?

Justification for Vote

The Subcommittee finds animal enzymes **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove animal enzymes from the National List
Motioned by: Kathryn Deschenes
Seconded by: Andrea Hatziyannis
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 1

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 2021 sunset review, the Board agreed that this material satisfies the OFPA evaluation criteria and unanimously supported the relisting of calcium sulfate.
During the Spring 2026 NOSB meeting, one public commentor recommended that an annotation be in place to restrict the use of calcium sulfate only for use in making tofu. One commentor stated this material is essential in tapioca-based syrups and powders in snack bars to provide cohesive structure and balanced structure. No public commenters objected to the relisting of calcium sulfate.

Questions to our Stakeholders
1. How is calcium sulfate currently used in organic production outside of the manufacturing of tofu?
2. How would limiting or restricting its use impact your production processes or product offerings?

Justification for Vote
The Subcommittee finds calcium sulfate **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove calcium sulfate from the National List
Motioned by: Amanda Felder
Seconded by: Kathryn Deschenes
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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

Carrageenan's status has shifted over time as scientific evidence, regulatory guidance, and organic-market expectations have evolved.

- In 1995, the NOSB classified carrageenan as nonsynthetic based on a TAP report, before NOP 5033-1 provided formal classification guidance. Because carrageenan remains listed at 7 CFR 205.605(a), certifiers generally continue to treat it as nonsynthetic.
- In 2012, the Handling Subcommittee recommended moving carrageenan to § 205.605(b) in light of updated manufacturing information, but the full Board later recommended relisting it at § 205.605(a), with specific CAS numbers and a prohibition on use in infant formula. That recommendation was not implemented.
- In 2016, the NOSB recommended removing carrageenan from § 205.605(a), but NOP retained it after comments indicated it remained necessary because fully natural substitutes were not available for all uses.
- In 2021, the NOSB again voted against removal, reaffirming its necessity.

The Board should also revisit whether carrageenan is properly classified as nonsynthetic under NOP 5033-1 [2026 TR lines 486–562]. Available information suggests that all or nearly all commercial carrageenan is produced through alkaline extraction, raising questions about whether it should instead be classified as synthetic. Stakeholder input on solvent-free extraction alternatives would help inform this determination. Finally, the Board may wish to reassess whether carrageenan remains necessary in organic processed foods. While some manufacturers consider it functionally useful, the record does not clearly show that feasible organic-compliant alternatives are unavailable for all current uses.

Public Comment from Spring 2026:

The written comments received on carrageenan reflect a community that cares deeply about the same thing—the integrity of the organic label—yet arrives at different conclusions from that shared commitment. Below, the perspectives are grouped by the nature of the concern rather than by author, so the Board can consider the underlying reasoning, evidence, and real-world experience that each brings. All commenters, whether they favor removal or continued listing, engaged thoughtfully and in good faith, and each deserves to be heard on those terms.

- **Shared ground.** Nearly every commenter—on all sides—acknowledged that virtually all commercial carrageenan is produced by alkaline extraction, and many explicitly agreed the Board should revisit whether it is correctly classified as non-synthetic under NOP 5033-1. This is a point of genuine common cause.
- **Point of divergence.** Commenters part ways on two questions: (1) whether the current human-health evidence warrants precaution strong enough to remove carrageenan, and (2) whether feasible alternatives truly exist for every remaining organic application.

A number of commenters asked the Board to remove carrageenan from the National List. Their comments are heartfelt and grounded in a protective instinct toward the people who rely on the organic label, particularly vulnerable eaters. Their principal arguments:

- **Human health and the precautionary principle.** These commenters point to a growing body of independent, peer-reviewed research—several studies published in 2024 and 2025—linking food-grade carrageenan to intestinal inflammation, impaired glucose tolerance and insulin resistance, and associations with type 2 diabetes and certain cancers, with people who have inflammatory bowel disease (Crohn's, ulcerative colitis) identified as most susceptible. They urge the Board to "err on the side of caution" where the health of the public may be affected, framing organic as a refuge for those seeking to avoid uncertain additives.
- **Concern about the evidence base.** Several commenters noted a perceived pattern in which studies suggesting safety were industry-funded while independent research raised concerns, and asked the Board to weigh author affiliations and funding sources transparently.
- **Necessity / availability of alternatives.** These commenters observe that many major brands reformulated away from carrageenan years ago—including products once said to be impossible without it, such as aseptic chocolate milk—and that gums such as gellan, guar, and xanthan, "shake-well" labeling, or simply omitting the additive can serve the same functions. From their vantage point, a widely available ingredient is not necessarily an essential one.
- **Environmental footprint.** Commenters cite overharvesting of cold-water species, bio-invasive risk from cultivated warm-water species, smothering of coral ecosystems, and alkaline wastewater from processing, connecting these to organic's duty to conserve biodiversity from "farm to fork."
- **Classification and OFPA.** Citing the 2026 TR, commenters argue carrageenan should be reclassified as synthetic under NOP 5033-1 and, once synthetic, could not simply be relisted at § 205.605(a); they also recall the Board's 2016 removal recommendation that was not implemented, and ask that the Board's advisory role be respected.

One commenter went further, asking that carrageenan be listed as a "prohibited natural" at § 205.604 in addition to removal, so that the material could not return through a future reclassification. Whether or not the Board agrees, the underlying worry—protecting sensitive consumers—is sincere and deserves acknowledgment.

Commenters recommended aligning this listing with the [2020 recommendation](#) on protecting marine ecosystems from harvest damage, which proposed adding the following annotation to the crop input marine microalgae listing:

- Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions.
- Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

The National Organic Program has previously stated that it does not plan to act on that recommendation.

A trade association representing food-additive manufacturers, a national organic trade association, an organic-industry consultancy, and several accredited certifying agents supported keeping carrageenan on the National List. Their comments come from close, practical familiarity with how organic products are actually formulated and certified, and they, too, speak for real people—formulators, small processors, and consumers who value particular products. Their principal arguments:

- **Functional necessity without a full replacement.** They describe carrageenan's distinctive protein interaction, its performance at very low usage levels, its thermo-reversible and versatile gelling across pH and temperature ranges, and its synergy within multi-hydrocolloid systems. In their experience these properties are not fully matched by any single alternative—especially for plant-based dairy and meat alternatives, neutral protein and cocoa beverages, and sliceable deli products where it controls syneresis and locks particulates in suspension. They caution that delisting could constrain vegan and vegetarian product innovation.
- **Safety as affirmed by regulators worldwide.** They note that carrageenan is permitted by major regulatory and standard-setting bodies globally (FDA, EFSA, Codex, Health Canada, and others), and that its long history of food use supports continued allowance.
- **Continued market presence via equivalency.** A certifier observed that, because of international organic-equivalency arrangements, carrageenan-containing organic products would remain

available to U.S. consumers regardless of National List status, a practical consideration for the Board to weigh.

Carrageenan continues to be used in the organic sector, though reliance varies widely among accredited certifiers. One certifier reported 17 operations using 23 distinct carrageenan ingredients in more than 45 products, while others identified only a few operations or clients, and several reported no current handling clients using carrageenan. When used, carrageenan appears in dairy products, plant-based dairy alternatives, animal-protein and meat products, beer, and other beverages, where it functions as an emulsifier, thickener, gelling agent, or stabilizer, often as a vegan alternative to gelatin. Processors that still rely on carrageenan report that no workable substitute exists for some applications, particularly those requiring specific mouthfeel, texture, or syneresis control. Removal advocates, however, note that many major brands have already reformulated without it. Because most certifiers treat carrageenan as a low-risk material for verification, they generally do not track the manufacturing method used (refined or semi-refined) or the molecular form present (kappa-, iota-, or lambda-), leaving a significant information gap. Reported use figures therefore likely capture only a subset of actual use.

Questions to our Stakeholders

1. Are there products that would not be available as organic if carrageenan is not relisted?
2. If carrageenan were removed from the National List, how long would you need to reformulate affected products, and what technical challenges would you face?
3. For products you believe cannot be reformulated, have you tested alternatives such as gellan, guar, xanthan, agar, or gelatin substitutes?
4. What information can you provide about commercially available carrageenan made without alkaline extraction, including any hot-water, enzyme-assisted, or other alternative production methods and sources?

Justification for Vote

The Subcommittee finds carrageenan **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove carrageenan from the National List
Motioned by: Kathryn Deschenes
Seconded by: Allison Johnson
Yes: 1 No: 3 Abstain: 0 Recuse: 0 Absent: 0

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 genetically modified organism (GMO) enzymes used in the production of GDL via the oxidation with enzymes production method (not the most common form of production).

Discussion
The 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 produces 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 or 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.

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 substance 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 of the synthesis of gluconic acid to ensure only non-synthetic sources, potentially leading to further clarification of the annotation. The annotation was reviewed and discussed by the full Board at the Spring 2026 meeting. The Board is hesitant to add additional language to the annotation, and will ask questions of the stakeholders to understand which type of GDL is predominantly utilized in the industry, and if there would be any impact to availability if the annotation was changed. The goal is to ensure the listing is not too restrictive without understanding the alternative methods available.

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. What are the methods for production of gluconic acid synthesis other than bromine water?
5. Is there an organic integrity concern requiring an annotation change? What would the recommended changes be to the annotation?

Justification for Vote

The Subcommittee finds glucono delta-lactone (GDL) **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List:

Subcommittee Vote

Motion to remove glucono delta-lactone (GDL) from the National List
Motioned by: Andrea Hatziyannis
Seconded by: Amanda Felder
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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. Tartaric acid is made from grapes, but 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].

The Handling Subcommittee asked stakeholders whether organic tartaric acid is available in significant quantities, whether tartrate salts could be removed before the addition of sulfur dioxide in winemaking, and whether there are any other barriers to organic tartaric acid production that could be lowered.

Public comments submitted for the previous sunset review, and again in this sunset review raised the possibility of increasing the supply of organic tartaric acid, including by removing the nonorganic version from the National List. 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. One certifier commented that tartrate salts are formed during wine storage, after fermentation is complete, and sulfur dioxide is typically added throughout the process, so it wouldn't be possible to remove the tartrates prior to addition of sulfur dioxide. Accordingly, there does not appear to be capacity for significant production of organic tartaric acid, so long as the rules for wine made from organic grapes remain in their current form.

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. Several certifiers certify operations that currently use tartaric acid, including one certifier reporting that 77 members use it.

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, and widespread use among certified operations, tartaric acid is a good candidate for relisting. However, a commenter noted that numerous synthetic pesticides are used in nonorganic production of wine grapes, and the Handling Subcommittee encourages the industry to continue exploring ways to increase production of organic tartaric acid.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds tartaric acid **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove tartaric acid from the National List
Motioned by: Allison Johnson
Seconded by: Kathryn Deschenes
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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].

https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelimhttps://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim

Discussion

Most of the past discussions pertained to the text of the previous sunset review, where ancillary substances were listed in a table by functional class. A previous sunset review questioned whether cellulose manufacture requires ancillary substances, and it was not resolved.

During the Spring 2026 NOSB meeting, one certifier commented that for their clients using cellulose, the casings contain ancillary substances while the powders generally do not. Another commentor noted that the most common ancillary substances used in cellulose were dextrose and enzymes when used for an anti-caking agent. In regenerative casings, glycerin and mineral oil were commonly used as ancillary ingredients. Public comments overall supported the relisting of cellulose. One commenter opposed to the relisting stated that cellulose is generally derived from wood pulp, which involves the clearing of natural ecosystems, and should be delisted. Commenters noted the specific usage of cellulose essential for casings, as an anti-caking agent in shredded cheese, and as a filtering aid for maple syrup production. The Subcommittee reviewed the ancillary substances used in the manufacture of cellulose and concluded that they pose minimal concerns and do not affect the substance's compatibility with organic production and handling.

Questions to our Stakeholders

1. What alternatives to cellulose are currently available?

Justification for Vote
The Subcommittee finds cellulose **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove cellulose from the National List
Motioned by: Amanda Felder
Seconded by: Allison Johnson
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

Chlorine materials – Calcium hypochlorite

Reference: § 205.605(b)(12) 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.
(i) 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

Calcium hypochlorite has historically been viewed by organic stakeholders as an important sanitation tool because of its ability to provide a reliable source of available chlorine for microbial control in agricultural water systems and food production environments. Technical reviews describe it as one of the most widely used chlorine-based disinfectants, with hundreds of EPA-registered products and long-standing use in water treatment, sanitation, and disinfection applications. Because it is relatively stable in dry form and can generate high levels of available chlorine when dissolved, it is commonly used where operators need a strong antimicrobial intervention.

Supportive comments generally emphasize that calcium hypochlorite plays a critical role in managing food safety hazards. Stakeholders from food production and handling sectors argue that the material is effective, familiar to operators, broadly accepted by regulators, and economically practical compared with some alternative technologies. Commenters supporting continued listing often note that microbial contamination events can have serious public health consequences and that chlorine materials—including calcium hypochlorite—remain among the most validated and widely understood sanitation tools available to organic operations. These commenters typically support maintaining the current organic allowance, provided Safe Drinking Water Act residual limits continue to apply.

In contrast, some public comments question whether the continued listing of calcium hypochlorite should be assumed without a broader review of sanitizer needs. Several commenters, particularly environmental and organic advocacy groups, have argued that NOSB should examine whether reliance on chlorine chemistry remains necessary given the emergence of alternative sanitation systems. Their position is not necessarily that calcium hypochlorite is ineffective; rather, they contend that the organic program should periodically revisit whether less chemically intensive approaches could achieve similar outcomes. These commenters frequently call for a more comprehensive review of sanitizers and disinfectants as a class before reauthorizing chlorine materials for another sunset period

Another recurring topic related to calcium hypochlorite is the distinction between sanitation of equipment and facilities versus direct contact with crops and foods. Historically, confusion arose because the National List annotations and subsequent regulatory language did not always clearly distinguish between these uses. NOP 5026 was developed specifically to address interpretation issues and clarify that chlorine-containing water may be used in certain direct-contact applications provided residual chlorine levels do not exceed the Safe Drinking Water Act maximum residual disinfectant limit. Nevertheless, subsequent petitions and comments indicate that questions persisted regarding how these provisions apply in practice. Since calcium hypochlorite is commonly used for water disinfection, it became indirectly implicated in many of these discussions.

Commenters also raised questions regarding the concept of essentiality, an OFPA review criterion. Some stakeholders asked whether all currently listed chlorine materials, including calcium hypochlorite, are necessary because other disinfectants may be available. However, the record does not reflect a consensus that alternatives can adequately replace calcium hypochlorite in every use pattern. In fact, supporters argue that having multiple chlorine materials available provides flexibility because different facilities, water chemistries, application systems, and operational conditions may favor one chlorine chemistry over another. Thus, many industry participants have viewed calcium hypochlorite not merely as interchangeable with other sanitizers but as part of an overall sanitation toolkit that allows operators to manage site-specific needs.

A further theme in the comments concerns regulatory consistency. Some commenters observed that municipal water supplies routinely contain disinfectant residuals generated from chlorine materials. As a result, stakeholders questioned whether it is logical to allow food operations to use water already treated with chlorine while restricting producers' ability to apply the same treatment directly under controlled conditions.

Key Issues Specifically Associated with Calcium Hypochlorite in Comments
<u>Arguments supporting continued use</u>

- Proven antimicrobial effectiveness in water treatment and sanitation.
- Long regulatory history and extensive industry familiarity.
- Important for irrigation systems, agricultural water, facilities, and equipment sanitation.
- Supports food safety objectives in organic production and handling.

<u>Concerns raised by commenters</u>

- Need for a broader assessment of alternatives prior to continued relisting.
- Questions regarding whether all chlorine materials remain essential under organic principles.
- Continued confusion regarding direct-contact versus non-food-contact uses.

- Desire for greater consistency among certifiers and reviewers interpreting NOP 5026 and National List annotations.

The public record does not reveal major controversy unique to calcium hypochlorite itself. Rather, comments portray calcium hypochlorite as a representative chlorine material caught within a broader policy debate. Stakeholders generally agree that it is an effective and important sanitizer. The disagreement centers on whether organic regulations clearly define its permissible uses, whether alternative sanitation approaches should receive greater consideration, and whether continued listing of chlorine materials is justified under organic essentiality criteria. The most consistent concern expressed across comments is not the performance of calcium hypochlorite, but the need for clearer regulatory language and a more comprehensive evaluation of chlorine sanitizers within the organic system.

Questions to our Stakeholders

1. Does calcium hypochlorite present unique worker safety, environmental, or handling concerns compared with other chlorine materials?
2. Have you experienced differences in how certifiers interpret or enforce the organic requirements for chlorine use? If so, please describe the specific issue(s) and how the interpretations differed.

Justification for Vote

The Subcommittee finds calcium hypochlorite **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove calcium hypochlorite from the National List
Motioned by: Kathryn Deschenes
Seconded by: Andrea Hatziyannis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

Chlorine materials – Chlorine dioxide

Reference: § 205.605(b)(12) 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

Among the four chlorine materials listed under the National Organic Program (NOP), **chlorine dioxide** occupies a somewhat distinctive position because it is often viewed by stakeholders as a technologically different disinfectant than traditional hypochlorite chemistries, even though it is regulated within the same "chlorine materials" category. Technical reviews describe chlorine dioxide as a strong oxidizing antimicrobial used in water treatment, food processing, agricultural water systems, equipment sanitation, and facility disinfection. Unlike sodium hypochlorite and calcium hypochlorite, chlorine dioxide acts through a different oxidation mechanism and is often valued for its effectiveness across a broad pH range and its ability to control microbial contamination in challenging water conditions.

Public comments submitted during the Spring 2026 NOSB sunset reviews and chlorine-material discussions generally acknowledge chlorine dioxide as an effective sanitation tool with a long history of use in food safety applications. Stakeholders supporting continued listing frequently emphasize that organic operations exist within a broader food safety framework that requires robust pathogen controls. These commenters argue that chlorine dioxide remains an important option because it provides effective microbial reduction while allowing operations flexibility to select the most appropriate disinfectant technology for their specific process, facility design, water quality conditions, and regulatory obligations.

From this perspective, removal of chlorine dioxide could unnecessarily limit sanitation options available to certified organic operations.

A recurring theme in supportive comments is the belief that chlorine dioxide fills operational needs that may not always be met by other chlorine materials. Stakeholders note that water quality varies considerably among agricultural and food handling operations. Because chlorine dioxide performs differently from hypochlorite-based disinfectants, commenters argue that maintaining multiple chlorine chemistries provides useful flexibility for controlling microbial contamination under different production scenarios. Although the public record generally discusses chlorine materials collectively, supporters often point to the broader principle that maintaining several approved sanitizers helps organic operations tailor sanitation programs to site-specific risks rather than relying on a single chemistry.

At the same time, chlorine dioxide has been drawn into the broader policy debate surrounding the role of sanitizers in organic systems. Environmental organizations and some organic advocacy groups have repeatedly argued that NOSB should undertake a more comprehensive evaluation of disinfectants and sanitizers before continuing chlorine material listings. Their comments are generally not directed specifically at chlorine dioxide's efficacy. Rather, they question whether the organic program has fully examined whether alternative substances, non-chemical interventions, improved sanitation management systems, or preventive food safety practices could reduce dependence on chlorine-based disinfectants overall. In these comments, chlorine dioxide is evaluated alongside calcium hypochlorite, hypochlorous acid, and sodium hypochlorite as part of a larger discussion about the future role of sanitation chemicals within organic production and handling.

Some commenters have also raised questions regarding essentiality, one of the key considerations used during NOSB review. These stakeholders ask whether chlorine dioxide, together with other chlorine materials, remains indispensable to organic production and handling or whether equivalent outcomes could be achieved through other allowed materials. However, the public comments reviewed do not establish a consensus that substitutes can fully replace chlorine dioxide across all uses. Indeed, technical reviews continue to identify a variety of applications in which chlorine materials play important roles in water treatment and microbial control. As a result, NOSB discussions have generally focused more on clarifying conditions of use than on eliminating chlorine dioxide from the National List.

One of the most significant regulatory issues affecting chlorine dioxide has involved interpretation of allowed uses rather than concerns about the substance itself. NOP Guidance 5026 was developed because certifiers and industry participants expressed uncertainty regarding whether chlorine materials could be used solely for disinfecting food-contact surfaces or whether they could also be used in direct crop, food, or animal-contact applications. The guidance clarified that chlorine-containing water may be used in direct-contact situations, provided residual chlorine levels comply with Safe Drinking Water Act limits. As one of the chlorine materials listed under the National List, chlorine dioxide became part of these broader discussions concerning the scope of allowed direct-contact uses.

Another theme appearing in public comments is the relationship between chlorine dioxide and municipal water treatment systems. Stakeholders have pointed out that many organic operations routinely use water that has already been disinfected using chlorine-based technologies. Consequently, several commenters questioned whether it is reasonable to permit the use of municipally treated water while restricting an organic producer's ability to apply similar water treatment methods directly. This argument has often been used to support retention of chlorine materials, including chlorine dioxide, particularly when their use results in water that remains within established drinking-water safety standards.

Major Themes Emerging from Public Comments

Supportive comments emphasized:

- Strong antimicrobial efficacy and broad utility in sanitation and water treatment.
- Operational flexibility for food processors, handlers, and agricultural producers.
- Importance of maintaining multiple disinfectant tools to address varying water and facility conditions.
  Consistency with food safety objectives and existing public health standards.

Critical or cautionary comments emphasized:

- Need for broader review of sanitizer and disinfectant policies in organic production.
- Evaluation of alternatives before concluding chlorine materials remain essential.
- Continued confusion concerning direct-contact versus non-contact uses.
  Inconsistent interpretation among certifiers and industry stakeholders.

The public record suggests that chlorine dioxide itself has generated relatively little material-specific criticism. Instead, it is most often discussed as part of the larger chlorine-materials category. Most stakeholders appear to recognize its value as an effective disinfectant and water treatment technology. The primary policy questions raised in comments concern regulatory clarity, consistency of interpretation, the availability of alternatives, and whether the organic program has sufficiently evaluated the long-term necessity of chlorine-based sanitizers. Consequently, discussions of chlorine dioxide within NOSB and NOP proceedings have focused less on concerns about the chemical itself and more on defining where, when, and under what conditions chlorine materials should be allowed within organic production and handling systems.

Questions to our Stakeholders

1. Does calcium dioxide present unique worker safety, environmental, or handling concerns compared with other chlorine materials?
   Have you experienced differences in how certifiers interpret or enforce the organic requirements for chlorine use or forms of chlorine dioxide? If so, please describe the specific issue(s) and how the interpretations differed.

Justification for Vote

The Subcommittee finds chlorine dioxide **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove chlorine dioxide from the National List
Motioned by: Kathryn Deschenes
Seconded by: Amanda Felder
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: § 205.605(b)(12) 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
Of the chlorine materials currently listed under the National Organic Program (NOP), hypochlorous acid (HOCl) occupies a somewhat unique position because it is both a specifically listed chlorine material and the primary antimicrobial species responsible for much of the sanitizing activity associated with chlorine-based disinfection systems. Technical reviews describe hypochlorous acid as an effective oxidizing antimicrobial used in food processing, produce washing, water treatment, and equipment sanitation. In recent years, it has gained increasing attention because it can be generated on-site and is often marketed as a more targeted sanitation technology than traditional bleach-based products.

Unlike calcium hypochlorite and sodium hypochlorite, which are often viewed simply as chlorine-releasing compounds, hypochlorous acid is frequently discussed by industry participants as a distinct sanitation technology. Stakeholders supporting its continued listing generally describe it as an effective tool that enables organic operators to achieve food safety objectives while minimizing operational challenges associated with other disinfectants. Public comments and technical reviews consistently recognize that food processors and produce handlers face increasing pressure to implement validated pathogen-control programs, and supporters argue that hypochlorous acid provides an important option within that broader food-safety framework.

A recurring argument from supporters is that hypochlorous acid contributes to operational flexibility. Organic operations vary considerably in size, water quality, product type, and sanitation needs. Commenters often emphasize that maintaining access to multiple chlorine materials allows operators to select technologies that best fit their facilities and processes. In this context, hypochlorous acid is viewed as one component of a broader sanitation toolkit rather than a stand-alone replacement for all other disinfectants. Technical reviews and stakeholder discussions suggest that many operators value having access to several chlorine-based antimicrobial approaches because microbial risks and treatment conditions differ substantially across production systems.

At the same time, hypochlorous acid has been included in broader public debates about whether chlorine materials, as a class, continue to satisfy organic principles of essentiality and compatibility. Some commenters have argued that NOSB should conduct a more comprehensive review of sanitizers and disinfectants before routinely renewing chlorine materials. Their concern is generally not directed specifically at hypochlorous acid; rather, it reflects a larger policy question regarding the role of synthetic antimicrobial substances within organic systems. These stakeholders frequently encourage greater emphasis on preventive sanitation practices, improved facility management, and alternative antimicrobial technologies before concluding that chlorine-based materials remain indispensable.

An important element of the public discussion involves the perception that hypochlorous acid may differ from other chlorine materials in terms of its use profile and how it is viewed by operators. Some stakeholders describe it as a newer or more refined sanitation tool compared with traditional bleach-type chemistries. Nevertheless, regulatory treatment under the National List has generally grouped hypochlorous acid together with calcium hypochlorite, chlorine dioxide, and sodium hypochlorite. As a result, most NOSB discussions have evaluated hypochlorous acid under the broader category of "chlorine materials" rather than conducting a completely separate policy analysis for the substance.

A substantial portion of public discussion involving hypochlorous acid has focused on regulatory interpretation rather than technical performance. NOP Guidance 5026 was originally issued because confusion existed regarding where chlorine materials could be used and how residual chlorine restrictions should be applied. The guidance clarified that chlorine-containing water may be used in certain direct-contact applications—including food, crop, and animal-contact situations—provided that residual chlorine levels remain within Safe Drinking Water Act limits. Because hypochlorous acid is often used in water-based disinfection systems, questions concerning direct-contact applications have been particularly relevant to its use.

Another theme emerging from public comments is the relationship between hypochlorous acid and alternative sanitizing technologies. Stakeholders advocating continued listing frequently argue that the material remains highly useful because it supports microbial control in a variety of operational settings. Commenters questioning continued listing generally do not challenge its effectiveness; rather, they ask whether similar outcomes could be achieved through other approved substances or improved management systems. The public record does not demonstrate consensus that available alternatives can fully replace hypochlorous acid across all uses, and this uncertainty has contributed to support for maintaining access to multiple chlorine-based options.

A further issue relevant to hypochlorous acid is the broader discussion regarding consistency between organic regulations and public-water practices. Stakeholders have observed that many organic operations already rely on water that has undergone chlorine-based disinfection before reaching the farm or processing facility. Some commenters therefore argue that organic producers should retain the flexibility to use chlorine materials directly under controlled conditions, particularly when resulting residual levels remain within drinking-water standards. This reasoning has been cited as a justification for retaining chlorine materials generally, including hypochlorous acid, within organic production and handling systems.

Major Themes Emerging from Public Comments

Supportive comments emphasized:

- Strong antimicrobial effectiveness and utility in food safety and sanitation programs.
- Flexibility for handlers and processors.
- Value of maintaining multiple approved sanitation technologies.
- Consistency with Safe Drinking Water Act residual limits and established public-health practices.

Critical or cautionary comments emphasized:

- Need for broader review of sanitation materials and alternative approaches.
- Questions regarding whether chlorine materials as a group remain essential.
- Continued uncertainty regarding direct-contact uses.
- Desire for greater consistency among certifiers and organic reviewers implementing NOP policies.

The public record suggests that hypochlorous acid has generally been viewed favorably as an effective sanitation and antimicrobial tool, and relatively few commenters have raised concerns unique to the material itself. Most discussion instead places hypochlorous acid within the larger debate surrounding chlorine materials and organic sanitation policy. Stakeholders broadly recognize its usefulness for microbial control, while debate continues regarding regulatory clarity, essentiality, alternatives, and interpretation of direct-contact uses. Consequently, the most significant issues surrounding hypochlorous acid are not questions about efficacy, but rather ongoing efforts to clarify how chlorine materials should be reviewed, regulated, and applied within organic production and handling systems.

Questions to our Stakeholders

1. Does hypochlorous acid present unique worker safety, environmental, or handling concerns compared with other chlorine materials?
2. Have you experienced differences in how certifiers interpret or enforce the organic requirements for chlorine use? If so, please describe the specific issue(s) and how the interpretations differed.

Justification for Vote

The Subcommittee finds hypochlorous acid **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove hypochlorous acid from the National List
Motioned by: Kathryn Deschenes
Seconded by: Andrea Hatziyannis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

Chlorine materials – Sodium hypochlorite

Reference: § 205.605(b)(12) 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
Among the chlorine materials listed under the National Organic Program (NOP), sodium hypochlorite is arguably the most familiar and widely recognized. Commonly referred to as liquid bleach, sodium hypochlorite has long been used throughout the food industry for sanitation, water disinfection, equipment cleaning, facility hygiene, and agricultural water treatment. As a result, discussions surrounding sodium hypochlorite often reflect broader debates about the role of chlorine-based sanitation in organic production and handling. While public comments rarely focus exclusively on sodium hypochlorite, the substance frequently serves as the reference point against which other chlorine materials are compared.

Supporters of continued listing consistently describe sodium hypochlorite as a cornerstone sanitation technology with a long history of effective pathogen control. Food processors, handlers, and agricultural operations note that it is widely understood, readily available, economical, and supported by extensive scientific and regulatory experience. Commenters frequently emphasize that sanitation failures can have significant food safety implications and argue that sodium hypochlorite remains one of the most practical tools available for controlling pathogenic bacteria, viruses, and other microorganisms in production environments. From this perspective, the material continues to meet an important need within organic systems despite its synthetic nature.

Many stakeholders also point to the operational versatility of sodium hypochlorite. Unlike some specialized sanitizers that may be used only under narrow conditions, sodium hypochlorite can be applied across a wide range of sanitation situations, including equipment cleaning, food-contact surface sanitation, water treatment, facility disinfection, and agricultural applications permitted under organic regulations. Public comments supporting relisting often note that operators value the ability to utilize a familiar sanitation system that can be integrated into existing food safety plans without requiring extensive new infrastructure or specialized equipment. Because organic operations are subject to many of the same food safety expectations as conventional operations, commenters argue that sodium hypochlorite provides an important means of achieving those objectives.

Another recurring theme in supportive comments is the importance of regulatory consistency between organic production and broader public health practices. Stakeholders have noted that municipal water systems across the United States commonly employ chlorine-based disinfection technologies to ensure potable water quality. Consequently, many organic farms and processing facilities routinely receive water that contains residual disinfectants associated with chlorine treatment. Several commenters argue that it would be difficult to justify prohibiting or severely restricting sodium hypochlorite use within organic operations while simultaneously permitting the use of municipally disinfected water. This argument has been particularly influential in discussions concerning water treatment.

Despite broad recognition of its effectiveness, sodium hypochlorite has also been at the center of comments questioning the long-term role of chlorine materials in organic agriculture. Environmental organizations and some organic advocacy groups have repeatedly encouraged the NOSB to undertake a more comprehensive review of disinfectants and sanitizers rather than continuing to evaluate chlorine materials individually during periodic sunset reviews. These commenters generally acknowledge that sodium hypochlorite works as intended but question whether organic principles require greater emphasis on preventive approaches, alternative sanitizers, or management systems designed to reduce reliance on chlorine chemistry. Their concern typically focuses on policy considerations rather than challenges to the material's antimicrobial performance.

Questions regarding essentiality have also emerged repeatedly in public comments. Under organic review criteria, substances must continue to demonstrate a need within organic systems. Some stakeholders have therefore asked whether sodium hypochlorite remains essential given the availability of other disinfectants such as peracetic acid, hydrogen peroxide, ozone-based technologies, and other sanitation approaches. However, comments reviewed during recent NOSB proceedings do not provide a clear consensus that alternatives can completely replace sodium hypochlorite across all use patterns. Industry participants frequently argue that different sanitizers perform differently under varying operational conditions and that maintaining multiple approved options allows producers and handlers to select the most effective approach for their particular circumstances.

One of the most significant policy discussions involving sodium hypochlorite concerns the interpretation of allowed uses under the National List and NOP Guidance 5026. Historically, stakeholders disagreed about whether chlorine materials were limited to disinfecting facilities and food-contact surfaces or whether they could also be used in direct crop, food, or animal-contact applications. NOP 5026 was issued specifically to address these questions and clarify that chlorine-containing water may be used in direct-contact situations provided residual chlorine levels do not exceed Safe Drinking Water Act limits. Because sodium hypochlorite is one of the most commonly used chlorine materials in water-based sanitation systems, it became heavily implicated in these interpretation issues.

A further issue raised indirectly in comments concerns the distinction between the active ingredient and the formulated product. Sodium hypochlorite products can vary considerably in formulation, concentration, and manufacturing processes. While the National List specifically addresses the active chlorine material, stakeholders have occasionally expressed concern about ensuring that reviews adequately consider all components associated with commercial sanitizer products. This issue forms part of a broader discussion regarding how formulated sanitizers should be evaluated within organic systems and whether NOP guidance clearly distinguishes between review of active ingredients and review of complete formulations. Public comments indicate that stakeholders continue to seek greater clarity on these matters.

Major Themes Emerging from Public Comments

<u>*Supportive comments emphasized:*</u>

- Extensive history of successful sanitation and pathogen control.
- Familiarity, affordability, and widespread availability.
- Compatibility with existing food safety and sanitation programs.
- Importance for water treatment, facility sanitation, and equipment disinfection.
- Consistency with municipal drinking-water disinfection practices.

<u>*Critical or cautionary comments emphasized:*</u>

- Need for broader evaluation of sanitizer alternatives and non-chemical interventions.
- Questions regarding whether all chlorine materials remain essential.
- Continued uncertainty regarding direct-contact uses.
- Desire for clearer distinctions between active ingredients, formulated products, and varying review approaches.
- Concerns about inconsistent interpretation among certifiers.

The public record indicates that sodium hypochlorite is generally recognized as one of the most established and operationally important chlorine materials available to organic producers and handlers. Few commenters dispute its effectiveness as a disinfectant. Instead, the debate largely centers on policy questions: whether chlorine materials remain essential under organic principles, how alternatives should be evaluated, and whether NOP rules and guidance clearly define where sodium hypochlorite may be used. As with the other chlorine materials, the most significant issues raised in public comments relate less to the chemistry itself and more to regulatory interpretation, consistency among certifiers, and the broader role of synthetic sanitizers within organic production and handling systems.

Questions to our Stakeholders

1. Does sodium hypochlorite present unique worker safety, environmental, or handling concerns compared with other chlorine materials?
2. Have you experienced differences in how certifiers interpret or enforce the organic requirements for chlorine use? If so, please describe the specific issue(s) and how the interpretations differed.

Justification for Vote

The Subcommittee finds sodium hypochlorite **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote

Motion to remove sodium hypochlorite from the National List
Motioned by: Kathryn Deschenes
Seconded by: Amanda Felder
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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 at § 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.

Public comments during the Spring 2026 NOSB meeting generally supported the relisting of potassium hydroxide. A few commentors asked for an annotation change to reframe the annotation from a negative (what is not allowed) to a positive (specifying what uses it is approved for). Public comments noted current use of this material as a boiler chemical, defoamer or egg wash, pH control, and an antimicrobial. The subcommittee discussed the potential of an annotation change. The subcommittee found that revising the annotation to list all permitted uses, rather than identifying prohibited uses, would result in an annotation that is unnecessarily lengthy and impractical to administer.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds potassium hydroxide **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove potassium hydroxide from the National List
Motioned by: Amanda Felder
Seconded by: Andrea Hatziyannis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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 substance 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 with?

Justification for Vote

The Subcommittee finds potassium lactate **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List:

Subcommittee Vote

Motion to remove potassium lactate from the National List
Motioned by: Andrea Hatziyannis
Seconded by: Allison Johnson
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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.

<u>Environmental</u>
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 asked stakeholders for comments on this concept.

The 2025 TR evaluated 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 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]. The Handling Subcommittee asked stakeholders for information about alternatives.

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 asked stakeholders for current information about this issue.

At the Spring 2026 meeting, the Board received numerous comments on this material, with the majority supporting relisting.

Several commenters noted that the current annotation is less restrictive than the one the Board had recommended and asked that the annotation be revisited. One certifier requires a commercial availability confirmation for products labeled "organic," but not for "made with organic" products.

Commenters noted that Europe disallowed a nano version of titanium dioxide due to health issues. Limited information was provided in response to the Handling Subcommittee's questions about nano particles. A certifier commented that the nano status is unclear, but that no one has filled out their nanotechnology affidavit with regard to this material.

Multiple commenters noted that rice hulls are not viable replacements for some uses, including in seasoning blends because of flow and mouthfeel. It was also noted that while calcium phosphate could be an alternative for some applications, there are also concerns about phosphate levels in the diet.

Multiple certifiers noted that certified operations do use this material.

In the Board's discussion at the Spring 2026 meeting it was noted that the current annotation does not appear to be working well, as it is both too restrictive (requiring a commercial availability search that is not likely to yield results for certain products) and too permissive (not aligning with the broader commercial availability search that the Board previously recommended). The Handling Subcommittee requests additional input on whether the current annotation is driving shifts in use from SAS to rice hulls.

Questions to our Stakeholders

1. Are there examples of organic operations that have switched to rice hulls from SAS as a result of the current annotation?
2. How would a certified operation complete a broader search for organic and nonsynthetic alternatives to SAS?

Justification for Vote

The Subcommittee finds silicon dioxide **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List:

Subcommittee Vote

Motion to remove silicon dioxide from the National List
Motioned by: Allison Johnson
Seconded by: Amanda Felder
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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 substance 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?

Justification for Vote
The Subcommittee finds sodium lactate **compliant** with the Organic Foods Production Act (OFPA) (7 U.S.C. 6518(m) and 6517) and the USDA organic regulations (7 CFR 205.600) and is not proposing removal from the National List:

Subcommittee Vote
Motion to remove sodium lactate from the National List
Motioned by: Andrea Hatziyannis
Seconded by: Kathryn Deschenes
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 0