

Sunset 2018 Review Summary
Meeting 2 – Subcommittee Review
Handling Substances § 205.605(a), §205.605(b), §205.606
November 2016

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Reference: 7 CFR 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)).”

(Linked below)

[Agar-agar](#)

[Animal enzymes](#)

[Calcium sulfate-mined](#)

[Carrageenan](#)

[Glucono delta-lactone](#)

[Tartaric acid](#)

Reference: 7 CFR 205.605(b) 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](#)

[Potassium hydroxide](#)

[Silicon dioxide](#)

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(2) [Beta-carotene extract color](#)

Agar-agar

Reference: §205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

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. It can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. Useful characteristic of agar-agar include that it can withstand high temperatures, and since it is practically tasteless and doesn't require the addition of cations to form gels, it doesn't interfere with taste profiles. It can be used in foods in combination with other thickening or gelling agents. It is classified as GRAS.

Manufacture:

Agar-agar is derived from red algae, the main species harvested are *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. (TR 2011, 165-176)

After pretreatment, the algae are placed in tanks for the extraction via hot water pressure, and then filtration. The last step is to remove water from the gel either through a freeze thaw process or by mechanical pressure. The gels are then dried with hot air resulting in a finished product of flakes, strips, or powder.

Based on this manufacturing information, the Handling Subcommittee acknowledges that a reclassification of agar-agar might be needed in the future once the NOP finalizes the Guidance for Material Classification.

International:

Agar-agar is not permitted for use in organic production in Japan. It is permitted for use in organic production by CODEX, the Commission of the European Communities, IFOAM, and Canada.

Discussion:

The 2011 TR did not find the substance to be harmful to human health, additionally the report stated that no excessive levels of heavy metals or other contaminants have been reported in agar-agar.

With regard to harm to the environment or biodiversity, the TR stated there is limited evidence to suggest that the harvesting of agarophytes (algae used to make agar-agar) may be harmful to

biodiversity. Additionally, harvesting wild agarophytes may also reduce biodiversity on nearby beaches. The TR concludes though that no studies were found to indicate whether or the not the harvesting of agarophytes in particular is harmful to biodiversity on nearby beaches or in the algae beds themselves (TR 2011 296-312).

The NOSB is in the process of reviewing the use of all marine plants currently on the National List and a limited technical report has been requested. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

A variety of organizations and manufacturers commented in support of keeping agar-agar on the National List. There were no commenters opposed. Two organizations commented that they would support relisting of the non-synthetic form only. A proposed annotation was “from Gelidium species only, processed without alkaline treatment and sourced from areas managed for sustainability”.

At the first posting for agar-agar, the Handling Subcommittee asked the public for input on any new developments with alternatives to agar-agar, why it’s used instead of alternatives, and what the unique characteristics are that make it essential to organic handling? Responses included: since there is no source for organic gelatin, agar-agar is essential for the manufacture of gummy products because it is superior to using carrageenan and gellan gum; it is used as a stabilizer and the alternative is carrageenan; it is used as thickener in soy cheese and no suitable alternatives have been found; it has stronger setting properties than animal based gelatins; it is less temperature sensitive than certain alternatives.

The Handling Subcommittee proposes that agar-agar remain on the National List

Additional Information Requested:

Based on information reviewed, the Subcommittee is not aware of any ancillary substances used in agar-agar. If the public is aware of any ancillaries please provide information via public comment.

Motion to Remove

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) if applicable: none

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Ashely Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 2 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 TR](#)

Petition(s): NA

Past NOSB Actions: [11/2000 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

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). (Technical Report 2011 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. (TR 2011 727-728)

Manufacture:

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

International:

The use of enzymes is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary substances:

Explained in the enzymes technical evaluation report - limited scope, (NOP 2015):

“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.

Additional Information Requested:

- 1). During the 2017 sunset review of enzymes (non-animal) the following chart was posted and the public submitted additional ancillary substances (now included in the chart). If you know of ancillary substances used in animal enzymes that are not found on the chart below, please submit spec sheets or names of materials. If there are ancillary substances on the chart that you think should not be allowed, please submit public comment explaining why.
- 2). “Mineral oils, untreated or mildly treated” are on the combined IARC/NTP list. The latest technical

evaluation report (TR) (March 12, 2015) for mineral oil that was done for the Livestock Subcommittee states that for refined mineral oil, the refining process removes the materials that pose the carcinogen concerns. It also mentions that according to the FDA database for “Everything Added to Food in the United States” (EAFUS), mineral oils are approved for use as direct, secondary direct, and indirect food additives for human and animal feed (FDA, 2014). FDA permits the direct addition of mineral oil to food for consumption under 21 CFR 172.842 and 172.878. Could you provide the committee with any information as to how prevalent or necessary mineral oil is as an ancillary for animal enzymes? Also, could you provide us with any information as to the type of mineral oil currently being used? For example: refined, mildly treated, or untreated mineral oil?

| 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, sodium |
| 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, micro-crystalline 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. |

Discussion:

Evaluation question #9 in the 2011 TR does not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

Evaluation question #10 in the 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, can cause allergic reactions in sensitive individuals (Tucker and Woods, 1995). FDA reports it is not aware of any allergic reactions associate with

the ingestion of food containing enzymes commonly used in food processing (FDA, 1995). (TR 2011 752-758).

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 review for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Public comment during the first posting included a number of producers in favor of animal enzymes remaining on the National List. Multiple commenters stated it was essential for making certain varieties of cheeses and that organically derived animal enzymes were not available. Multiple organizations commented that organic alternatives should be explored more fully; if not currently available the barriers should be identified as well as how to overcome them. One organization felt animal enzymes were probably not essential since the majority of enzymes of used in the U.S. were non-animal.

The Handling Subcommittee proposes that animal enzymes remain on the National List

Motion to Remove

The Subcommittee proposes removal of animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 2 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](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review:

Uses:

- 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

- Sequestrant, filler, carrier, pH buffer, abrasive agent
- Cosmetics and toothpaste

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 mining crude gypsum, it is ground and separated. It is normally sold in pure form but may contain impurities of calcium carbonate and natural occurring silica. The material is GRAS.

International:

IFOAM – restricted “For soybean products, confectionery and in bakers’ yeast” but not restricted to mined sources. CODEX – restricted to “Cakes & biscuits/soy bean products/baker’s yeast. Carrier” but not restricted to mined sources. Japan – restricted to “Limited to be used as coagulating agent or used for confectionary, the processed beans products or bread yeast” but not restricted to mined sources. Canada – 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.” EU - 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.

Ancillary substances: None reported in 2001 TAP

Discussion:

Several comments were received on this substance. 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 2006¹. 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 TAP. While the handling subcommittee finds enough information at the current time to renew calcium sulfate, future NOSB’s should consider if a new Technical Review would be useful to review current data on alternative manufacturing methods, any new data available on environmental or human health concerns, and/or whether an annotation should be recommended.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of calcium sulfate.

¹ https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/pubnomsupport/gypsum1_508.pdf

Motion to Remove

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) if applicable:
none

Vote in Subcommittee

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Carrageenan

Reference: §205.605(a)

Technical Report: [1995 TAP](#), [2011 TR](#); [2016 Limited Scope TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987 –misspelled as ‘carrageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review

Use:

Carrageenan (CAS # 9000-07-1) is a generic term referring to a family of linear polysaccharides (i.e., complex carbohydrate chains) that are extracted from species of red seaweeds (Class *Rhodophyceae*). It is an FDA-approved direct food additive with an average molecular weight of 200-800 kDa, and may be referred to as “undegraded” or “native” carrageenan in the literature. The actual molecular weight of food-grade carrageenan represents a spectrum of molecular weights that are naturally present in live seaweed.

Carrageenan can function as a bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, or thickener. It can promote gel formation and thicken, stabilize and improve palatability and appearance of foods. It is typically used at a rate ranging from 0.03% to 0.75%, and its most common uses are in dairy products, non-dairy "milk" analogs, meats, and drink mixes. It has been used in food processing for centuries.

Manufacture

During the 2012 sunset review concerns were raised about whether the manufacturing process to create carrageenan from seaweed might turn it into a synthetic material by the NOSB definition. Concerns were also raised about the environmental consequences of growing and harvesting these red seaweeds. As far as classification, the NOSB is still waiting for final guidance on the Classification of Materials and will not re-visit this issue until the guidance is final. A comprehensive technical report on issues related to seaweed harvesting is in development, but the results were not available in time for this review.

Effect on Human Health

During the 2012 sunset review, public comment indicated considerable controversy surrounding this ingredient, both among the scientific community and the public. The scientific community disagreed over the research methodology used in studies and meta reviews that were not always consistent with how carrageenan behaves when ingested in food. Several public interest organizations supported one scientific group's approach over the others because of concerns that carrageenan caused inflammation or worse. The NOSB could not thoroughly investigate these issues within the very short period of time between the sunset announcement and the vote to renew. The members of the 2012 Handling Subcommittee did promise the public to do a more thorough analysis at the time of the next sunset review. Therefore, the Handling Subcommittee commissioned a limited scope technical report (see 2016 limited scope TR, linked above) to supplement the one that was done in 2011. This report focused on the effects of the substance on human health: Evaluation question #10. The Subcommittee posed very specific questions about the research methodology regarding the molecular weights of carrageenan, the relative value of *in vivo* vs. *in vitro* studies, and the newest studies since the last TR was done in 2011.

The TR came back with the following statement, "Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature." (lines 173 - 174). And this, " However, since different animal species, different animals within the same species, and different human intestinal cell lines have produced different experimental results, it is reasonable to expect that humans may also experience varying degrees of sensitivity to carrageenan in the diet." (lines 177 - 180).

It is also worth noting that in the time since the last review, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) re-evaluated carrageenan for use in infant formula and changed their opinion on restricting its use to have an unrestricted status. (See TR for citation).

In the first posting the Handling Subcommittee made the following statement: "We are troubled that the research showing inflammation and glucose intolerance is all from one research team and has not been replicated". Public comment from the first posting reached almost 1000 pages, much of it with scientific debate and opinion about whose research to believe and whose to discard.

We have examined most of the references that were provided as citations regarding the replication issue and found that the claims of replication could not be substantiated. There were studies that had not been conducted yet², studies by the same authors as the ones who showed inflammation³, studies using carrageenan as an agent to test other chemicals (but not the carrageenan itself)^{4,5}, and studies that were cited but without conclusions that supported the glucose intolerance issue.⁶ Furthermore, one study claimed to support carrageenan extensively degrading into poligeenan in the digestive tract,

² "The clinical impact of carrageenan and diabetes, currently being studied in Germany" (University of Tuebingen, Dr. Robert Wagner and Dr. Norbert Stefan). <https://clinicaltrials.gov/ct2/show/NCT02629705>.

³ Bhattacharyya S, Feferman L, Unterman T, Tobacman JK. Exposure to common food additive carrageenan alone leads to fasting hyperglycemia and in combination with high fat diet exacerbates glucose intolerance and hyperlipidemia without effect on weight. *J Diabetes Res.* 2015;2015:513429. doi: 10.1155/2015/513429

⁴ Jung TW, Lee S, Hong HC, et al. AMPK activator-mediated inhibition of endoplasmic reticulum stress ameliorates carrageenan-induced insulin resistance through the suppression of selenoprotein P in HepG2 hepatocytes. *Mol Cell Endocrinol* 2014;382:56-73.

⁵ Baek HS, Yoon JW. Direct involvement of macrophages in destruction of beta-cells leading to development of diabetes in virus-infected mice. *Diabetes* 1991;40(12):1586-97

⁶ Taché S, Peiffer G, Millet A-S, Corpet DE. Carrageenan gel and aberrant crypt foci in the colon of conventional and human flora-associated rats. *Nutr Cancer* 37:193–198 (2000).

but in fact did not show that result."⁷

The Subcommittee also looked at very recent work from the researchers who attempted to replicate these results.⁸ One of the key points made in the McKim article of 2016 was the challenge of using in vitro adverse effect data to predict risk for human disease. Among the conclusions presented: "The present work has shown that CGN does not cross intestinal epithelial cells, and is not cytotoxic to these cells. CGN did not increase cellular oxidative stress nor did CGN induce the expression of pro-inflammatory genes."

We understand why the TR came back with a somewhat nebulous statement about the research, because the experimental methods used in many experiments on both sides of the issue appear to be flawed. Without good research methodology and scientists who disagree over every conceivable point regarding carrageenan research, we can only agree that definitive conclusions cannot be made about the effects of carrageenan in the diet on human health.

The NOSB Handling Subcommittee is aware of research that came to our attention in the sunset review of other emulsifiers such as lecithin and guar gum which suggested that all of these ingredients may be contributing to metabolic syndrome, inflammatory bowel disease and obesity, simply by their impact on microbes in the gastrointestinal tract.⁹ This had been supported by previous research on Crohn's disease.¹⁰ While carrageenan has been more extensively studied than the other non-synthetic emulsifiers, there may be reason for concern that all emulsifiers can lead to inflammation and it is not a unique function of carrageenan.

Alternatives

The OFPA at 6518(m)(6) specifically directs that the NOSB "shall consider – the alternatives to using the substance in terms of practices or other available materials." Therefore, in the first posting of carrageenan, for the April 2016 NOSB meeting, the NOSB requested specific information about use of carrageenan, alternatives and necessity for this material.

Stakeholder responses indicated that carrageenan has been removed from many products over the last few years, and the products are either made without any replacement material, or with a different material. Stakeholder comments indicated that for the following products, for example, carrageenan was no longer necessary: whipping and heavy cream, chocolate milk, protein shakes, milk powders, yogurt, sour cream, cottage cheese, sugar free spreads, puddings, pie fillings, gummy bears, frozen soy desert, soy milk, processed meats, non-dairy beverages (nut and grain "milks") and beer.

We found that for some uses, particularly in dairy products and non-dairy milk-like beverages, there were suitable alternatives such as gellan gum, xanthan gum, and guar gum, although without carrageenan there is a tendency for sediments to collect at the bottom, and the beverage has to be shaken vigorously.

⁷ Pittman KA, Golberg L, Coulston F. Carrageenan: the effect of molecular weight and polymer type on its uptake, excretion and degradation in animals. *Food Cosmet Toxicol* 1976;14:85–93.

⁸ McKim J.M. et al. *Food and Chemical Toxicology* 96 (2016) 1 - 10

⁹ Chassaing, B. et al. Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome. *Nature* 519, 92–96 (March 2015)

¹⁰ Roberts, C. et al. Hypothesis: Increased consumption of emulsifiers as an explanation for the rising incidence of Crohn's disease *Journal of Crohn's and Colitis*, Volume 7, Issue 4, 1 May 2013, Pages 338–341

There is some question as to whether there are alternatives to carrageenan in some infant formulas where it is needed to keep all the other synthetic nutrients in the liquid solution. However, we note that there is infant formula without carrageenan available in Europe.

For processed meat, such as sliced sandwich meats, commenters reported both success and lack of success in removing carrageenan. The shelf life of some of these meats is compromised without carrageenan since they don't hold together as well.

There are categories of organic products where no substitute has emerged. One key group is in vegetarian/vegan foods where gelatin is not acceptable because it is made from animals. These include gel capsules for vegetarian and vegan supplements.

Discussion

The Handling Subcommittee examined the issue of scientific bias, and found that there was no evidence to support the sweeping claims that all research in support of the safety of carrageenan is funded by industry. All scientific papers are peer reviewed and there is no evidence that the reviewers are influenced by industry. We are unable to draw any conclusions from the bitter fight going on between scientists.

During the first posting (April 2016) the Subcommittee posed a question regarding sensitivity to carrageenan, and whether or not that was enough reason to prohibit it in organic food. It appears that there are no epidemiological studies of populations regarding sensitivity but there are a number of anecdotal reports. Statements were made that the pathways of inflammation triggered by carrageenan were universal in all humans, but like the lack of replication, there was no evidence given in support of this statement.

The NOSB has spent a considerable amount of time reviewing research and public comment on carrageenan since the 2012 sunset review of this material. We find that the body of scientific evidence does not support claims of widespread negative human health impacts from consumption of carrageenan in processed foods. We appreciate that there may be some individuals who have sensitivity to the material, but even that is not entirely clear from the body of scientific research.

We recognize that consumer demand to remove carrageenan has already led to the removal of carrageenan from a number of categories of products and that other alternatives could be used to replace carrageenan in additional products. Subcommittee members think that there are alternatives to using carrageenan and recommend removing this material from the National List.

The Handling Subcommittee notes that any member of the public could petition for an annotation to limit the use to only those products for which there are no alternatives.

Motion to Remove

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) if applicable: OFPA 6518(m)(6) - availability of alternatives.

Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

Yes: 5 No: 2 Abstain: 0 Absent: 1 Recuse: 0

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](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review

Use:

Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly in the production of silken tofu. In tofu production GDL serves as a coagulant. GDL can also be used as a curing agent, leavening agent, pH control agent and sequestrant.

Manufacture: There are a variety of ways a GDL can be produced. The most common form has gluconic acid production is called the Blom process in which gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium hydroxide or calcium carbonate is added to this to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via acid base reactions and fermentation (2016 Technical Review pg. 10-11). Other processes to make GDL involve oxidation with bromine water (which is not allowed by the National List annotation) and oxidation with purified enzymes.

International:

GDL is not listed on the permitted substances lists of Canada, EU, Japan, Codex or IFOAM.

Ancillary Substances:

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

Discussion:

The original petition and primary use of GDL is for the coagulation of tofu. Several coagulants for tofu exist including magnesium chloride, calcium chloride, calcium sulfate and magnesium sulfate. Acids such as citric or lactic acid can be used as well. Each of these substances produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu, sulfate salts produce soft tofu and GDL produces silken tofu. Citrus and Lactic acids produce acidified tofu where are often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

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

The Handling Subcommittee sought further information from the public. In particular, if GDL is being used in applications other than tofu production for organic processed foods. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic good. Further, the handling subcommittee asked if GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salt sufficient to produce all forms of tofu. In response companies commented that alternatives on the list result in distinctly different and more firm tofu and that GDL is critical to silken, jelly-like tofu. Several tofu manufacturers commented in favor of retaining GDL. Lastly, it was asked, should GDL produced from enzymes be prohibited or further restricted due to concerns about GMOs. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means, however, no information was presented on the commercial viability of this approach.

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

Motion to Remove:

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) if applicable:
none

Motion by Tom Chapman

Seconded by Ashley Swaffer

Yes: 0 No: 6 Abstain: 1 Absent: 1 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](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review

Uses:

Tartaric acid is a natural organic acid that is 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.

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

International:

The use of tartaric acid (C₄H₆O₆; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredients 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, 2011).

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).

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, and stabilizer. Tartaric acid from a plant source (i.e. nonsynthetic L(+) tartaric acid) is permitted for use as a food additive in organic food production

(although exclusions of the GFSA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

Discussion:

The Handling Subcommittee, in its initial request for public comment, asked for comments regarding the use of tartaric acid and its essentiality in organic processing.

During the Spring 2016 meeting the NOSB received several comments in support of the relisting of tartaric acid. Those comments included:

- “Tartaric Acid is used in our process to correct natural acid deficiencies in grape juice/wine and to reduce the pH of grape juice/wine where ameliorating material is used in the production of grape wine. The removal of Tartaric Acid from the National List will have a direct impact on our quality of wine. To my knowledge there has been no organic replacement or any other material that has the same effect or provides the same quality as the material in question.”
- “Every wine we make has tartaric acid in it. It is used as a preservative and stabilizes the wine color by lowering the pH of wine. If we weren’t able to lower the pH we would have to use a higher amount of sulfur dioxide as a preservative that would exceed the 100 ppm total amount. It is also used as a stylistic tool to enhance the flavor and mouthfeel of the wine. We would discontinue our organic wines if we lost tartaric acid.”
- “We should investigate whether tartaric acid from organic grape wine is available or would be available if we didn’t have this listing.”
- “Tartaric acid is the single most important input allowed in organic winemaking that helps counteract California’s warm climate that causes low pH in grapes. It is therefore vital in producing quality wine made from organic grapes. Nearly all wines produced need some acid adjustment because very rarely do grapes ripen to the proper acid level to make wine. They therefore require pH and acidity correction to ensure proper fermentation and aging. Our almost 50 years of winemaking have demonstrated to us that some acid correction is almost always necessary, and tartaric acid is the most effective product available to make this adjustment. Tartaric Acid is a very important part of the organic winemaking process and we strongly support its continued use.”
- “Tartaric acid is used in sour candies to enhance fruit flavors and sour intensity. Alternatives are less stable to warm temperature environments.”
- “Tartaric acid is an absolute necessity for winemaking in California and for most warm weather winemaking regions. As grapes come in we replace some of the lost acidity with tartaric acid. Without it the wine would become susceptible to spoilage organisms and lack in flavor.”

Tartaric acid satisfies the OFPA evaluation criteria and the Handling Subcommittee supports its relisting.

Motion to Remove

The Subcommittee proposes removal of tartaric acid - made from grape wine, from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None

Vote in Subcommittee

Motion by: Ashley Swaffar

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Cellulose

Reference: §205.605(b) Cellulose - for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review:

Cellulose (CAS # 9004-34-6 alpha 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. Uses in organic handling include: 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 even before the creation of OFPA, with cellulose being allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

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 (such as: corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc.) through a delignification process that results in a chemically changed synthetic end product. The original process for making regenerated cellulose casing is called the viscose method. It converts cellulose fibers into regenerated fibers and films and with some minor changes is still in use today (this process was invented in the 1890's). Cellulose is considered GRAS under CFR 121.101 (LSRO 1973).

The current Sunset review of cellulose by the Handling Subcommittee and ultimately the full NOSB included: a review of historic information, information provided during public comment period (oral and written) for the Spring and Fall 2016 NOSB meetings, a new Technical Evaluation Report (Feb.11, 2016), and further research of available information that was conducted. This review also included a look at what possible ancillary substances might be used along with cellulose in its production for specific uses.

Internationally, cellulose is permitted under most organic standards outside of the U.S. for at least some uses and applications in organic processing or handling. Some examples of those allowed uses are:

- **Canada** - 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).
- **IFOAM** - 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 and Japan** - No uses identified.

Discussion:

During the 1st posting of cellulose the Handling Subcommittee asked 5 specific questions to aid in its review:

- The NOP is still working on the 2012 NOSB recommendation to add the word “powdered” to part of the annotation. Thus, no NOSB action on this issue is required at this time. Numerous comments on this discussion point gave a mixed reaction as to what impact the addition of the more restrictive wording to the annotation might have on organic handling. It was inconclusive.
- Organic handlers and some certifiers acknowledged that cellulose is still very much in use in organic handling and/or processing, and that for these specific uses there still does not seem to be a suitable alternative at this time. Thus, organic stakeholders that use this material via one of the three currently allowed uses, have provided information on how necessary cellulose is to their handling process.
- The TR states that: Although it is theoretically possible to use cotton and other natural fibers as sources of cellulose for filtering, making food-grade cellulose in a functional form requires synthetic processes. Alternative plant sources are also limited by technical considerations and production capacity.
- During public comment and also mentioned in the TR were concerns (also stated during previous sunset reviews) regarding the use of wood pulp as a source for cellulose and the environmental impact that this could possibly have. Also, concerns were raised about environmental problems caused by waste cellulose generated from food processing. The new TR states that conversion of cellulosic food wastes into useful products is the subject of research, as well as that involving additional cellulose waste from filtration aids and/or spent casings. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs, and governmental regulations. Thus, research is underway looking at the best use of the waste products and/or spent materials, which should help to ease those concerns in due time.

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in processing, many may remain in the final product in tiny amounts.

Information provided in the latest Technical Evaluation Report (TR) (Feb. 11, 2016) and also during

public testimony (written and oral) provided the Subcommittee the following list of ancillary substances that are sometimes used in the production of cellulose for use in organic handling and processing. The TR was very clear that there are well defined sources of commercially available cellulose that do not include any ancillary substance, as well as those that might use ancillaries listed in the chart below:

| Functional Class | Ancillary Substance Name |
|---|---|
| Carriers and fillers, agricultural or non-synthetic | 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 |
| | |

Subcommittee discussion points and request for additional input:

- “Mineral oils, untreated or mildly treated” are on the combined IARC/NTP list. The latest Technical Evaluation Report (March 12, 2015) for mineral oil that was done for the Livestock Subcommittee states that for refined mineral oil, the refining process removes the materials that pose the carcinogen concerns. It also mentions that according to the FDA database for “Everything Added to Food in the United States” (EAFUS), mineral oils are approved for use as direct, secondary direct, and indirect food additives for human and animal feed (FDA, 2014). FDA permits the direct addition of mineral oil to food for consumption under 21 CFR 172.842 and 172.878. Please provide the Subcommittee with any information as to whether or not mineral oil is needed/or used as an ancillary for cellulose? Also, please provide us with any information as to the type of mineral oil currently being used? For example: refined, mildly treated, or untreated mineral oil.
- The TR mentions releasing agents that are used for peeling, retaining moisture, or that help to add smoke in sausage making, but no specific ones were mentioned (we were able to identify one: mineral oils). The Handling Subcommittee requests from handlers who are using releasing agents a list of any releasing agents that you are aware of, so that we could amend our list of allowed ancillaries for use in cellulose formulations. Also, please provide us with any other ancillary substances that are currently in use that we have not listed.
- It appears that processed cheese can be made with/or without cellulose. Thus, it brings into question whether or not cellulose is necessary or essential in organic shredded cheese production (it appears manufacturers are making it both ways). Could you provide the NOSB with information as to why some shredded cheeses are made with cellulose, while others are

not? What makes the use of cellulose necessary in your process?

Motion to Remove

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) if applicable: None.

Vote in Subcommittee

Motion by: Harold V. Austin IV

Seconded by: Lisa De Lima

Yes: 1 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](#)

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 Date: 5/29/2018

Subcommittee Review

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. It is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as GRAS for humans (21 CFR 184.1631), which are allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. In fruit and vegetable peeling, potassium hydroxide serves to weaken the glycolytic bonds of pectin, which is responsible for skin adhesion. Weakening these bonds allows the peeling of fruit and vegetable skins by water spray or other mechanical methods.

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.

International:

- **Canada** - Canadian General Standards Board Permitted Substances List - Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (CAN/CGSB 2011)

Table 6.6).

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)** – Allowed for pH adjustment for sugar processing (FAO/WHO Joint Standards Programme 1999, Table 4).
- **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.”
- **Japan Agricultural Standard (JAS) for Organic Production**—“Limited to be used for processing sugar as pH adjustment agent” (Japan MAFF 2000).
- **IFOAM – Organics International (IFOAM)** – Not found.

History:

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 Committee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercially processing methods used for peaches, the NOSB full board favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Discussion:

The Handling Subcommittee in its initial request for public comment asked:

1. For what purposes is potassium hydroxide used in organic processing?
2. Are there alternatives for those uses?

Public comments:

During the Spring 2016 meeting the NOSB received several comments regarding potassium hydroxide. Those comments included:

- Potassium hydroxide is used as a cleaning agent and is not used in our organic product as it is also prohibited by TTB to be added to wine but is approved as a cleaning agent. The removal of Potassium hydroxide from the National will have a huge impact for us; there is nothing at the moment that can be used as a replacement to effectively clean as well as potassium hydroxide. To my knowledge there has been no organic replacement or any other material that has the same effect or provides the same quality as the material in question.
- It is a better fit as a processing aid that is much gentler to the proteins in buttermilk
- Potassium hydroxide is a hazardous material, possibly one of the most hazardous and toxic on the National List.
- Of the certifiers that wrote in stated approximately 74 of their clients use this product.

While there is concern about the toxicity and hazards of this material the Subcommittee would like to see public comments address the questions put forth in this document.

This material satisfies the OFPA evaluation criteria and the Handling Subcommittee supports the relisting of potassium hydroxide.

Motion to Remove

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) if applicable:
None

Vote in Subcommittee

Motion by: Ashley Swaffar

Seconded by: Scott Rice

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Silicon dioxide

Reference: §205.605(a) 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](#)

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 Date: 11/03/2018

Subcommittee Review

Use:

Synthetic amorphous silicon dioxide is used as a food additive for various functions including:

- An anticaking agent in foods
- A stabilizer in beer production, and filtrated out of the beer prior to final processing
- An adsorbent in tableted foods
- A carrier
- A defoaming agent
- Used in organic seed pellets

Manufacture:

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) should be 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 organics the material would have to be petitioned to be 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:

Silicon Dioxide is permitted in organic handling by Canada, CODEX, European Union, IFOAM, and Japan. In the EU its use is restricted to an anticaking agent for herbs & spices, of plant origin. In Japan its use is limited to processed foods of plant origin as gel or colloidal solution.

Ancillary substances: None reported in 2010 TR

History:

In 2010 a petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of commercially produced rice based certified organic alternative to silicon dioxide. In 2011, the NOSB did not pass the petition. New data was presented in the petition claiming that a reformulation of the rice based alternative could now be substituted for silicon dioxide at nearly 1:1 rations, but the Handling Committee 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 and even though they did not vote to remove silicon dioxide in its entirety they did pass (Yes: 11, No: 3) a recommendation to amend the annotation of silicon dioxide to:

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetics allowed—Silicon dioxide—providing sufficient evidence showing non-synthetic alternatives are not commercially available for a specific product/process is presented.

Resulting in its current listing as: Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available

The Subcommittee, in its 2010 recommendation, also publically noted that additional information and clarification of processors' needs regarding silicon dioxide would be needed for future deliberations by the NOSB.

Discussion:

The 2010 TR did not find the manufacture or use of silicon dioxide to be harmful to people or the environment. The Subcommittee asks if silicone dioxide should remain on the list based on §205.600(b) - In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes

During the first posting, the Handling Subcommittee asked the public for the following information:

1. Are there instances where due to lack of availability of organic alternatives, you must use silicon dioxide?
2. Are there instances where the organic alternative does not perform the needed function and therefore you must use silicon dioxide? If so, what are those functions? And what was the undesired result that lead to the need to use silicon dioxide?

Public comment in response to the above questions included:

Silicon dioxide is essential for certified organic seed pellets; for anticaking agent in organic powders, including organic cheese powders; rice hulls aren't able to meet the various applications where silicon dioxide is used; in organic dry flavors rice hulls have not performed as needed to disburse flavor actives evenly, and take up moisture; the rice hull application as a substitution for silicon dioxide as an anti-caking agent has not worked at the 2% application, instead the rice hull rate has been 15-50%; rice hulls do not function like silicon dioxide when used as a flow agent for rice syrup solids; used in beer clarification.

Comment from multiple organizations asked that the NOSB revisit the original annotation put forth by the Board in 2011, in order to encourage the development and commercialization of alternative organic silica products. No new information was brought forth to indicate that the manufacture or use of silicon dioxide is harmful to people or the environment. Public comment by producers indicated that organic rice hulls are not a viable alternative for all current uses. The Subcommittee recommends that silicon dioxide remain on the National List.

Additional Information Requested:

Based on information reviewed, the Subcommittee is not aware of any ancillary substances used in silicon dioxide. If the public is aware of any ancillaries please provide information via public comment.

Motion to Remove

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) if applicable: none

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Tom Chapman

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Colors: Beta-carotene extract

Reference: §205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(2) Beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7).

Technical Report: [2011 TR](#)

Petition(s): [2007](#), [2009](#)

Past NOSB Actions: [04/2007 recommendation](#), [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 06/27/2007 ([72 FR 35137](#)); National List amended 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Subcommittee Review

Discussion:

Beta-carotene was petitioned by color manufacturers in 2007. No TAP was requested. The NOSB Handling Subcommittee rejected the petition to add this material to 205.606 stating: “the petitioner did not provide credible information regarding the lack of supply of organic raw material, and the ability to process them as organic”. (Vote: 4:1) However, at the March 2007 NOSB meeting the material was approved.

The Interim Final Rule (FR 35141) includes the following: “Though a significant number of comments were received, very few comments submitted were from processors or handlers. Comments from this segment of the industry would be helpful in developing a final rule. A number of comments expressed concern regarding the information and criteria used for determining the fragility of the organic ingredient supply or organic availability of the proposed 38 nonorganic agricultural ingredients.”

The Interim Final Rule also includes the following: “As a result of the district court's final order and judgment in *Harvey v. Johanns* and requests for an extension of the public comment period on AMS-TM-07-0062, AMS is issuing this interim final rule to: (1) Permit the use of the 38 ingredients during the extended comment and final rulemaking periods to minimize the impact to the organic industry; and (2) extend the comment period (60 days) to receive additional comments regarding the addition of the 38 non-organic agricultural ingredients to § 205.606. Effective Date Effective June 9, 2007, these 38 substances were prohibited for use in processed products labeled as ‘organic.’ Continued loss of the use of these products would disrupt the trade of food products currently being labeled as ‘organic’. Therefore, the continued use of these products as ingredients in foods labeled as ‘organic’ is necessary to prevent possible significant business disruption for organic producers and handlers. Accordingly, pursuant to 5 U.S.C. 553, it is found, and determined, upon good cause, that it is impracticable, unnecessary, and contrary to the public interest to give further notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this interim final rule until 30 days after publication in the Federal Register.”

In 2009, another manufacturer petitioned to add an amendment to the listing: “...Derived from carrots or algae”. The petitioner stated: “Our research over the past few years shows that at this time the only source of beta-carotene that can be extracted using NOP compliant nonsynthetic methods is algae. The algae derived beta-carotene uses extraction methods of CO₂, ethanol or vegetable oil.”

A Technical Report was requested and received in July 2011.

The TR indicated that a common source of beta carotene color was derived from the micro-algae *Dunaliella salina* and *Dunaliella bardawil*. These species are cultivated in Australia, for example. The TR, lines 327-350, describes the intensive culture system of production in a high salt, nitrate rich medium.

The TR further states: “Dunaliella species are commonly observed in salt lakes in all parts of the world from tropical to temperate to polar regions where they often impart an orange-red color to the water. As in commercial cultivation of the production, β -carotene is accumulated as droplets in the algal chloroplast stroma, especially under the environmental conditions in high temperature, high salinity, high irradiance, and nutrient limitation (low nitrogen). Then, β -carotene may be obtained from algal biomass or dried powder by using hot edible oil extraction and supercritical carbon dioxide, see EQ #2. In addition, it is desirable to re-utilize the culture medium remains after harvesting (biomass removal). *Dunaliella* growth medium could be recycled biologically by treating the medium with bacteria that are naturally present in medium because of the high concentration of glycerol, amino acids, and other organic compounds (Ben-Amotz, 1995). In a review article conducted by Dufosse et al. (2005), they concluded that algal forms are the richest source of pigments and can be produced in a renewable manner, since they produce some unique pigments sustainably. The report also stated that the production of β -carotene from *Dunaliella* will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature. (TR 530-545).

The TR supported the petitioner’s research findings. Therefore the Handling Subcommittee voted 4: 0 with 3 absences to approve this amendment, and the NOSB in December 2011 voted 14: 0 to approve the amendment.

The NOSB in 2011 found that the material met all the OFPA Criteria, and in 2013 the Final Rule was published (78 FR 31815).

The NOSB is in the process of reviewing use of all marine plants which are presently on the National List, and will be requesting a limited Technical Report. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

Additional information requested by NOSB

1. Has there been any change in the ability of manufacturers to produce beta-carotene color from carrots using NOP compliant extraction methods?
2. Is this color necessary for organic processors?
3. Which species of algae are used and from where are they harvested?
4. If the typical species used are from the genus *Dunaliella* (as cited in the TR) is harvesting of these species of micro algae from the wild, certified wild-crafted, or cultivated?
5. When used as a color, is this material also a source of Vitamin A?

Public comment on continued listing of this material indicates support from producers of the colors and support from those producers who use the color. Some certifiers indicate that the material is not widely used. Consumer groups consider this color is not essential (205.600(b) (6)), and if made from carrots, that organic carrots are available (205.600(b) (1)) and thus this material is not compatible with sustainable agriculture (OFPA 6518(m) (7)), and that the substance’s primary use is a color (205.600 (b) (4)).

Motion to Remove

The Subcommittee proposes removal of beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) 6518 (m) (7) and 7 CFR 205.600(b) (1) and (4) and (7) .

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 2 No: 5 Abstain: 0 Absent: 1 Recuse: 0