Sunset 2023
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), § 205.606
April 2021

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 are on the National List which 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, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 5, 2021 as explained in the meeting notice published in the Federal Register.

These 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 found to be: (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.

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

For Comments on Nonorganic Agricultural Substances at 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.

Written public comments will be accepted through April 5, 2021 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

- 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
- Silicon dioxide
- Potassium lactate
- Sodium lactate

Agar-agar

Reference: §205.605(a)
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

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. Useful characteristic of agar-agar includes the 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 derived from red algae, the main species harvested being Gelidium and Gracilaria, the second of which can be cultivated. After harvesting, the algae is cleaned with water, dried in the sun, pressed into bales, and shipped to processors for agar-agar extraction. Prior to extraction the Graciliara species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution) followed by rinsing with water and sometimes a weak acid to neutralize the alkali. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides. This chemical change produces agar-agar with increased gel strength. Without this pretreatment, the gels extracted from Graciliara species would be too weak for most food applications (2011 Technical Report (TR), 165-176). After pretreatment, the algae is placed in tanks for extraction via hot water pressure, followed by filtration. The last step is to remove water from the gel either through a freeze-thaw process or by mechanical pressure. The gel is then dried with hot air resulting in a finished product of flakes, strips, or powder.

Based on this manufacturing information, the Handling Subcommittee acknowledges that a reclassification of agar-agar at § 205.605(b) Synthetics allowed, might be needed in the future once the NOP finalizes the Guidance for Material Classification.

International Acceptance
Canadian General Standards Board Permitted Substances List
Agar-agar is permitted for use in organic production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Agar-agar is permitted for use in organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Agar-agar is permitted for use in organic production.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Agar-agar is permitted for use in organic production.

Japan Agricultural Standard (JAS) for Organic Production
Agar-agar is not permitted for use in organic production in Japan.

Environmental Issues
The current world demand for agar-agar is reportedly increasing, which has placed pressure on the overharvested natural sources. There were no studies found to indicate whether or not the harvesting of agarophytes, in particular, is harmful to the biodiversity on nearby beaches or in the algae beds. There are alkaline waste waters that result from the manufacture of agar-agar, but there were no documents found that show this to be a problem to the environment, at this time.

Discussion
Based on the different manufacturing processes, and the 2011 TR, there does appear to be a question as to whether two forms of agar-agar exist. While there are extraction processes that are natural (non-synthetic) and without chemical modifications, , there are others that can be considered synthetic. An example of the synthetic method would be when the Graciliara species of algae are subjected to an alkaline pretreatment (heated in sodium hydroxide solution) to modify the polysaccharides in the algae. This process brings about a chemical change in the polysaccharides (L-galactose-6-sulfate groups are converted to 3,6-anhydro-Lgalactose), increasing the gel strength of the agar-agar. Data indicates that without this treatment the gel extracted would be too weak for most food applications. While the 2011 TR lists several methods of extraction, it states that only 1 -2% of the agar-agar supply is from the natural form of extraction. Furthermore, the product from the natural extraction method does not appear to be readily available in the U.S. market.

Agar- agar is currently listed on the National List at §205.605(a) Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (a) Nonsynthetics allowed. During the 2018 sunset review it was suggested that based on the manufacturing process, agar-agar could also be listed at §205.605(b) Synthetics allowed.

Questions to our Stakeholders

1. Have there been any new developments with natural alternatives to agar-agar?

2. Are there sufficient quantities of agar-agar produced using non-synthetic extraction methods to exclude agar-agar produced using synthetic methods?

Animal enzymes

Reference: §205.605(a) 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): NA
Past NOSB Actions: 11/2000 meeting minutes and vote; 11/2007 recommendation; 12/2011 recommendation; 11/2016 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 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

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 (Enzyme Technical Association 2001) (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. For example, the amount of animal-derived rennet used to clot milk is 0.036 percent (2011 TR , lines 727-728).

Manufacture
Traditionally, the fourth stomach or other organs of goat kids or calves are 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 Permitted Substances List
The use of enzymes is permitted in organic processing in Canada.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The use of enzymes is permitted in organic processing in the EU.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The use of enzymes is permitted in organic processing in CODEX.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The use of enzymes is permitted in organic processing by IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
The use of enzymes is permitted in organic processing in Japan.

Ancillary substances
Explained in the 2015 Limited Scope TR:

> "Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further

formulation (Whitehurst & Van Oort, 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients, which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis. To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

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.

Environmental Issues

The manufacture or use of animal enzymes is not found to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

Discussion

There are no true alternatives to animal enzymes. Enzymes can only be substituted with another enzyme with the same function. One alternative to animal derived rennet for the production of cheese is genetically engineered chymosin, which is incompatible with organic food handling due to the use of excluded methods to produce it. The 2000 TAP for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Questions to our Stakeholders

1. Since the last review, have organic animal enzymes become commercially available?
   a. If so, is there sufficient supply that meets the needs of the organic industry?
   b. If not, what are the barriers?

2. Are there ancillary substances used in animal enzymes that are not found on the chart above, or are there ancillary substances on the chart that you think should not be allowed? Please submit public comment explaining which substance and why.

Calcium sulfate-mined

Reference: §205.605(a)
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
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
- Coagulate in tofu manufacturing. Calcium sulfate is essential to soft and silky tofu types.
- Yeast food and dough conditioner, water conditioner.
- Firming agent (in canned foods).
- Jelling ingredient.
- Baking powder.
- Dentistry (bone regeneration).

Manufacture
Calcium sulfate can be obtained from natural sources or synthetic sources. 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. It can form as a by-product from many different kinds of 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 Permitted Substances List
Restricted to "as a carrier for cakes and biscuits; for soybean products; and for bakers' yeast" and source is restricted to "sulfates produced using sulfuric acid are prohibited."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Restricted to use as a coagulation agent and carrier only but is not restricted to mined sources. Mexico – restricted to acidifiers, acidity, anti-caking agent, antifoam, filler and coagulant but not restricted to mined sources.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Restricted to "Cakes & biscuits/soybean products/baker's yeast. Carrier" but not restricted to mined sources.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Restricted "For soybean products, confectionery and in bakers' yeast" but not restricted to mined sources.

Japan Agricultural Standard (JAS) for Organic Production
Restricted to" Limited to be used as coagulating agent or used for confectionary, the processed beans products or bread yeast" but not restricted to mined sources.

Ancillary substances
None reported in the 2001 TAP.

Environmental Issues
Mining of calcium sulfate (as gypsum or alabaster) has exposed several public land areas, including Grand Staircase-Escalante National Monument in Utah, to extractive impacts. It is unclear the full extent of these activities to date, or landscape and critical area damage that could occur in the future. This question could potentially be addressed more fully in more current Technical Report (TR), as the most recent report on calcium sulfate is a 2001 Technical Advisory Panel (TAP), especially given that the sunset under consideration is the mined version.

Discussion
Several comments were received on this substance during the previous sunset review in 2016. Manufacturers and trade associations emphasized its use in tofu production. Several companies noted it was critical to production of tofu and soy cheese. One manufacturer noted they would like it retained but they currently use magnesium chloride instead. Another manufacturer noted magnesium chloride produced a softer tofu than calcium sulfate. 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. Another interest group raised concerns about the environmental and human health concerns of mining and noted a toxicological review completed by the National Toxicology Program in 2006. This review noted: "None of the long-term studies can be considered adequate tests of chronic toxicity or carcinogenicity by modern standards." Furthermore, it focused more on exposure from the 2001 World Trade Center attacks, and the limited information from mine workers was from a 1976 study that was available during the original 1996 TAP. While the previous sunset review considered the renewal of calcium sulfate valid, a previous NOSB noted that future sunset reviews should consider if a new TR could help in a review of current data on alternative manufacturing methods, environmental or human health concerns, and/or whether an annotation should be recommended.

In 2016, the subcommittee agreed this material satisfies the OFPA evaluation criteria and the Handling Subcommittee supported the relisting of calcium sulfate, which subsequently was upheld by the full board.

Questions to our Stakeholders

1. Is there clear evidence of unacceptable environmental impacts from the mining of calcium sulfate?

2. Is there clear evidence of unacceptable human health impacts from calcium sulfate mining?

Carrageenan

Reference: §205.605(a)
Technical Report: 1995 TAP, 2011 TR; 2016 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
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987 – misspelled as 'carageenan'); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
Carrageenan, also referred to as Irish moss, 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. It is listed as Generally Recognized as Safe (GRAS) on the FDA list of food additives.

Manufacture
Carrageenan is made 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 centrifuge and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder form for addition to foods.

There are three main kinds of carrageenan which are primarily extracted from different seaweed species (or 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.

- 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

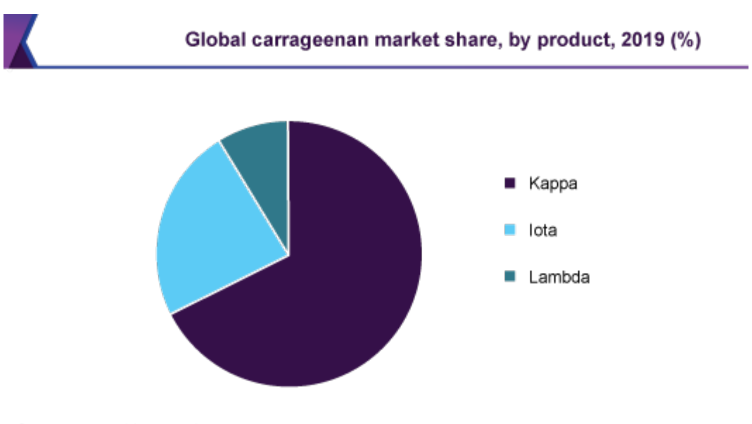

Figure 1. Most of the global production is of kappa-carrageenan (Source www.grandviewresearch.com).

Most of the seaweeds used in carrageenan production are sourced from the Philippines and China and are grown in seaweed farms.

International Acceptance

Canadian General Standards Board Permitted Substances List

Canada allows carrageenan as a food additive under their organic standard with no limits on usage.

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

The EEC allows carrageenan as an additive to organic dairy foods. The joint FAO/WHO Expert Committee on Food Additives (JECFA) determined in 2015 that carrageenan is a safe additive for infant formula at doses up to 1000mg/L.

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

Carrageenan is listed as a food additive permitted for use in plant-based foods, dairy products, and dairy analogues (excluding fats, oils, and fat emulsions) within the guidelines for organically produced foods (Matthee, 2007).

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

JAS allows carrageenan as an additive to organic dairy products.

East African Organic Product Standard and the Pacific Organic Standard

Both list carrageenan as an additive allowed in organic food processing.

Environmental Issues

Farming of seaweed used to extract carrageenan raises 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) and the turnover to harvest is quite short, at only 6 weeks. However, increased demand for seaweed has resulted in the establishment of some farms which 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).

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, Cannon and Smith, 2020).

The impacts of seaweed aquaculture are not all negative. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, removed impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some of effects of climate change (Duarte, Wu, Xiao, Bruhn and Kraus-Jenson, 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.

Discussion

Carrageenan has a long history of use as a food additive, used to make dairy-based puddings in Ireland for nearly 1500 years and found in soups in China since 600 BC. Also known as Irish moss, it did not become broadly used in industrial food preparation until the 1930s. It is currently a $500 million dollar industry.

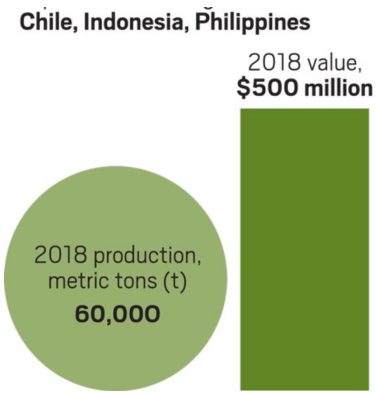

Figure 2. Carrageenan production in 2018 (Taylor, 2019).

Due primarily to their role as thickening and emulsifying agents, carrageenan and other algae-based foods represent one of the fastest growing segments of the food sector. Seaweed production is projected to grow an [additional 12.6% a year] over the 5 year period from 2020-2025 as the demand for processed foods continues to grow.

Despite this extensive history of human consumption, there have been concerns in the United States that carrageenan can cause a myriad of health problems as part of the human diet (Bixler, 2017). Most of this controversy stems from research led by Dr. Joanne Tobacman (Tobacman, Bhattachayya, Borthakur, and Dudeja, 2008). Her research has suggested that carrageenan promotes intestinal ulcers, contributes to Irritable Bowel Syndrome, and could be carcinogenic.

Critics of Dr. Tobacman and associates work believe that Tobacman has been conducting experiments using not carrageenan, but a degraded form of carrageenan, poligeenan, that is a known inflammatory agent and not considered safe for consumption. Poligeenan is only produced from carrageenan under high heat and extreme acid conditions and is therefore not created during the process of human digestion. Poligeenan "is distinct from food-grade carrageenan." In fact, poligeenan is well-known for producing an inflammatory response and is used to provoke edema for study in rats when injected under the skin. The results from Tobacman's studies have not been replicated when independently assessed.

Further muddying the waters, much of the early work on carrageenan and poligeenan do not distinguish between the intact and the degraded form, calling both carrageenan. Therefore, older scientific papers need careful reading to determine whether the researcher used poligeenan or carrageenan. Intact carrageenan, like cellulose and other fibre, is a large molecule that passes through the human digestive tract without being broken down or absorbed. Despite the lack of replication of this work, there are numerous anecdotal reports from people who find relief from digestive complaints when they remove carrageenan from their diet. Currently, changes in perceived health must therefore be considered correlative and not demonstrative of causation.

In 2007, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered it "inadvisable to use carrageenan or processed eucheuma seaweed in infant formulas," but then partially reversed this position in 2014, concluding that "these new studies allay the earlier concerns that carrageenan, which is unlikely to be absorbed, may have a direct effect on the immature gut." The Committee also took account of the previous toxicological database on carrageenan, which “did not indicate other toxicological concerns” and “that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern.” Infants are considered to be the most sensitive population to the potential effects of carrageenan. The 2011 Technical Report (TR) reports that “the group acceptable daily intake (ADI) for carrageenan and processed Eucheuma seaweed was categorized as “not specified” by JECFA, … [which] means that the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect in food and from its acceptable background levels in food does not… represent a hazard to health”.

As part of the 2016 NOSB sunset review, “an extensive list was prepared of all the food product categories in which carrageenan is used. In most of the product types there are versions that are currently being sold that do not contain carrageenan. These often contain other types of gums such as gellan, guar, or xanthan.” At that time, products for vegetarians and vegans where carrageenan is used in place of gelatine were singled out as difficult to produce without carrageenan.

Eliminating carrageenan may be achievable through the elimination of many processed foods where it is found essential by manufacturers Most international organic standards permit use of carrageenan, including the EU, Canada, Japan, and IFOAM (see the International Acceptance section above). During the last sunset review, the NOSB recommended removal of carrageenan from the National List (Yes: 10 No: 3 Abstain: 1 Absent: 1 Recuse: 0). The basis of this decision largely reflected the intense consumer controversy associated with this substance, as well as concerns about its compatibility with a system of sustainable agriculture. Also invoked was the NOSB Guidance on Compatibility from the Appendix of the NOSB Policy and Procedures Manual that poses this question for consideration, “Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?” It is important to note that the NOP did not take the NOSB recommendation to remove carrageenan from the National List and carrageenan is currently allowed in organic production.

Questions to our Stakeholders

1. Should there be an effort to outline best management practices for seaweed farming and harvesting?

2. Do seaweed farming practices for carrageenan production conflict with the proposed Marine Materials guidelines passed by the NOSB last year?

3. Is carrageenan essential for production of organic products? Which products?

4. Are carrageen alternatives available to replace all current uses?

5. Would lack of carrageenan availability limit opportunities to produce vegan products?

6. Is there new information on the safety of carrageenan?

References

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Glucono delta-lactone

Reference: §205.605(a) 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
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 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly in the production of 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.

Manufacture
There are a variety of ways GDL 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 acid base reactions and fermentation (2016 TR, pg. 10-11). Other processes to make GDL involve oxidation of D-glucose with bromine water (which is not allowed by the National List annotation) and purified enzymes (TR 281-282).

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.

International Acceptance
Canadian General Standards Board Permitted Substances List
GDL is not listed on the permitted substances list of Canada.

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

GDL is not listed on the permitted substances list of the EU.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
GDL is not listed on the permitted substances list of CODEX.

International Federation of Organic Agriculture Movements (IFOAM) Norms
GDL is not listed on the permitted substances list of IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
GDL is not listed on the permitted substances list of Japan.

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 review 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 (also listed at §205.605(a) nonsynthetic). The TR also raised concerns about the potential for GMO enzymes used in the production of GDL via the oxidation with enzymes production method (not the most common form of production).

Discussion
The original petition and primary use of GDL is for the coagulation of tofu. Other coagulants for tofu include magnesium chloride, calcium chloride, calcium sulfate, and magnesium sulfate. Acids such as citric or lactic acid can be used as well. Each of these substances produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu, sulfate salts produce soft tofu and GDL produces silken tofu. Citrus 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.

The Handling Subcommittee sought further information from the public, in particular, whether GDL is being used in applications other than tofu production for organic processed foods. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic product. Further, the Handling Subcommittee asked if alternative tofu coagulants such as calcium and sulfate salt would be sufficient to produce all forms of tofu if GDL were removed from the national list. In response, companies commented that alternatives on the list result in distinctly different and more firm tofu and that GDL is critical to 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.

This material satisfies the OFPA evaluation criteria and the Handling Subcommittee supports the relisting of glucono delta-lactone.

Questions to our Stakeholders

1. How widespread is the use of GDL in organic applications?

2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?

3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?

4. Is the lack of International acceptance significant?

5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Tartaric acid

Reference: §205.605(a) 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
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
According to the 2011 TR, tartaric acid naturally occurs in many plants, especially grapes, bananas, and tamarinds. 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.

The 2011 TR further notes that tartaric acid and its salts have a very 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.

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.
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 (TR, 2011).

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 details the production of tartaric acid:

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, 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 Permitted Substances List

The use of tartaric acid ($C_4H_6O_6$; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredient classified as a food additive in beverages. Use of the synthetic form is allowed only if the nonsynthetic form of tartaric acid is not commercially available. Tartaric acid derived from nonsynthetic sources is also permitted for use as a processing aid in beverages (the Canadian General Standards Board, 2020).

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

The European Economic Community (EEC) permits the use of tartaric acid as a food additive in organic food if derived from a plant source, which is presumably grapes (EEC 889/2008, 2008).

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

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, and stabilizer. Tartaric acid from a plant source (i.e. nonsynthetic L (+) tartaric acid) is permitted for use as a food additive in organic food production (although exclusions of the GFSA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

International Federation of Organic Agriculture Movements (IFOAM) Norms. Allows the use of tartaric acid only for wine.

Japan Agricultural Standard (JAS) for Organic Production

Limited to be used for processed foods of plant origin.

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 (TR 2011).

Discussion

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

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

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

Questions to our Stakeholders

1. Is tartaric acid still an essential ingredient for organic processing?
2. Are there any organic/natural alternatives for wine making?
3. Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?
4. Are there any ancillary substances that are associated with tartaric acid?

Cellulose

Reference: §205.605(b) 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
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347);Annotation change effective 12/27/2019 (83 FR 66559)
Sunset Date: 11/03/2023

Subcommittee Review

Use

Cellulose is used as a processing aid for filtration of juices; as an anti-caking agent ingredient for use in shredded cheese; and as a processing aid in the form of peelable/non-edible hot dog and sausage casings. Some of these uses in organic handling have been around since before the enactment 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 (EMBL, 2015)(TR 2-11-2016). 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 GRAS under CFR 121.101 (LSRO 1973).

The 2016 TR and public comments submitted in previous sunset reviews of cellulose provided the following list of ancillary substances that are sometimes used in the production of cellulose. The TR was very clear that there are well defined sources of commercially available cellulose that do not include any ancillary substances, as well as those that might use ancillaries listed in the chart below. During the 2018 sunset review, public comment identified additional ancillary substances used in the production of cellulose. The review noted the Handling Subcommittee would develop a follow-up proposal to include these ancillaries, however it is not clear if this progressed.

Functional Class	**Ancillary Substance Name**
Carriers and fillers, agricultural or nonsynthetic	Potato starch, dextrose
Carriers and fillers, synthetic	Propylene glycol
Preservatives	Polysorbate 80, enzymes
Binder/Plasticizer	Lecithin, propylene glycol, mineral oil
Anti-caking & anti-stick agents	Mineral oil, animal oil, vegetable oil, resin
Releasing agents	Mineral oil

International Acceptance

The 2016 TR notes the following international allowances:
Canadian General Standards Board Permitted Substances List
Allowed as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings (CAN/CGSB 2015).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Cellulose is authorized for use in the wine sector only for use as an inert filtering aid (EU Commission 2008).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
No specific listing.

International Federation of Organic Agriculture Movements (IFOAM) Norms
In Appendix 4, Table 1 "List of approved additives and processing/post-harvest handling aids" as a processing and post-harvest handling aid with no annotation (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic Production
No specific listing.

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.

Discussion
Despite the concerns noted above, the Board noted that comments received during the 2018 Sunset review "helped to provide the full Board with a detailed rationale as to why this material is still essential to organic handlers, even though some have found alternative processes to work for their specific needs. There was no information presented that made this committee feel this material should not be re-listed."

Questions to our Stakeholders

1. Is cellulose still essential to organic production?

2. Are there ancillary substances in use that are not identified in the table in this document?

3. Are there alternative sources of cellulose to those from virgin forests that might minimize concerns regarding impact on primary forests?

4. What percentage of cellulose in use is derived from grain and vegetable products vs. from wood/forestry?

Chlorine materials – Calcium hypochlorite

Reference: §205.605(b) 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
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
Recent Regulatory Background: Amendment to annotation effective 1/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 1/28/2024

Subcommittee Review

Use
Calcium hypochlorite is an 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. 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 Cl2).

Calcium hypochlorite is an "indirect" food additive approved by 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 (EPA, 1991).

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 or the Environmental Protection Agency 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 triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

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 vacuumed.

International Acceptance
Canadian General Standards Board Permitted Substances List
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination.

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 (http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10). 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 and 2011 Technical Reports (TR) (referenced above.).

Discussion

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

Questions to our Stakeholders

The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is calcium hypochlorite essential for organic food production and handling?

2. How well does calcium hypochlorite work for the specific need identified?

3. Since calcium hypochlorite was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?

4. How does calcium hypochlorite fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

5. Is calcium hypochlorite a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?

6. How does calcium hypochlorite fit into rotations and/or the need for back up materials?

7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Chlorine dioxide

Reference: §205.605(b) 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

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

Recent Regulatory Background: Amendment to annotation effective 1/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Sunset Date: 1/28/2024

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. 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 or the Environmental Protection Agency 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.

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) (HSDB, 2005). 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.

International Acceptance
Canadian General Standards Board Permitted Substances [List](http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf)
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination.

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 (http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10). 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 2006 and 2011 Technical Reports (TR) (referenced above).

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

Questions to our Stakeholders
The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is chlorine dioxide essential for organic food production and handling?

2. How well does chlorine dioxide work for the specific need identified?

3. Since chlorine dioxide was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?

4. How does chlorine dioxide fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

5. Is chlorine dioxide a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?

6. How does chlorine dioxide fit into rotations and/or the need for back up materials?

7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: §205.605(b) 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
Petition(s): 2015
Past NOSB Actions: 2016 NOSB Recommendation
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559)
Sunset Date: 1/28/2024

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. 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 or the Environmental Protection Agency 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 triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

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. (TR lines 48-68).

International Acceptance
Canadian General Standards Board Permitted Substances List
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

Japan Agricultural Standard (JAS) for Organic Production
https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

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 2006 and 2011 Technical Reports (TR) (referenced above.).

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

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

Questions to our Stakeholders
The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to

address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is hypochlorous acid essential for organic food production and handling?

2. How well does hypochlorous acid work for the specific need identified?

3. Since hypochlorous acid was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?

4. How does hypochlorous acid fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

5. Is hypochlorous acid a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?

6. How does hypochlorous acid fit into rotations and/or the need for back up materials?

7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Sodium hypochlorite

Reference: §205.605(b) 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;

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

Recent Regulatory Background: Amendment to annotation effective 1/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Sunset Date: 1/28/2024

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. 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 (http://www.cfsan.fda.gov/~dms/opa-indt.html). 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 (EPA, 1991).

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 or the Environmental Protection Agency 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 triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

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 (Na2CO3).

International Acceptance
Canadian General Standards Board Permitted Substances List
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF
Products for cleaning and disinfection referred to in Article 23 (4).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination.

Japan Agricultural Standard (JAS) for Organic Production
https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

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 (http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10). 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 2006 and 2011 Technical Reports (TR) (referenced above.).

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

Questions to our Stakeholders
The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is sodium hypochlorite essential for organic food production and handling?

2. How well does sodium hypochlorite work for the specific need identified?

3. Since sodium hypochlorite was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?

4. How does sodium hypochlorite fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

5. Is sodium hypochlorite a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?

6. How does sodium hypochlorite fit into rotations and/or the need for back up materials?

   How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Potassium hydroxide

Reference: §205.605(b) 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
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 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

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).

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.

The 2016 TR notes that potassium hydroxide is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as Generally Recognized As Safe (GRAS) for humans (21 CFR 184.1631), which is allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. According to the TR, peaches peeled for canning or pickling 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 again citric acid is used to neutralize the pH of the fruit.

For certain grains and legumes potassium hydroxide is used to remove tannins that interfere with nutrient uptake. For example, it increases solubility of protein in soybeans. It can be 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 'nixtamilization' - 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).

Manufacture
The 2016 TR notes that the FDA specifies that food grade potassium hydroxide 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.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (C CAN-CGSB-32.311-2015E).

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

Caustic potash is on Annex VII, "Products for cleaning and disinfection" (EU Commission 2008). However, it does not appear in Annex VIII, "Certain products and substances for use in production of processed organic food, yeast and yeast products."

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

Permitted for use in cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.007.1.1.1 yeast-leavened.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Not found.

Japan Agricultural Standard (JAS) for Organic Production

"Limited to be used for processing sugar as pH adjustment agent" (Japan MAFF 2000).

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 nutrient loading of potassium may result in algal blooms and eutrophication (2016 TR).

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.

Discussion

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

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

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

During previous reviews a number of stakeholders commented about the use of potassium hydroxide as a cleaning and sanitizing agent. As such, it provides a different mode of action as compared to chlorine materials.

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 peaches.

Questions to our Stakeholders

1. Is potassium hydroxide still critical for the lye peeling of peaches?
2. Are there alternatives to potassium hydroxide for cleaning/sanitizing?
3. For what other purposes is potassium hydroxide currently being used in organic processing?
4. Are there any ancillary substances that are used with potassium hydroxide?

Potassium lactate

Reference: §205.605(b) 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: 4/2016 recommendation
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559)
Sunset Date: 1/28/2024

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.

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.

International Acceptance
Canadian General Standards Board Permitted Substances List
Sodium lactate and potassium lactate are not listed for use in processing. Lactic acid is allowed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Potassium lactate is not permitted for use in organic food processing in the European Union. Lactic acid, the precursor substance, is allowed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Sodium and potassium lactates are not specifically listed on any of the appendices in the IFOAM, but the precursor, lactic acid, is allowed.

Japan Agricultural Standard (JAS) for Organic Production
Sodium lactate and potassium lactate are not listed in the JAS standard and therefore are not permitted. The JAS standard specifically states, "The use of any materials except for those described as below is prohibited."

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 issued 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 (Environmental Protection Agency 2008).

Discussion
Many stakeholders view this listing as "enormously complicated" saying that it is the procedural history that is complicated and not the material itself. Potassium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the NL 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 NL. 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 leading to it being added to the NL effective 1/28/2019. The Handling Subcommittee finds significant merit to keep potassium lactate on the NL under section 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

While sodium lactate and potassium lactate appear to be used nearly interchangeably, there are certain uses, such as "low sodium" meat alternatives that require potassium lactate specifically. This is relevant, as the US has an equivalency agreement with the EU for organic standards and the EU does not permit the use of potassium lactate as a food additive. A better understanding of the EU rationale for excluding potassium lactate but allowing sodium lactate could be helpful.

Questions for our Stakeholders

1. What distinguishes potassium lactate from sodium lactate in terms of functionality? Is that difference important?

Silicon dioxide

Reference: §205.605(b) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.
Technical Report: 1996 TAP, 2010 TR
Petition(s): 2010 petition to remove
Past NOSB Actions: 09/1996 minutes and vote; 11/2005 recommendation; 12/2011 recommendation; 11/2016 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 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
Synthetic amorphous silicon dioxide is used as a food additive for various functions including as:
- An anticaking agent in foods
- A stabilizer in beer production, and filtrated out of the beer prior to final processing
- An adsorbent in tableted foods
- A carrier
- A defoaming agent

Manufacture
Synthetic amorphous silicon dioxide can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment. According to FDA regulations, silicon dioxide (as a food additive) is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. Silicon dioxide can be produced as a nanomaterial, but for use in organic production such a material would have to be petitioned and placed on the National List. As stated in NOP Policy Memorandum from March 2015:

> As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been
> 1) petitioned for use;
> 2) reviewed and recommended by the NOSB; and
> 3) added to the National List through notice and comment rulemaking.

Currently there is no silicon dioxide produced with nanotechnology on the National List.

International Acceptance
Canadian General Standards Board Permitted Substances List
Silicon dioxide is listed in Table 6.3 Ingredients Classified as Food Additives, and Table 6.5 Processing Aids.

European Economic Community (EEC) Council Regulation, EC No. 889/2008
Silicon dioxide is listed in Annex VIII of the Commission Regulation, Section A Food Additives, Including Carriers for use in preparation of foodstuffs of plant origin as an anticaking agent for herbs and spices. Also listed as a gel or colloidal solution in Section B Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production.

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

Silicon dioxide (Amorphous) is listed in Annex 2 Permitted Substances for the Production of Organic Foods, Table 3 Ingredients of Non-Agricultural Origin as an additive in foods of plant origin permitted for use in herbs, spices, seasonings, and condiments (e.g. seasonings for instant noodles). Also allowed as a processing aid in gel or colloidal solution.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Silicon dioxide (amorphous) is listed in Appendix 4, Table 1 List of Approved Additives and Processing/Post-Harvest Handling Aids.

Japan Agricultural Standard (JAS) for Organic Production
Silicon dioxide listed in Attached Table 1 Food Additives, limited to be used for processed foods of plant origin as gel or colloidal solution.

Ancillary Substances
None reported in the 2010 TR and none noted in public comment during the 2016 sunset review.

Environmental Issues
The 2010 TR stated silica dust is produced during its manufacture and use, however at the time of writing there was no data on ambient air concentrations of amorphous silica and ambient levels are not well quantified for crystalline silica. Exposure levels are considered the highest in occupations involved with packing, weighing, reprocessing, and cleaning. While the Subcommittee recognizes the risk of exposure to crystalline silica dust during the mining, manufacture and processing of silica, there does not appear to be a great deal of study on the effects of amorphous silica as is used in the manufacture of silicon dioxide. Studies that have explored exposure to amorphous silica dust suggest such exposure may not lead to silicosis or fibrosis as can result from crystalline silica exposure. These existing studies point to the need for further work in this area. (Merget R, Bauer T, Küpper HU, Philippou S, Bauer HD, Breitstadt R, Bruening T. Health hazards due to the inhalation of amorphous silica. Arch Toxicol. 2002 Jan;75(11-12):625-34. doi: 10.1007/s002040100266. PMID: 11876495; McLaughlin JK, Chow WH, Levy LS. Amorphous silica: a review of health effects from inhalation exposure with particular reference to cancer. J Toxicol Environ Health. 1997 Apr 25;50(6):553-66. doi: 10.1080/15287399709532054. PMID: 15279029.)

The 2010 TR noted the EPA concluded that silicon dioxide and silica gel do not pose unreasonable risks to the environment, including non-target organisms, when used at their registered levels. This conclusion is based on the belief that silicon dioxide and silica gel are chemically unreactive in the environment, occur naturally in various forms, and are practically non-toxic to non-target organisms.

Discussion
A 2010 petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of a commercially produced rice-based certified organic alternative to silicon dioxide. In 2011, the NOSB did not move the petition to remove forward and silicon dioxide remained on the list. Data was presented in the petition claiming that a reformulation of the rice-based alternative could be substituted for silicon dioxide at nearly 1:1 ratio. However, 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.

The Subcommittee did however wish to acknowledge the availability of a natural alternative. Even though the Subcommittee did not vote to remove silicon dioxide, it passed a recommendation in 2011 to amend the annotation of silicon dioxide, resulting in its current listing which requires the use of organic rice hulls when commercially available. In its recommendation, the Subcommittee noted that additional information and clarification of processors' needs regarding silicon dioxide is needed for future deliberations by the NOSB.

In its last sunset review in 2016, public comment indicated that organic rice hulls are *not* a viable alternative for all current uses:

- As an anticaking agent in organic powders, including organic cheese powders
- In organic dry flavors in which rice hulls have not adequately or evenly disbursed flavor actives and have taken up moisture
- As an anticaking agent at a recommended 2% application rate, when instead the rice hull rate has been 15-50%
- As a flow agent for rice syrup solids
- As a clarifier in the production of beer

Questions to our Stakeholders

1. Are there organic alternatives to silicon dioxide that are more suitable to the uses described above, in which rice hulls are not viable?

2. Is there reliable, consistent commercial availability of rice hulls for the applications in which it performs well?

3. How prevalent is the use of silicon dioxide as a defoamer?

4. How prevalent is the use of silicon dioxide for other allowed purposes, e.g. anticaking agent, flow agent, flavor disbursement?

Sodium lactate

Reference: §205.605(b) 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: 4/2016 recommendation
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559)
Sunset Date: 1/28/2024

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.

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.

International Acceptance
Canadian General Standards Board Permitted Substances List
Sodium lactate and potassium lactate are not listed for use in processing.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The European Chemicals Agency (ECHA) primarily evaluates sodium lactate by its precursor, lactic acid, and concluded "Lactic acid does not have to be labeled for environmental effects, and no short or long-term effects are expected for any exposure levels that do not lower the pH to unacceptable levels. As such no relevant hazards are foreseen."

Sodium lactate is allowed for use in processing foodstuffs of animal origin only and is listed for use in: "Milk-based and meat products.".

International Federation of Organic Agriculture Movements (IFOAM) Norms
Sodium and potassium lactates are not specifically listed in any of the appendices in the IFOAM, but the precursor, lactic acid, is allowed.

Japan Agricultural Standard (JAS) for Organic Production
Sodium lactate and potassium lactate are not listed in the JAS standard and therefore are not permitted. The JAS standard specifically states, "The use of any materials except for those described as below is prohibited."

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 (Environmental Protection Agency 2008).

Discussion
Many stakeholders view this listing as "enormously complicated" saying that it is the procedural history that is complicated and not the material itself. Sodium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the NL 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 NL. 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 leading to it being added to the NL effective 1/28/2019. The Handling Subcommittee finds 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.

Questions to our Stakeholders

1. Why do JAS, IFOAM, and the Canadian standard prohibit the use of sodium lactate?