

Sunset 2023
Meeting 2 - Review
Handling Substances § 205.605(a), § 205.605(b), § 205.606
October 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 scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, 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

Written public comments will be accepted through September 30, 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. A useful characteristic of agar-agar is its ability to withstand high temperatures. Since agar-agar is practically tasteless and does not require the addition of cations to form gels, it doesn't interfere with taste profiles. Agar-agar can be used in foods in combination with other thickening or gelling agents. Agar-agar is classified as generally recognized as safe (GRAS) by the FDA.

Manufacture

Agar-agar is derived from red algae, the main genera harvested being *Gelidium* and *Gracilaria*, the second of which can be cultivated. After harvesting, the algae are cleaned with water, dried in the sun, pressed into bales, and shipped to processors for agar-agar extraction. Prior to extraction, the *Gracilaria* 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 *Gracilaria* species would be too weak for most food applications (2011 TR lines 165-176). After pretreatment, the algae are placed in tanks for extraction via hot water and pressure, followed by filtration. Water is removed from the gel through a freeze-thaw process or by mechanical pressure. The gel is then dried with hot air resulting in a finished product of flakes, strips, or powder.

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 if the harvesting of agarophytes, in particular, is harmful to the biodiversity of nearby beaches or algae beds. Agar-agar manufacture produces alkaline wastewater, but there were no documents found that show this to be a current problem to the environment.

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 *Graciliara* species 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-L-galactose), increasing the gel strength of the agar-agar. Data indicate 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.

There were several comments during the Spring 2021 meeting supporting the relisting of agar-agar. It is an essential tool in the development and innovation of organic foods. Several commentors noted there is a distinct difference between synthetic and non-synthetic forms based on species of red algae. However, commercial availability of non-synthetic agar-agar is insufficient and may not be effective for some applications.

Justification for Vote

The Subcommittee proposes removal of agar-agar from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove agar-agar from the National List

Motion by: Kim Huseman

Seconded by: Jerry D’Amore

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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

International Acceptance

[Canadian General Standards Board 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.

There was overwhelming support during the comment period of the 2021 Spring meeting to relist animal enzymes on the National List. Comments addressed the non-existence of organic animal enzymes and the

inability to achieve a reliable organic supply; cost was listed as a barrier as well. Several mentioned the lack of adequate alternatives in order to produce the type(s) of cheese being manufactured. There was one opposing comment suggesting more research needs to be done regarding the essentiality of catalase, animal lipase, pancreatin, pepsin, and trypsin.

Justification for Vote

The Subcommittee proposes removal of animal enzymes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove animal enzymes from the National List

Motion by: Kim Huseman

Seconded by: Jerry D'Amore

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 11/03/2013 ([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 [use] 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

The Handling Subcommittee received several comments 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.

Subcommittee review

At the Spring 2021 NOSB meeting, the Subcommittee heard from several certifiers about somewhat limited use of the material among their members, although despite limited use, their support for relisting was clear. One non-profit stakeholder shared concern flagged by the Subcommittee about potential negative impacts from mining for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only.

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?

Justification for Vote

The Subcommittee proposes removal of calcium sulfate-mined from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove calcium sulfate-mined from the National List

Motion by: Wood Turner

Seconded by: Jerry D'Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 11/03/2013 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#)).

Sunset Date: 5/29/2023

Subcommittee Review

Use

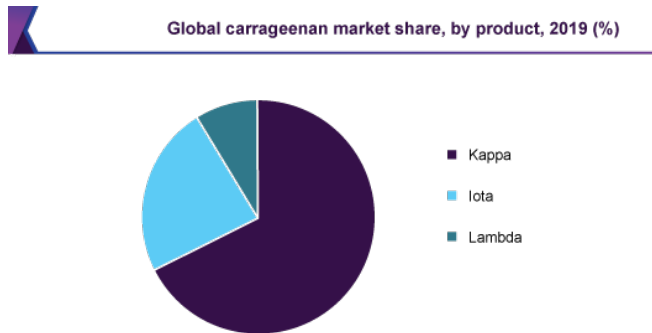
Carrageenan is a food additive used as an emulsifier, thickener, and gelling compound primarily in meat and dairy products. It is often used as a vegan alternative to animal sourced gelatin. It is listed as generally recognized as safe (GRAS) on the FDA list of food additives.

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 centrifugation and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder for addition to foods.

There are three main kinds of carrageenan (kappa, iota, and lambda 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.



Source: www.grandviewresearch.com

- 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

[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.

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

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

[Japan Agricultural Standard \(JAS\) for Organic Production.](#) JAS allows carrageenan as an additive to organic dairy products.

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

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

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).

The 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. The turnover to harvest is quite short, at only 6 weeks. However, increased demand for seaweed has resulted in the establishment of some farms that involve first destroying important nearshore habitats like mangrove swamps or eelgrass beds to provide growing environments. Drifting mats from the established farms can also smother other nearby habitats, such as coral reefs. For example, when seaweed farming was introduced to India, to promote aquaculture for carrageenan, the seaweed rapidly invaded and smothered coral reefs in a nearby marine reserve (Baglar, 2008).

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 can be positive. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, remove impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some effects of climate change (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. It did not become broadly used in industrial food preparation until the 1930s. It is currently a \$500 million dollar industry.

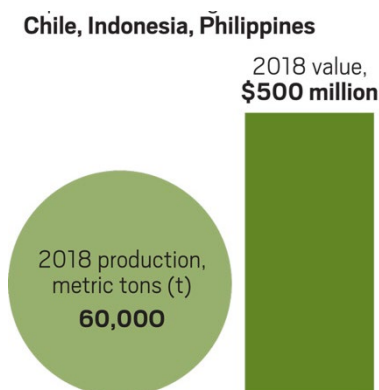


Figure 2. Carrageenan production in 2018 (Taylor, 2019)

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 gelatin were singled out as difficult to produce without carrageenan.

Eliminating carrageenan may be achievable through the elimination of many processed foods where it is considered 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 based on lack of essentiality (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 implement the NOSB recommendation to remove carrageenan from the National List, and carrageenan is currently allowed in organic production.

Stakeholder Input

There were fourteen stakeholder thoughts and/or concerns (both oral and written) registered during the 2021 Spring NOSB meeting. Eight were in favor of keeping carrageenan on the National List and four were opposed. The remaining two indicated that carrageenan was not used within their community. While there was general support within the stakeholder community to keep carrageenan on the National List, it was deemed an unnecessary addition by the NOSB as there are alternative products that serve the same functionality.

Justification for Vote

The Subcommittee proposes removal of carrageenan from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of alternatives.

Subcommittee Vote

Motion to remove carrageenan from the National List

Motion by: Jerry D’Amore

Seconded by: Kyla Smith

Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

References:

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

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

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

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

Matthee, M. (2007) *The Codex Alimentarius Commission and its standards*. Maastricht University.

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

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

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

Glucono delta-lactone (GDL) is produced by crystallization from an aqueous solution of gluconic acid. There are a variety of ways gluconic acid can be produced. The most common method to produce gluconic acid is called the Blom process, where gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium hydroxide or calcium carbonate is added to the fermentation process to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via fermentation and acid base reactions (2016 TR, 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 the use of 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 \(CXG 32-1999\)](#)

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

Discussion

The original 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. Citric and lactic acids produce acidified tofu that is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

The Handling Subcommittee requested public comment regarding the use of GDL in organic processed foods other than tofu production. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic product. Further, the Handling Subcommittee asked if alternative tofu coagulants such as calcium and sulfate salt would be sufficient to produce all forms of tofu if GDL were removed from the national list. In response, companies commented that alternatives on the list result in distinctly different and firmer tofu and that GDL is critical for silken, jelly-like tofu. Several tofu manufacturers commented in favor of retaining GDL.

Lastly, the Subcommittee asked stakeholders whether GDL produced from enzymes should be prohibited or further restricted due to concerns about GMOs, an issue that is referenced in the 2002 TAP and noted as an issue for ongoing monitoring. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the Board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means, however, no information was presented on the commercial viability of this approach.

Subcommittee review

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

The Handling Subcommittee heard from several certifiers about somewhat limited use of the material among their members, although despite limited use, support for relisting was clear. One non-profit stakeholder shared a concern flagged by the subcommittee about potential negative impacts from mining

for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only. Another stakeholder suggested GDL is nonessential, though several certifiers reported that a number of their members and clients are currently using GDL.

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

Questions to our Stakeholders

1. How widespread is the use of GDL in organic applications?
2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?
4. Is the lack of International acceptance significant?
5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Justification for Vote

The Subcommittee proposes removal of glucono delta-lactone from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove glucono delta-lactone from the National List

Motion by: Wood Turner

Seconded by: Jerry D'Amore

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 11/03/2013 ([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 acid, in that potassium hydroxide is added to the waste mixture. Activated carbon is also added to remove unwanted pigmentation. The potassium tartrate is precipitated by adding saturated pure tartaric acid solution and then the precipitate is redissolved with acidic water at 70° C. Potassium and sulfate ions must be removed from the remaining solution, so cation exchanges are performed followed by evaporation. The solution is then crystallized at 4° C.

International Acceptance

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

The use of tartaric acid (C₄H₆O₆; 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 \(CXG 32-1999\)](#)

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 GFSMA 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 impart a different taste 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 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.

Subcommittee Review

A number of public comments supported relisting of this material. Commenters highlighted that tartaric acid is essential in wine production and that organic wines rely on this material. However, several stakeholders questioned whether there could be an adequate supply of tartaric acid made from organic grape wine. The listing could discourage the development of an organic tartaric acid. The sale of tartaric acids made from organic wines could also provide additional revenue for organic vintners. This is an open-ended question and the answer to it was not resolved in public comments. Since the question is not resolved, relisting at this point in time is prudent. However, as the organic wine market continues to grow, the Board encourages the inclusion of an analysis of the availability of tartaric acid from organic grapes during the next sunset review, and also encourages the organic wine industry to move towards production of tartaric acid from organic grapes.

Justification for Vote

The Subcommittee proposes removal of tartaric acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove tartaric acid from the National List.

Motion by: Steve Ela

Seconded by: Jerry D'Amore

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 11/03/2013 ([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 enacting of OFPA, with cellulose allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture

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

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth (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 Generally Regarded as Safe GRAS under 21 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).

[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).

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

[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

Cellulose remains essential to organic handling for a few products. The NOSB asked the stakeholders whether there were other ancillary substances (beyond those listed above) that might be used in the production of cellulose. In the April 2021 meeting comments, stakeholders identified glycerin/glycerol as another ancillary substance.

A notable comment by a stakeholder was that sourcing cellulose should be done in a way that minimizes environmental impact. This concern echoes public comments from earlier sunsets of cellulose, as mentioned in the previous section (Environmental Issues) of this document.

Overall, based on the written and oral comments prior to the April 2021 meeting, there continues to be support for relisting cellulose.

Justification for Vote:

The Subcommittee proposes removal of cellulose from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote:

Motion to remove cellulose from the National List at §205.605(b)

Motion by: Kyla Smith

Seconded by: Jerry D'Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recused: 0

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: Added to National List 2/20/2001 ([65 FR 80547](#)); 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 Environmental Protection Agency (EPA)-registered pesticide (OPP Nos. 014701). Calcium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

Calcium hypochlorite is an "indirect" food additive approved by Food and Drug Administration ([FDA](#)). Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (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 FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hypochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triphosphate 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 vacuum dried.

International Acceptance

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

Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

[European Commission Directorate-general for Agriculture and Rural Development](#)

Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food processing operator has to comply with the “hygiene package” regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

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

Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<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.

Summary of Public Comments

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

Justification for Vote

The Subcommittee proposes removal of calcium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove calcium hypochlorite from the National List

Motion by: Asa Bradman

Seconded by: Jerry D’Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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: Added to National List 2/20/2001 ([65 FR 80547](#)); 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 Cl₂).

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

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases.

Manufacture

To form chlorine dioxide, sodium chlorate (NaClO₃) and sulfuric acid (H₂SO₄) are reacted with sulfur dioxide (SO₂), or chloric acid is reacted with methanol (CH₃OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl₂) 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](#)

Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

[European Commission Directorate-general for Agriculture and Rural Development](#)

Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food

processing operator has to comply with the “hygiene package” regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

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

Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aocedata.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.

Summary of Public Comments

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

Justification for Vote

The Subcommittee proposes removal of chlorine dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove chlorine dioxide from the National List

Motion by: Asa Bradman

Seconded by: Jerry D'Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 to add](#)

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. 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 Cl₂).

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

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an

enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

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](#)

Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

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

Not listed

Human Health and Environmental Issues

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

Summary of Public Comments

Public comment and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized “by specific use or application” with clear identification of the hazards to humans and the environment (NOC 2020). Further, “Restructuring the National List so that cleaners, sanitizers and disinfectants have a

designated section... would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education... Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021).” Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS will recommend a work agenda item to advance these suggestions.

Justification for Vote

The Subcommittee proposes removal of hypochlorous acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove hypochlorous acid from the National List

Motion by: Asa Bradman

Seconded by: Jerry D’Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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: Added to National List 2/20/2001 ([65 FR 80547](#)); 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. 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 Cl₂).

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 FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triphosphate 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](#)

Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

[European Commission Directorate-general for Agriculture and Rural Development](#)

Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food processing operator has to comply with the “hygiene package” regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

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

Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in

occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<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.

Summary of Public Comments

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

Justification for Vote

The Subcommittee proposes removal of sodium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove sodium hypochlorite from the National List

Motion by: Asa Bradman

Seconded by: Jerry D’Amore

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 \(CXG 32-1999\).](#)

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, as 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 commercial processing methods used for peaches, the NOSB favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

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.

Subcommittee Review

Stakeholder comments on potassium hydroxide were mixed, with some supporting relisting and others asking for a more thorough review and a possible annotation change for this listing.

Proponents of relisting noted that there are no management practices that would eliminate the need for this material, that it is needed for pH adjustment and potassium fortification, and there are differences in solubility as compared to possible alternatives. Delisting of this material would lead to difficulties with product stability and increased manufacturing losses. One commenter noted that if this product were delisted they would leave the organic category.

Opponents to relisting noted the human health hazards from the corrosivity of potassium hydroxide, the environmental concerns from the disposal of large amounts of water with soluble potassium and alkali ions, and whether it continues to be essential for organic peach processing. Others noted that the annotation is problematic in that it lists uses that are not allowed rather than uses that are allowed. Annotations that list allowable uses are very specific in that other uses are definitively prohibited. Annotations that only list methods that are prohibited allow for any other uses, including those that were not anticipated at the time of listing. However, annotation changes cannot be done during the sunset review and would need to be the reviewed as a separate work agenda item.

While the Subcommittee recognizes the arguments of the opponents to this material, the removal of this material would be disruptive to organic handlers and at this point in time it is still essential for organic handling.

Justification for Vote

The Subcommittee proposes removal of potassium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove potassium hydroxide from the National List.

Motion by: Steve Ela

Seconded by: Asa Bradman

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 do not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, the necessary precursor of potassium lactate. However, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (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 National List was based on the fact that both of the materials used to produce potassium lactate (lactic acid and potassium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Potassium lactate was added to the National List effective January 28, 2019. The Handling Subcommittee finds significant merit to keep potassium lactate on the National List at § 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

Summary of Public Comments

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

Justification for Vote

The Subcommittee proposes removal of potassium lactate from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove potassium lactate from the National List

Motion by: Jerry D’Amore

Seconded by: Steve Ela

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 filtered 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. 834/2007 and 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 \(CXG 32-1999\)](#)

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.

Summary of Public Comment

Most stakeholders were in favor of relisting based on essentiality. Public comments noted that alternatives, such as organic rice hulls, are not able to be used to achieve suitable functionality in all applications. There were a few comments that suggested the NOSB review the current annotation against the original annotation passed by the Board to ensure the intent of the original annotation is accurately conveyed.

Justification for Vote

The Subcommittee proposes removal of silicon dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove silicon dioxide from the National List

Motion by: Kyla Smith

Seconded by: Kim Huseman

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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. Lactic acid is allowed.

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

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 National List was based on the fact that both of the materials used to produce sodium lactate (lactic acid and sodium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Sodium lactate was added to the National List effective January 28, 2019. 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.

Summary of Public Comments

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

Justification for Vote

The Subcommittee proposes removal of sodium lactate from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove sodium lactate from the National List

Motion by: Jerry D’Amore

Seconded by: Kim Huseman

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0