Sunset 2021
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2019

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2021. This list 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.

Request for Comments

Written public comments will be accepted through October 3, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Sunset 2021
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Note: With the exception of activated charcoal, L-malic acid, microorganisms, peracetic acid/peroxyacetic acid, and sodium acid pyrophosphate, the materials included in this list are undergoing early sunset review as part of the November 18, 2016, NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 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)).''

§205.605(a) *Nonsynthetics allowed:*

Acid, Citric
Acid, Lactic
Calcium chloride
Dairy cultures
Enzymes
L-Malic acid
Magnesium sulfate
Microorganisms
Perlite
Potassium iodide
Yeast

§205.605(b) *Synthetics allowed:*

Activated charcoal
Alginic acid
Ascorbic acid
Calcium citrate
Ferrous sulfate
Hydrogen peroxide
Nutrient vitamins and minerals
Peracetic acid
Potassium citrate
Potassium phosphate
Sodium acid pyrophosphate
Sodium citrate
Tocopherols

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

Celery powder
Fish oil
Gelatin
Orange pulp, dried
Seaweed, Pacific kombu
Wakame seaweed (*Undaria pinnatifida*)

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Acids – Citric

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP - Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Citric acid is widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. It is also an ingredient in dietary supplements and a nutrient, sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), raising agent, and emulsifying salt for many other products. It is also used to improve baking properties of flours, and as a stabilizer, and to inhibit color and flavor deterioration in fruits. Roughly 75% of all citric acid commercially produced is used by the food industry with the remainder used in cleaning agents, or in the cosmetics and pharmaceutical industries.

Manufacture:
First isolated from lemons, it was extracted from lemons and limes until 1919 when production shifted to fermentation (a biological process by which sugars are metabolized to acids, gases, and/or alcohol). Today, the mold *Aspergillus niger* is cultured with low pH values and high levels of sugars and mineral salts to economically produce high yields through fermentation. Various chemical synthesis of citric acid appeared but none have reached the economics derived from the fermentation process. The fermentation process has been refined over the years to produce high levels of citric acid instead of high levels of the by-product oxalic acid. Some public commenters expressed a concern that the fermentation process involves the use of synthetic chemical reactions that were not considered in the original 1995 classification.

International Acceptance:
Citric acid is an allowed ingredient in all international organic standards reviewed in the 2015 TR. The only noted annotation is that Japan Agriculture Standards allow citric acid but only as a pH adjuster for processed fruits and processed vegetables.

Environmental Issues:
Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will degrade to produce non-toxic and non-persistent environmental products. The last time EPA evaluated citric acid was 1992 at which time they found it posed no environmental risk.

Discussion:
Citric acid has GRAS status (Generally Recognized as Safe) by the FDA. Citric acid has many uses in food production. It has a history of safe use in organic foods dating back to 1995. Natural citric acid may be

isolated from organically grown fruit but has not been commercially available in the quantities that would be required to service the organic sector.

According to 2019 spring public comment citric acid is used to control PH, as an acidulant, a buffer, in gel formation, to stabilize colors, and as an ingredient in dietary supplements. In the organic produce sector it's widely used in the formulation of disinfectants and sanitizers allowed for use in direct contract with organic food without the need for a rinse, a practice essential for complying with FSMA requirements. It's also used for controlling pH in wash water used for the post-harvest handling of fresh fruits and vegetables. Additionally, neutralizing the PH of wash water thereby reduces the amount of chlorine that needs to be added to the water (in order to achieve the desired levels of "free chlorine"). Four certifiers submitted public comment indicating a total of 240 Organic Systems Plans which include citric acid.

Two commenters wrote that citric acid should be classified as synthetic unless it is possible to define non-synthetic citric acid by annotation. The TR found citric acid to be non-synthetic since it is processed via fermentation.

No new information was brought forward in terms of harm to human health or the environment.

Questions:
1. Are there any commercially available sources of citric acid derived from organically grown crops?

Subcommittee Vote:
Motion to remove citric acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Acids – Lactic

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting

Transcript 2015 pp. 263). It has been in use as an acidulant and pH regulator for many years. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material with no restrictions on use.

Common uses include, but not limited to:

1. In sugar confectionery, it is used in a continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and Mesentericur groups of bacteria.
6. Lactic acid can be used as a meat carcass "wash" or in meat products to reduce microbial contamination.
7. It is used in jams, jellies, and frozen fruit desserts.
8. In dairy products such as cottage cheese, the addition of lactic acid is preferred by some manufacturers to fermentation.
9. Used in imitation dairy products such as non-dairy cheese and non-dairy yogurt powder.
10. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.
11. Buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
12. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
13. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
14. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.
15. Lactic acid is used for flavor development and the control of microorganisms in soy cheese.

Manufacture:

First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid.

International Acceptance:

Lactic acid is permitted under all five major organic standards (US, EU, Canada, Japan Agriculture, and IFOAM). Canada classifies it as non-organic "for fermented vegetable products or in sausage". CODEX permits its use "food of plant origin", or "food of animal origin". European Economic Council permits use in processing foodstuffs of both plant and animal origin, or for the regulation of pH in yeast production. Japan Agriculture Standards permits use in processed vegetables or rice products, sausage, for dairy products, and for cheese.

Environmental Issues:

The fermentation process produces calcium sulfate waste (sometimes sold as fertilizer) but it is not known to create any negative environmental impacts.

Discussion:

Lactic acid is a "Direct Food Substance Affirmed as Generally Recognized as Safe," or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061.

Uses from the 2019 spring public comment period include: an acidulant, flavor enhancer, buffer, coagulating agent, pH. control agent, as a carcass wash, and as a processing aid in conjunction with celery powder. In the organic produce sector it's widely used in the formulation of disinfectants and sanitizers allowed for use in direct contract with organic food without the need for a rinse, a practice essential for complying with FSMA requirements.

Two commenters commented that lactic acid should be classified as synthetic, due to the material being a product of fermentation.

No new information was brought forward in terms of harm to human health or the environment.

Subcommittee Vote:
Motion to remove lactic acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium chloride

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Calcium chloride.**
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: Used in a wide variety of food processing applications including as a firming agent (in tofu, cut fruit and canning applications), as a sodium replacement, to adjust water mineral content in brewing applications and as a nutritional electrolyte application.

Manufacturing: Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified as nonsynthetic. The starting material is a natural brine solution that is pumped out from underground salt beds. Synthetic materials are used in the purification process, but without changing the chemical structure of the material. Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (TR 2015)

International: Calcium Chloride is allowed for use with various annotations under the Canadian, EU, Japanese, IFOAM and Codex standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following question: Is this material currently in use by the organic food processing industry and in what applications? Public comment from trade associations, certifiers and manufacturers were supportive of relisting, noting that it is in use as a buffering agent in fruit preps, in cheese-making, in olive packing, in dairy analogs, as a disinfectant when used in conjunction with chlorine to mitigate effects on plant tissues, and as a tool to mitigate acrylamide in baking applications. Other comments were received from interest groups questioning the purity of commercially available calcium chloride at 6% impurities. The current United States Pharmacopeia **Food Chemicals Codex** (USP FCC) monograph for calcium chloride allows for up to 7% impurities. No context was given for why this is an area of concern.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove calcium chloride from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Dairy cultures

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Dairy cultures.**
Technical Report: 1995 TAP; 2014 TR for Ancillary Substances
Petition(s): N/A
Past NOSB Actions: 05/2003 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Dairy cultures are used by organic dairy processors to make yogurt, cheese, cultured sour cream and other fermented milk products. The use of these cultures can increase the digestibility of milk products, create different flavors and textures, and provide potential health benefits to the consumer.
There are a variety of ways a dairy culture can be produced but generally a dairy or other medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different traditional dairy products. According to the 2014 technical report (TR) on microorganisms, there is widespread international acceptance of microorganisms and dairy cultures.

Ancillary substances may be present in dairy cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the

microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in dairy cultures in 2015. These include:

Functional class	**Substance name**
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Dairy cultures have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of certain dairy products. They pose minimal health risks, and in many cases can enhance health. In the October 2015, NOSB review of dairy cultures comments were received from trade associations, industry, certifiers and a technical organization. All comments were generally in favor of continued allowance of dairy cultures. The question was asked whether these should be listed separately or combined with microorganisms. Most industry stakeholders, while agreeing the dairy cultures were covered under microorganisms, still wanted a separate listing for dairy cultures. Several certifiers and a technical organization agreed that the listing of dairy cultures was redundant to microorganisms and could be removed. The ancillary substances used in dairy cultures has raised potential concerns about their compatibility with organic handling standards, but that has not prevented the support for continued listing of these cultures.

Public comments received during the Spring 2019 NOSB meeting showed widespread support for relisting of the dairy cultures. Several comments noted issues with ancillary substances. One commenter noted that it was their understanding that liquid dairy cultures might contain preservatives such as sodium benzoate and that it should be reviewed as an ancillary substance. Additionally, the Food Additives Council submitted additional ancillary substances that should be added to dairy cultures:

Food Additives Council list of ancillary substances submitted to NOSB meeting docket: AMS-NOP-18-0071, April 2019. Page 10 of document #: AMS-NOP-18-0071-0790

Ancillary Substances for Food Cultures	
Substance	**Function**
Magnesium sulphate	Anti-caking
Silicon dioxide	Anti-caking
Calcium chloride	Carriers - Fillers
Casein hydrolysate	Carriers - Fillers
Casein peptone	Carriers - Fillers
Corn starch	Carriers - Fillers
Dextrose monohydrate	Carriers - Fillers
Fructose	Carriers - Fillers
Lactose	Carriers - Fillers
Maltodextrin	Carriers - Fillers
Maltose	Carriers - Fillers
Milk powder	Carriers - Fillers
Peptone	Carriers - Fillers
Rice hydrolizate	Carriers - Fillers
Skim milk powder	Carriers - Fillers
Sodium caseinate	Carriers - Fillers
Sorbitol	Carriers - Fillers
Starch	Carriers - Fillers
Sucrose	Carriers - Fillers
Trehalose	Carriers - Fillers
Whey (powder)	Carriers - Fillers
Whey protein	Carriers - Fillers
Yeast Extract	Carriers - Fillers
Zein from corn	Carriers - Fillers
Lactase	Enzyme
Nitrogen, liquid	Freezing agent
Acetic acid	pH control - buffer
Ammonium chloride	pH control - buffer
Ammonium hydroxide	pH control - buffer
Calcium carbonate	pH control - buffer
Calcium phosphate dibasic	pH control - buffer
Citric acid	pH control - buffer
Dipotassium hydrogen phosphate	pH control - buffer
Formic acid	pH control - buffer
Monoammonium phosphate	pH control - buffer
Monopotassium phosphate	pH control - buffer
Phosphoric acid	pH control - buffer
Potassium citrate	pH control - buffer
Potassium hydroxide	pH control - buffer
Sodium citrate	pH control - buffer
Sodium hydroxide	pH control - buffer
Sodium phosphate, monobasic	pH control - buffer
Trisodium citrate dihydrate	pH control - buffer

Other commenters noted that the dairy culture listing no longer needs to be separated from the listing for microorganisms. One commenter stated: "During previous comment periods we have urged the NOSB to retain dairy cultures as a separate listing on the National List. This was in large part because at the time the NOSB was just beginning to have a more thorough review of ancillary substances, and we had some questions about whether this would affect the listing for dairy cultures. We now can see that the discussion document for microorganisms lists the same ancillary substances as those listed for dairy cultures, allaying our concern that combining these listings might inadvertently impact ancillary substances understood to be in dairy cultures. Now that there is more clarity on this point, we would not object to combining the dairy culture listing with the listing for microorganisms."

While there is widespread support for the use of dairy cultures, the Handling Committee believes that this listing is now redundant and is covered by the listing for microorganisms. We would suggest that removing dairy cultures from the National List would have no negative impact since they are already covered under the microorganism listing. Functionally, these dairy cultures would continue to be allowed, just not listed under a separate category.

Subcommittee Vote:
Motion to remove dairy cultures from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Enzymes

§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)).")
Reference: 205.605(a) Nonsynthetics allowed: **Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.**
Technical Report: 1995 TAP; 1996 TAP; 2011 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
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. Commonly used in the production of sweeteners, chocolate syrups, bakery products, alcoholic beverages, precooked cereals, infant foods, fish meal, cheese and dairy products, egg products, fruit juice, soft drinks, vegetable oil and puree, candy, spice and flavor extracts, and liquid coffee, and are used for dough conditioning, chill proofing of beer, flavor development, and meat tenderizing. Enzymes can also be used to help reduce production costs, reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-148)

Microbial rennet describes a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic agriculture.

Bromelain is extracted from the pineapple's fruit, stem, peel and juice. First the fruit is crushed. Bromelain is then further isolated, separated, and purified using chromatography, ultrafiltration, precipitation, freeze drying, and other procedures. (TR 2011 494-496)

Pectinase is produced by the controlled fermentation of nonpathogenic and nontoxicogenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

Ancillary substances are 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.

The following additional ancillary substances were identified through public comment during the last sunset review:

> Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.
>
> Carriers and fillers: 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, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.
>
> Preservatives: 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 acide, trisodium citrate, zinc sulfate.

Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.

pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Public comment submitted during the Spring 2019 NOSB meeting suggest adding several other ancillary substances to this list:

Anti-Caking & Anti-Stick Agents: manganese sulphate, magnesium sulphate, microcrystalline cellulose powder

Carriers and Fillers: corn gluten, corn steep powder, dextrose, lactose, propylene glycol, soya flour, soya oil, soyatone, sucrose.

Preservatives: propyl p-Hydroxybenzoate, sodium metabisulfite, sodium nitrate.

Stabilizers: calcium lactate, ethylene diamine tetra acetic acid, glycerine, sodium alginate.

pH control, Buffers: adipic acid, di potassium phosphate (K2HPO4), diammonium phosphate, disodium phosphate (Na2HPO4), hydrochloric acid, mono potassium phosphate (KH2PO4), tri ammonium citrate.

During the last sunset review in 2015, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change. 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.

The 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).

Public comments received during the Spring 2019 NOSB meeting widely favored relisting of enzymes and numerous examples were listed of their use in organic handling. One group did object to the review of enzymes as a class noting that this broad review was insufficient to address classification and adherence to all OFPA criteria. They noted that enzymes should be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

Subcommittee Vote:
Motion to remove enzymes from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

L-Malic acid

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **L-malic acid (CAS # 97-67-6).**
Technical Report: 2003 TR; 2019 TR
Petition(s): L-Malic Acid 11/01/02
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:
(This summary references the 2019 TR unless otherwise noted)

Uses
Malic acid exists in D-, L-, and racemic DL-forms, which is a mixture of equal parts of D- and L-. L-malic acid is the form listed at 205.605(a), while the D- and DL-forms are not approved for use in organic production. L-malic acid is used as a flavor enhancer, flavoring agent, adjuvant, and pH control agent in a variety of foods. The 2002 malic acid petition also notes it is used dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and tea as a flavor enhancer and food acidulant, and that malic acid provides greater tartness and better taste retention than other major food acids.

Malic acid has a smooth, persistent sourness and can be blended with other organic acids, sugars, sweeteners, and flavors. It also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring.

U.S. Food and Drug Administration (FDA) lists L-malic acid as a Generally Recognized as Safe (GRAS) food additive as a pH control agent, flavor enhancer, flavoring agent, and adjuvant in all food types except for baby food. The listing also includes maximum good manufacturing practice (GMP) levels for various applications. (21 CFR Section 184.1069; U.S. FDA 2018)

Manufacture
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice.

In the first round of sunset review in Spring 2019, a number of commenters questioned whether commercially available L-malic acid is indeed from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process.

Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

1. Production of fumaric acid either synthetically from petroleum or by fermentation of carbohydrates; and
2. Enzymatic conversion of fumaric acid to L-malic acid by immobilized microbes producing the enzyme fumarase.

There are two options for obtaining the fumaric acid in the first step in this process; more detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

1. The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., Rhizopus spp.)
2. The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin

Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most if not all, of the L-malic acid on the market is therefore synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).

L-malic acid can also be made from ethanol and biodiesel production waste but again, this is not the production method that commonly supplies the market. Thin stillage is a byproduct of corn fermentation in the production of ethanol from which *Aspergillus niger* ATCC 9142 can produce L-malic acid (West 2017). Another L-malic acid production process is the fermentation of crude glycerol obtained from production of biodiesel. Non-engineered *Ustilago trichophora* can be used for high yield production. *A. niger* MTCC 281 can also produce L-malic acid from crude glycerol (Iyyappan et al. 2018ab).

L-malic acid can also be produced by microbes in a one-step fermentation processes fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism.

The production of DL-malic acid is a synthetic process according to NOP Guidance 5033-1; the maleic acid undergoes a chemical change that is not the result of a naturally occurring biological process (USDA 2016b). Note this is similar to the method of production for synthetic fumaric acid used as precursor for industrial L-malic production.

Research quantities of D-malic acid and L-malic acid can be obtained by chemically separating the racemic DL-malic acid into its components in a process called chiral resolution. Chiral resolution is an expensive process that is not used to make large commercial quantities. D- or L-malic acid produced by chiral resolution is synthetic according to NOP Guidance 5033-1 because the isomers are isolated by chemical processes (USDA 2016b; West 2017).

International Acceptance

Canada, Canadian General Standards Board—CAN/CGSB-32.311-2015, Organic Production Systems Permitted Substances List

http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172

In Table 6.3, “Ingredients classified as food additives,” “Malic acid” is listed as a food additive with no restrictions (Canada 2018).

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

http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM

In Table 3 of "Annex 2: "Permitted substances for production of organic foods," "Malic acid" with INS 296 is a permitted food additive listed without conditions (Codex 2001).

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

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32007R0834

http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889

Malic acid is not specifically mentioned in EC No. 834/2007. In EC No. 889/2008, Annex 8, "Certain productions and substances for use in organic processed foods," "Malic acid" with E number 296 is allowed as a food additive (EU 2007; EU 2008).

Japan Agricultural Standard (JAS) for Organic Production

http://www.maff.go.jp/e/jas/specific/criteria_o.html

On page 4, "Attached Table 1, Food Additives," DL-malic acid INS 296, is an approved food additive with the annotation, "Limited to be used for processed foods of plant origin"(JAS 2012).

IFOAM – Organics International

http://www.ifoam.bio/en/ifoam-norms

L-malic acid assigned INS 296 is listed on page 79 in Appendix 4, "Table 1: List of approved additives and processing aids for post-harvest handling." L-malic acid is listed both as a food additive and post-harvest handling aid without restrictions (IFOAM 2014).

Environmental & Human Health Issues

The manufacture of L-malic acid by fermentation is fairly benign to the environment. Waste products such as spent cells and fermentation media can be composted. Processing chemicals include low toxicity acids and bases; while some of these can be recycled, they may end up in industrial landfills (West 2017; Dai et al. 2018). L-malic acid is found extensively throughout the environment in rotting fruit in agricultural or garden applications. Because it is soluble in water, L-malic acid eventually leaches out into the soil, where it is degraded by microbes. Manufactured malic acid is not deliberately released into the environment, and the amounts released incidentally into the environment through manufacturing processes and spills are likely to be small compared to the amounts already found in nature. The impacts of the manufactured material on beneficial insects, diversity, and other important aspects of environmental quality are negligible compared to natural exposures from rotting vegetation (Baker and Grant 2016).

Animal tests show that malic acid has low acute toxicity. Because it is easily metabolized in the body and occurs naturally in many fruits, there are no known reports of animal or human toxicity (Cornell Cooperative Extension 2016). Malic acid is an eye and skin irritant. The consumption of acidic soft drinks can lead to erosion of tooth enamel, and can cause tooth decay.

Discussion

A number of commenters noted that while there may have been nonsynthetic versions available in the past, it is unlikely that commercially available nonsynthetic quantities exist. As certifiers, material review organizations, and the 2019 TR attest, applying NOP Guidance 5033 and 5033-1 to this full production method would result in classifying L-Malic acid as a synthetic material. Until this material is reclassified, certifiers have been verifying the following for L-malic acid: that it is not made using the "big 3" (genetic modification, sewage sludge, irradiation); that it is L-malic acid (not DL- or D-); and that it is the form with the same CAS# as is identified on the National List.

A number of certifiers noted that L-malic acid appears on the organic system plans of their certified operations and is still widely used. Several manufacturers also commented on the essentiality of this material to their production. A couple of organizations opposed relisting this material as information was based on an older TR that did not sufficiently address the manufacturing process. The updated 2019 TR appears to address these concerns with extensive information on the manufacturing process.

It is clear to the Subcommittee that this material should be reclassified and placed on 205.605(b) to reflect that the commercially available sources are a product of a synthetic manufacturing process. This reclassification cannot be completed via sunset review, so the subcommittee is proposing to relist this material and address the reclassification as a separate work plan item for consideration at a future meeting.

Subcommittee Vote:
Motion to remove L-malic acid from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Tom Chapman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Magnesium sulfate

§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))."
Reference: 205.605(a) Nonsynthetics allowed. **Magnesium sulfate, nonsynthetic sources only.**
Technical Report:1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Magnesium sulfate has a wide variety of uses in food processing and personal care products. It is used as a firming agent in the production of tofu. According to the 2011 technical report (TR), magnesium sulfate is sometimes combined with other coagulators in the production of tofu. Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages.
Magnesium sulfate is generally regarded as safe (GRAS), listed at 21 CFR 184.1443. The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population. A common name for magnesium sulfate is Epsom salt.

Manufacture:
Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite ($MgSO_4 \bullet H_2O$) and epsomite (($MgSO_4 \bullet 7H_2O$), respectively.

International:
The Canada Food Inspection Agency, Food and Drug Regulations permit the use of non-synthetic sources of magnesium sulfate, which are classified as a food additive. Sulfates produced using sulfuric acid are prohibited.

Ancillary Substances:
None identified.

Discussion:
The 2011 TR notes that dietary doses of magnesium generally do not pose health risks. The TR does not fully address the environmental impact of mined forms of magnesium sulfate, noting it is not mined in the U.S. and therefore mining-related impacts are not an issue in the U.S. The TR does not address international mining impacts.

A number of alternative coagulants can be used in tofu production; however, these alternatives will affect texture, chewiness, color and other properties of the final product.

Calcium sulfate can be used in beer processing as an alternative to magnesium sulfate to increase water hardness and its mined form is on the National List.

While many other flavor enhancers are on the National List, it is unclear if any of these substances are suitable alternatives to magnesium sulfate.

Two food manufacturers noted their support of this material however, it was not clear if these manufacturers use this material. The Subcommittee is still seeking comment on the specific use and essentiality of this material.

Subcommittee Vote:
Motion to remove magnesium sulfate from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Microorganisms

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Microorganisms—any food grade bacteria, fungi, and other microorganism.**
Technical Report: 2003 TAP; 2014 TR; 2015 Ancillary Substances
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 minutes and vote; 11/2009 sunset recommendation

Recent Regulatory Background: Added to National List with annotation 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date 9/12/2021

Subcommittee Review:
Microorganisms used in organic handling include those that are used as probiotics, for fermentation, and bacteriophages used for food safety. Microorganisms are used by organic processors to make many well-known products including miso, shoyu, sake, and yogurts. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

There are a variety of ways microorganisms can be produced. As noted in the 2014 technical report (TR), generally a medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different products. Depending on the organism desired, different mediums ranging from milk products to rice may be used to create the starter culture. After a culture is generated, the starter culture may be inoculated directly into a product that will be altered by the microorganisms or the culture may be preserved by drying, encapsulating, freezing or other method and used at a later time in the handling process.

Ancillary substances may be present in microorganism cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in microorganisms in 2015. These include:

Functional class	**Substance name**
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, the Food Additives Council submitted additional ancillary substances that should be added to microorganisms:

Food Additives Council list of ancillary substances submitted to NOSB meeting docket: AMS-NOP-18-0071, April 2019. Page 10 of document #: AMS-NOP-18-0071-0790

Ancillary Substances for Food Cultures	
Substance	**Function**
Magnesium sulphate	Anti-caking
Silicon dioxide	Anti-caking
Calcium chloride	Carriers - Fillers
Casein hydrolysate	Carriers - Fillers
Casein peptone	Carriers - Fillers
Corn starch	Carriers - Fillers
Dextrose monohydrate	Carriers - Fillers
Fructose	Carriers - Fillers
Lactose	Carriers - Fillers
Maltodextrin	Carriers - Fillers
Maltose	Carriers - Fillers
Milk powder	Carriers - Fillers
Peptone	Carriers - Fillers
Rice hydrolizate	Carriers - Fillers
Skim milk powder	Carriers - Fillers
Sodium caseinate	Carriers - Fillers
Sorbitol	Carriers - Fillers
Starch	Carriers - Fillers
Sucrose	Carriers - Fillers
Trehalose	Carriers - Fillers
Whey (powder)	Carriers - Fillers
Whey protein	Carriers - Fillers
Yeast Extract	Carriers - Fillers
Zein from corn	Carriers - Fillers
Lactase	Enzyme
Nitrogen, liquid	Freezing agent
Acetic acid	pH control - buffer
Ammonium chloride	pH control - buffer
Ammonium hydroxide	pH control - buffer
Calcium carbonate	pH control - buffer
Calcium phosphate dibasic	pH control - buffer
Citric acid	pH control - buffer
Dipotassium hydrogen phosphate	pH control - buffer
Formic acid	pH control - buffer
Monoammonium phosphate	pH control - buffer
Monopotassium phosphate	pH control - buffer
Phosphoric acid	pH control - buffer
Potassium citrate	pH control - buffer
Potassium hydroxide	pH control - buffer
Sodium citrate	pH control - buffer
Sodium hydroxide	pH control - buffer
Sodium phosphate, monobasic	pH control - buffer
Trisodium citrate dihydrate	pH control - buffer

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated in negative health effects, but are something that should be continually monitored. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Microorganisms have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of many products. They pose minimal health risks, and in many cases can enhance health. As noted in the 2014 TR, the health effects can be expressed directly through the interactions of the ingestion of the live microorganisms (probiotic effect) or indirectly as the result of ingesting the metabolites synthesized by the microbes during fermentation (biogenic effect). Food-grade bacteria may also be used for improved vitamin production, raw food materials are often fortified with food grade bacteria that produce an excess of B vitamins in situ and bacteriophages are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing (2014 TR).

In general, microorganisms are essential to the production of many organic foods and they are widely used in the industry. Public comments received as part of the Spring 2019 NOSB meeting noted that microorganisms are essential to organic handling and there was widespread support for their relisting. Additional comments suggested combining the dairy culture listing with the microorganism listing since diary cultures are microorganisms. In the past there have been some commenters wanting to keep those listings separate due to the ancillary substances list being different for the two listings, however, at this point in time the ancillary substance list is suggested to be equivalent. Commenters that were against combining the two listings are now in favor of just listing microorganisms and having the dairy culture listing be part of the microorganism listing.

Finally, there were several comments about the definition of microorganisms. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms. One commenter noted that this listing is not clear stating: “It is apparent that it is intended to cover those microorganisms present as living organisms in foods such as cheese, yogurt, vinegar, pickles, tempeh, wine, and so forth. However, there are other products that are made from (or with the assistance of) microorganisms, and it is not clear whether the listing is intended to cover them. These include nutritional yeast and spirulina, both cultured microorganisms that are no longer living. They also include products of fermentation that have been isolated from the fermentation organisms, including glycerin, gellan gum, L-malic acid, and others. We assume that the listing does not cover the last group, but that those organisms and their manufacture should be evaluated in the course of evaluating their products that are on the National List (NL). If the listing is intended to cover the group of killed microbial products, then the evaluation should include algae as well as the other organisms addressed in the technical review. These comments do not suggest that microorganisms should be delisted, but rather that additional attention needs to be paid to this particular listing and the definitions associated with it.

Subcommittee Vote:
Motion to remove microorganisms from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Perlite

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **Perlite—for use only as a filter aid in food processing.**
Technical Report: 1996 TAP

Petition(s): N/A

Past NOSB Actions: 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses
Perlite is used as a filter aid in food processing, such as filtration of juices, beer, wine, and vegetable oils.

Manufacture
Perlite is an amorphous volcanic glass that occurs naturally and is sourced primarily from mines in the U.S., Greece, Turkey and China. The high-water content of the mineral causes it to expand many times its original volume when exposed to temperatures of 850-900 °C.

International
Canada General Standards Board Permitted Substances List allows the use of perlite as a filtering aid.

Codex Alimentarius lists perlite as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

IFOAM Norms Appendix 4 – Table 1 lists perlite as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of perlite for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

Ancillary Substances
None identified.

Discussion
The listing of perlite has been consistently supported by the NOSB and organic stakeholders. There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

During the first round of comments in spring 2019, several food manufacturers noted the use of this material for filtration and several certifiers noted its presence on the organic system plans of operations they certify.

Subcommittee Vote:
Motion to remove perlite from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Potassium iodide

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Potassium iodide.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 Formal recommendation by the NOSB; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Potassium iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points. Iodization of salt completely eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as food additive in the following functions:

- A nutrient in table salt as a source of iodine
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment. (2015 TR pg 15)

Manufacture: Potassium iodide can be refined nonsynthetically from sea water and in salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] (2015 TR pg 27).

International: Nonsynthetic potassium iodide is listed on the Canadian standards for use where required by law and the synthetic form is allowed in products in the 70-95% category. It could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following questions: Is Iodine utilized as a sanitizing agent for food processing equipment? If so, in what applications? If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If so, should this separate listing be removed and are certifiers limiting the use of iodine to non-synthetic forms even with the synthetic allowance at 205.605(b) for the Nutrient Vitamin and Mineral listing?

The NOSB did not receive any public comment about its use as a sanitizer. Public comment was received about its use in infant formula and in fortified foods. Regarding its redundant listing, one certifier commented in support of this being redundant to the more general nutrient vitamin and minerals listing. However, several comments about the general nutrient vitamin and minerals listing favored individual listing over the group listing. Lastly, one comment was received requesting an annotation to state "as a source of iodine" when required by law, however no context was given why the requiring law was not sufficient.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove potassium iodide from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Yeast

§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)).

Reference: 205.605(a) Nonsynthetics allowed: **Yeast—When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.**
Technical Report: 1995 TAP (Smoked Yeast); 1995 TAP (Baker's Yeast); 2014 TR
Petition(s): 2006 Petition; 2010 Petition Supplement; 2010 Petition memo
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 3/2007 NOSB committee recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290): Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

In general, yeast species (brewer's yeast) used in anaerobic conditions are for fermentation whereby they convert sugars to ethanol. This process includes ciders, beers, wines, and distilled spirits. Other uses for yeast are generally in aerobic conditions where they may be used as leavening agents (baker's yeast), for the addition of vitamins or minerals (nutritional yeast, chromium yeast, selenium yeast, torula yeast), as probiotics that may prevent or treat pathological conditions (probiotic yeast), and for flavoring (smoked yeast, torula yeast) (2014 TR). As the TR notes, they may be used synergistically or in conjunction with bacteria or other materials to create specific foods such as when kombucha is fermented with yeast and acetic acid bacteria to create fermented, sweetened tea.

The way the yeast is used in processing as well as the action of the yeast depends on the type of end products produced as well as the specific type of yeast being utilized.

Many yeasts are ubiquitous in the environment and in some cases handlers use these wild yeasts to make breads or for fermentation. However, since most handlers prefer more control over the specific type and strain of yeast that is utilized, most yeasts are grown under controlled conditions and then sold to end users. Typically, yeast is grown in a lab environment so as to prevent contamination from undesirable or pathogenic organisms. The lab grown yeast is then used to inoculate growth media for industrial production (2014 TR). In a number of cases there are several iterations of inoculation and addition of growth media in order to achieve the desired quantities. The yeast may then be used directly for food production or be concentrated and packaged for future use. Traditionally, smoked yeast is made by passing smoke through dried yeast, but it may also be manufactured using chemical processes. This necessitated the annotation that when smoked yeast is used, documentation that the yeast is smoked by natural processes must be submitted by the user.

According to the 2014 TR, There are a few yeast species that are formulated with no ancillary substances, however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products. During the prior sunset review in 2015, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as problematic for exposure.

Yeast is widely used and has been for centuries. Many organic products rely on the use of yeast for their distinctive features and characteristics. While there has been broad support for the relisting of yeast on the National List in past reviews, significant discussion has been centered on ancillary substances and whether organic forms of yeast are available. Yeast underwent a significant review that led to a change in the listing in 2010. The 2014 Technical Review added information about the current status of various yeasts and looked at the ancillary substances. There are many types of yeast and yeast is used to produce many substances, so this is a constantly changing playing field. As part of the prior sunset review many commenters noted that organic yeast forms are readily available, but that for certain uses there are some forms that are not yet organically produced in sufficient quantity or quality. These included torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. This led to the extensive annotation for the listing of yeast on the National List.

During the prior sunset review in 2015, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may

remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as problematic for exposure.

Finally, it should be noted that while yeast itself is often considered as a minimal risk material to both the environment and in use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR).

Public comment from the Spring 2019 meeting was overwhelmingly in favor of relisting of yeasts as annotated. Commenters noted that since yeast is commonly not available in organic form necessary for certain flavors, yeasts are not always available in the quantities needed, and that organic yeast quality can vary, the annotation and listing should remain as is.

Subcommittee Vote:
Motion to remove yeast from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

§205.605(b) Synthetics allowed:

Activated charcoal

§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))."
Reference: 205.605(b) Synthetics allowed: **Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.**
Technical Report: 2002 TAP
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 sunset recommendation ; 11/2009 sunset recommendation.
Regulatory Background:
Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Use
Activated charcoal is used in processing as mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity.

Manufacture
Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

International
Canada General Standards Board Permitted Substances List allows the use of activated charcoal as an ingredient classified as a food additive. Shall be of plant origin. Prohibited for use in the production of maple syrup.

Codex Alimentarius lists activated carbon as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists activated carbon for the preparation of foodstuffs of plant origin.

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of active carbon for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists charcoal for oenological use, with a restriction that limits use to musts and new wines still in fermentation, rectified concentrated grape must and white wines. No more than 100g dry production per hl.

Ancillary Substances
None identified.

Discussion
Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

During the first round of comments in the spring, several food manufacturers noted the use of this product, with at least one stating they have not identified a suitable non-synthetic alternative. One organization wishes to see its use limited to filtration of water and limit the available forms to those made via steam activation.

Subcommittee Vote:
Motion to remove activated charcoal from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Alginic Acid

§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))."
Reference: 205.605(b) Synthetics allowed: **Alginic acid (CAS #9005-32-7).**
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2015 formal recommendation (reclassification)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Proposed rule 1/17/2018 (83 FR 2498); Reclassified effective 01/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review:

Use:
Alginic acid is used in the food industry as an emulsifier, emulsifier salt, formulation aid, stabilizer, and thickener for soups and soup mixes. FDA limits the use of alginic acid to soups and soup mixes.

Manufacture:
Alginic acid is derived from wild harvested brown cold-water seaweeds. Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment, and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in a pure alginic acid and its classification as a synthetic. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, the free acid form does not appear in nature (2015 TR - Alginic Acid, Lines 283-286).

International Acceptance:
The 2015 TR noted the following:
Canadian General Standards Board - permits the use of alginic acid under the Organic Production Systems Permitted List as a non-organic food additive. It is also found in the same table under the heading Alginates.
CODEX – alginic acid is permitted under the Guidelines for the Production of Organically Produced Foods as a food additive of non-agricultural origin for foods of plant origin. The General Standard for Food Additives within CODEX list a number of provisional uses that FDA does not identify such as a bulking agent, foaming gent, glazing agent, in various food types.
European Economic Community (EEC) lists alginic acid as an approved food additive for use in the production of processed organic foods.
Japan Agricultural Standards (JAS) allows alginic acid as a food additive limited to only processed foods of plant origin.
The International Federation of Organic Agriculture movements (IFOAM) lists alginic acid as an approved additive for use in organic processed products without any annotations.

Environmental Issues:
Alginic acid is derived from harvesting brown wild seaweed. There has been little research into production of alginic acid and alginates from a biological fermentation process. However, commercially available quantities are sourced from brown seaweed, (2015 Technical Review – Alginic Acid, Lines 299-300). Most are derived from wild harvested seaweed, but some seaweed is cultivated. Brown seaweed is harvested in cold water. Recent public comments expressed concern of over-harvesting and the impact on local ecosystems. Some negative comments cited that wild harvested seaweed is a bio-accumulator of heavy metals.

Discussion:
In the 1995 TAP review for alginic acid, reviewers determined the material was non-synthetic. However, given the Classification of Materials document (in draft form in 2015) and the information presented in the 2015 TR, it was recommended by the NOSB that alginic acid be reclassified as synthetic. In January 2019, it was relisted from 205.605(a) nonsynthetic, to 205.605(b) synthetic. The majority of public comment from the 2015 sunset review was in favor of relisting alginic acid. Those in favor of its relisting noted the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting and assert that the properties imparted by alginic acid are essential for some processed food formulations. Those opposed cited that wild seaweed is a bio-accumulator of heavy metals, and over harvesting was detrimental to local ecosystems.
The Federal Register Notice published December 27, 2018, effective January 28, 2019 (Vol. 83, No.247, pp 66559-66574), amends the National List and moves Alginic Acid from 606.605(a), nonsynthetic substances allowed etc. to 606.605(b), synthetic substances allowed etc. The complete listing under 205.605(b) is Alginic acid (CAS# 9005-32-7)

During the spring 2019 public comment period the board received no comments from manufacturers citing their use of alginic acid and there were no reports from certifiers of the material being included in any

Organic Systems Plans. One interest group asked that the listing be reviewed with the broader context of marine materials and to consider adding an annotation related to harvest restrictions and risk-based testing for toxic materials. Another commenter thought alginic acid should be delisted due to lack of essentiality and environmental impacts of seaweed cultivation.

The TR reported no residues of heavy metals in excess of FDA tolerances. In regard to seaweed harvesting the TR reported that the majority of brown seaweed species harvested for production of alginic acid are wild harvested. However in countries like China & Japan large scale seaweed cultivation and production can negatively affect coastal waterways.

Questions:

1. Is alginic acid essential for handling operations? If so, why?
2. The 2015 TR cites possible hydrocolloids alternatives including agar agar, carrageenan, gellan gum and xanthan gum. Please comment on whether or not these alternatives have been used successfully in place of alginic acid.

Subcommittee Vote:
Motion to remove alginic acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: Essentiality
Motion by: Lisa de Lima
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Ascorbic acid

§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)).")
Reference: 205.605(b) Synthetics allowed: **Ascorbic acid.**
Technical Report: 1995 TAP; *2019 TR pending (to be posted at https://www.ams.usda.gov/rules-regulations/organic/national-list/a)*
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties. Ascorbic acid is often added to processed foods for nutritional purposes and is one of the most common sources of Vitamin C, which provides many important biological functions. Several animals, including humans, a

variety of primates and guinea pigs have lost the ability to produce ascorbic acid and must obtain this essential vitamin through their diets. As it is water soluble, and cannot be stored in the body, it must be consumed daily.

However, its addition as a nutritional fortifier also provides preservative properties. The preservative nature of the compound is derived from its reducing nature, through which it reacts with oxidized species (including radicals and molecular oxygen) to prevent enzymatic browning and food spoilage.

Ascorbic acid is GRAS as a chemical preservative (21 CFR 182.3013), a dietary supplement (21 CFR 182.5013), and nutrient (21 CFR 182.8013) when used in accordance with Good Manufacturing Practices. The FDA has identified ascorbic acid as a required nutrient in infant formula (21 CFR 107.100).

Manufacture:
For more than 50 years, the predominant industrial production of ascorbic acid involved synthesis using the Reichstein and Grussner process, a six-step process developed in the 1930's. The process begins with D-glucose and involves hydrogenation, oxidizing, and treatment with acetone and then hydrogen chloride to yield L-ascorbic acid. Despite the effectiveness of the purely synthetic production of ascorbic acid with the Reichstein process, most modern industrial production processes use fermentation with additional bio-oxidation steps adding a bio-catalyst which eliminates the need for the chemical steps. Despite the use of various microorganisms for the bulk of the synthesis, the use of acid in the final step of the process to convert the 2-keto-L-gluconic acid to ascorbic acid results in the substance's classification as "synthetic," according to the guidelines in NOP 5033-1.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Ascorbic acid is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 4.2 as allowed for "soil amendments and crop nutrition," and "synthetic and non-synthetic sources may be used as a pH regulator." Ascorbic acid is listed in Table 6.3 as an "ingredient classified as a food additive," and in Table 6.5 as a "processing aid for use as an anti-browning agent prior to the extraction or concentration of fruit or vegetable juice." Table 7.3 lists ascorbic acid as a "food-grade cleaner, disinfectant, and sanitizer permitted without a mandatory removal event."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ascorbic acid is listed in the CODEX (GL 32-1999) in Table 3.1 as a "food additive, including carriers."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Ascorbic acid is not listed in EC No. 834-151 2007. Ascorbic acid is listed in EC No. 889/2008 as a "food additive, including carriers," and is approved for "preparation of foodstuffs of plant origin and animal origin."

Japan Agricultural Standard (JAS) for Organic Production
Ascorbic acid is listed in the JAS for Organic Production Notification No. 1606 as a "food additive, limited to be used for processed foods of plant origin."

International Federation of Organic Agriculture Movements (IFOAM)
Ascorbic acid is listed in IFOAM as an "approved additive and processing/post-harvest handling aid."

Environmental Issues:
The 2019 Technical Report found no published studies on the persistence or impacts to biodiversity of ascorbic acid. Given the natural prevalence of the substance in plants and animals, the incorporation of

ascorbic acid in the handling/processing of organic food products is unlikely to provide any significant increase to environmental levels of the substance.

Discussion:
During the first review in Spring 2019, the Subcommittee requested additional information on the use of excluded methods in the production of ascorbic acid. In the 2019 Technical Report, the authors note that the microorganisms employed for the synthesis of ascorbic acid are not genetically modified.

During the first review, public comment from a juice products trade group supported its relisting. Other comments noted its necessity for flavoring food products, as a pH adjustor for protein coagulation such as in protein processing and cheese production, color stabilization in fruit juice, and as an antioxidant and vitamin C source. Several certifiers noted its widespread presence in the organic system plans of the operations they certify.
One interest group noted the predominant use of ascorbic acid is to fortify processed foods to pre-processing vitamin C levels. They further noted it is primarily used as a synthetic antioxidant and preservative and should be removed from the National List. The subcommittee notes that evaluation criteria at 205.600(b) restricting a material's use as a preservative or its use to recreate or improve flavors, colors, textures, or nutritive value lost during processing is limited to processing aids and adjuvants.

The 2019 Technical Report notes alternative acids such as citric and lactic acid, nonsynthetic substances permitted at 7 CFR 205.605(a). These weak acids inhibit food discoloration, however the inability of these acids to provide the reducing power of ascorbic acid prevents preservative action against reactive oxidized species and limits their efficacy against viral contamination. The Technical Report cites the use of controlled atmosphere with little to no oxygen to retard microbial-based spoilage. However, the use of controlled atmospheres in packaging and processing has also been known to affect the color and other organoleptic properties of the foods. Other alternatives include the use of fruit juices to fortify foods. However, this strategy is limited; the relative instability of ascorbic acid and the presence of additional substances present in fruit juices that may result in undesired changes to the organoleptic properties of the processed foods.

Subcommittee Vote:
Motion to remove ascorbic acid from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium citrate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Calcium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 4/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Calcium citrate is used as an ingredient in dietary supplements, although there are other calcium sources for supplementation purposes permitted at §205.605(b) under the listing Nutrient Vitamins and Minerals. Calcium citrate can be used as a sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), as a raising agent and an emulsifying salt. It is also used to improve the baking properties of flours and as a stabilizer. It can also be used as a water softener due to its chelation properties. It is used to wash processing equipment in order to eliminate off flavors, and as a pH adjuster and chelator in cleaning and sanitizing products. It is also used for its chelating properties to remove scale from boilers, evaporators and other processing equipment. Calcium citrate is widely used in cosmetic and personal care products for many of these same functions.

Manufacture:
Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization.
Citric acid is listed under 21 CFR 184.1195 as Generally Recognized as Safe (GRAS). It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate. It is permitted in food with no limitations other than current good manufacturing practice. It is also permitted by FDA in infant formula.
Calcium citrate is GRAS as listed at 184.1195
The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inerts).
International:
Allowed by Canada, European Economic Community (EEC) (as an ingredient in the preparation of foods of animal origin), and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary Substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including calcium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of calcium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: to fortify nutritional supplements with calcium, used in fruit filling to thicken and stabilize gel structures (yogurt, pastries), to develop a sugar-acid-pectin gel found in jams/jellies/fruit spreads, and as a buffer in fruit and flavor preps. One commenter would like to see all the citrates be restricted to uses that are compliant with 205.600(b)(4), however that restriction only applies to processing aid and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove calcium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 2 Absent: 0 Recuse: 0

Ferrous sulfate

§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))."
Reference: 205.605(b) Synthetics allowed: **Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).**
Technical Report: 1995 TAP; 2015 TR Nutrient Vitamins and Minerals
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.). Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues. Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function. (2015 TR, pg 15)

Manufacture: Ferrous sulfate is made by reacting sulfuric acid with iron. [21 CFR 184.1315] (TR 2015, pg 28)

International: Ferrous sulfate is listed on the Canadian standards for use where required or allowed, it could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following question: If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this item be removed? Comments were received in support of this listing from industry, noting its use in infant formulas. There was some support for removing this listing as redundant to the Nutrient Vitamins and Minerals listing but there was also opposition to the group listing of vitamins and minerals. One interest group questioned if ferrous sulfate was the best source of iron supplementation or if alternatives were available. They also noted a whole-food diet could be sufficient to meet iron deficiencies. Alternatives were not offered and details on how a whole-food diet would be sufficient for various and diverse populations, including those at risk for iron deficiency were not provided.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove ferrous sulfate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Hydrogen peroxide

§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))."
Reference: 205.605(b) Synthetics allowed: **Hydrogen peroxide.**
Technical Report: N/A (2015 TR Crops)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Hydrogen Peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H_2O_2. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR §205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as "organic" or "made with organic(specified ingredients or food group(s))." (7 CFR 205.605(b)).

Manufacture:
According to the TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H_2) and oxygen (O_2): $H_2 + O_2 \rightarrow H_2O_2$

International:
Canada: Allowed for many uses, including as food-grade cleaners, disinfectants and sanitizers" that are allowed without mandatory removal of residues, and "cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production".

European Union: Allowed for similar uses to Canada and U.S.

IFOAM: Allowed as cleanser and disinfectant among other uses.

Japan: Not listed.

Codex: Allowed as a cleanser and disinfectant among other uses

Ancillary substances:
Other ingredients may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials present including caprylic acid and mono-and di-potassium salts of phosphorous acid, which is an oxidant stabilizer. Phosphorous acid is listed on the EPA Safer Choice list as a yellow triangle.[1]

Human Health and the Environment:
Concentrated solutions may be corrosive to eyes, exposed skin, and mucous membranes. Warnings for high concentrations include:
Corrosive. Causes irreversible eye damage. May be fatal if swallowed or absorbed through the skin. Causes skin burns or temporary discoloration on exposed skin. Do not breathe vapor. Do not get in eyes, on skin or on clothing. Wear protective eyewear such as goggles or face shield. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Extensive toxicological testing of hydrogen peroxide has been completed, and it is unlikely to cause chronic systemic toxicity or reproductive, development, or carcinogenic effects. However, chronic exposure to vapors may damage lungs. Hydrogen peroxide is reported to have low to moderate toxicity to aquatic invertebrates and no danger to fish. Because hydrogen peroxide is unstable and breaks down into water and oxygen gas, long-term impacts on the environment are unlikely. According to the TR, some toxic chemicals used to manufacture hydrogen peroxide including alkyl anthraquinones, aromatic solvents and metal catalysts (e.g., nickel and palladium) are removed from the product and can be returned to the reactors to make more product. Overall, this material is relatively safe but should be used according to FDA, USDA, and EPA labels and regulations.

No new information was brought forward in terms of harm to human health or the environment.

Discussion:
Hydrogen peroxide (HP) continues to receive strong support by the organic community and has been consistently relisted on the National List. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds if not thousands of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. When used appropriately HP should not have adverse impacts on human health and the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove hydrogen peroxide from 205.605(b) of the National List based on the following criteria in

[1] Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.

the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Nutrient vitamins and minerals

§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)).")
Reference: 205.605(b) Synthetics allowed: **Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.**
Technical Report: 1995 TAP - Minerals; 1995 TAP - Vitamins; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2011 Handling Subcommittee Proposal; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Nutrient Vitamins and Minerals are used to recreate or add nutritional content to foods. Sometimes this nutritional content is added due to public health guidance (e.g. Iron in cereal to combat iron anemia), to mimic analog products (calcium fortification of non-dairy milks, fortification of infant formulas), to make up nutrients lost in processing (Vitamin A in skim milk) or for product marketing purposes (enriched flours). There are very few legally required fortified foods. Those that are required are listed on the chart below, noted from the 2015 technical review:

Standards of Identity in Title 21 CFR that require Nutrient Fortification

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.100 21 CFR 107.10	All nutrients known to be essential and listed therein
Margarine	21 CFR 166.110	Vitamin A
Milk	21 CFR Part 131	Vitamins A & D (required by some states)

There are more food classes with standards of identity that allow for the use of fortification, however these fortifications are optional. It should be noted that foods eligible for the "Women, Infants and Children" federal programs may be required to be the fortified standard of identity form.

The specific use of vitamins and minerals will depend application and on the specific substances being used. Vitamins in application are substances with vitamin activity and there are several substances that may have a vitamin activity for a specific vitamin. Similarly, for minerals the substances used are those with bioavailable mineral content. These substances will often be processed with accessory additives to make the vitamins or minerals stable and useable in food applications.

Manufacturing: The 2015 technical review states:

According to Vandamme (Vandamme 1992), “vitamins are now either prepared chemically or biotechnologically via fermentation or bioconversion processes. Several vitamins and related biofactors are now (1992) only or mainly produced chemically (vitamin A, cholecalciferol (D3), tocopherol (E), vitamin 432 K2, thiamine (B1), niacin (PP or B3), pantothenic acid (B5), pyridoxine (B6), biotin (H or B8), folic acid (B9)]or via extraction processes (β-carotene or provitamin A, provitamin D3, tocopherol, vitamin F-group). However, for several of these compounds microbiological or algal methods also exist or are rapidly emerging. Other vitamins are produced practically exclusively via fermentation (ergosterol or provitamin D2, riboflavin (B2), cyanocobalamin (B12), orotic acid (B13), vitamin F-group ATP, nucleosides, coenzymes, etc.] or via microalgal culture (β-carotene, E, F). Both chemical and microbial processes are run industrially for vitamin B2, while vitamin C (ascorbic acid) is produced via a combination of chemical reactions and fermentation processes. In the past twenty-five years, numerous patents have been issued disclosing fermentations by genetically modified microorganisms to produce various water-soluble vitamins… As the above descriptions detail, most vitamin and mineral nutrients are synthetic substances, even including some with natural or agricultural origins… Most vitamins and minerals are not available from nonsynthetic sources…. The current National List listings creates confusion for those nutrient vitamins and minerals specifically listed at §205.605(a), which requires a nonsynthetic source, whereas “Nutrient vitamins and mineral” are a class of “allowed synthetics.” For example, the producer of a nutritional product may not be sure if supplemental magnesium as magnesium sulfate is restricted to a nonsynthetic source. “

The technical report details many individual manufacturing methods.

International:
The Codex and EU standards only allow the use of synthetic vitamin and minerals where required by law. The Canadian standards allow synthetic vitamin and minerals where required by law as well as in “non-dairy substitute products” on a “voluntary basis, if legally permitted.” Canadian standards also allow for use of “Ferrous sulphate—Shall be used if legally required and may be used, on a voluntary basis, if legally permitted.” IFOAM allows by law or when “strongly recommended in food products in which they are incorporated.” Japanese standards do not allow for vitamins and minerals (2015 TR, pg 20-21). All standards list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate) – the review above does not include these individual substances, just categorical listings.

Discussion:
Brief History of this issue

- In 1995 the NOSB added nutrient vitamins and minerals to the National List with the following annotation, ‘‘Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.’’ A second recommendation was also passed entitled ‘‘Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.’’ This stated, ‘‘Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.’’

- The final rule that was published in 2000 (65 FR 13512) had the current annotation. It was recognized soon after that the cross reference to the FDA’s fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing was necessary.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamin and minerals.

In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a memo to the NOSB in April 2010 explaining this clarification.

- The existing annotation is not what the original NOSB recommended in 1995. In 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting and the NOSB supported relisting with the existing annotation for the 2012 sunset review.

- On January 12, 2012 a proposed rule was published in the Federal Register (77 FR 1980) to change the annotation 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 groups(s)).''

  (b) Synthetics allowed,

  Vitamins and minerals. For food— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10.

- This proposed rule clarified that the "nutrients" that were not on these CFR sections had to be petitioned individually for the National List because this listing did not cover them.

- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule (77 FR 59287), which renewed without change the original listing, as per the NOSB April 2011 recommendation.

- In 2011 through 2013 many other nutrients were petitioned. Some were recommended to be listed by the NOSB while others were not. No rulemaking in this area has occurred.

- In 2014 the Handling Subcommittee commissioned a new Technical Report in preparation for Sunset 2017 reviews. This was completed in February 2015 and clarifies which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.

- In 2015 the NOSB voted to renew the listing and included the following note about the technical review and public comment:

  "Since this is a huge group of different substances, the TR went into length about their manufacturing processes, effects on human health, effects on the environment and uses. There was no information among these pages that gave concern that these substances did not meet the review criteria. Likewise public comment was received with concerns about the unnecessary use of synthetic ingredients, but no new information was provided in comments from the first posting regarding the review criteria beyond the alternatives and compatibility issues.

  Regarding alternatives, the primary alternative is for people to get their vitamins and minerals from the food itself rather than supplementation. …There is no literature to suggest that the manufacture or use of vitamins and minerals with ancillary substances is harmful to the environment or to biodiversity."

- In 2016 the Handling Subcommittee brought forward a discussion document with two options:

  Option 1

  > Proposed Annotation #1: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed

only when their use is required by law or to meet an FDA standard of identity in which they are incorporated.

Proposed Annotation #2: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic” (except as noted in annotation #1).

Proposed Annotation #3: §205.605 (a) Vitamins and minerals, non-synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled Organic.

Option 2

Proposed Annotation #4: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and “made with organic (specified ingredients or food group(s))”.

- To Date the NOSB has taken no further action on this subject

During the 2019 sunset cycle the NOSB posed the following questions for public comment at the Spring meeting:

1. Is the current listing meeting the needs of the organic community, certifiers and industry – if not, how should it be revised?
2. How are certifiers dealing with non-synthetic nutrient vitamins and minerals currently?
3. It is speculated that the 2012 rulemaking was stopped due to the impact this change would have on the currently established organic infant formula market which has both established manufacturers and consumers. How should the NOSB move this topic forward in light of this issue?
4. Given added Vitamins and Minerals need to be listed on ingredient panels, are consumers enabled enough to make educated purchasing decisions on fortified foods – if not, please explain.

In response to the first question – public comment was mixed, with some commenters wanting more restrictions and some wanting a wide interpretation. Those using the widest interpretation either supported status quo or a change in annotation that would enshrine the status quo. Most certifiers thought the accuracy of the citations needed improvement, and it needed to be clearly enforceable. Others are seeking a more restricted listing. It should be noted that any annotation changes would need to be completed separate from this sunset review.

In response to question 2: Certifiers indicated that all were using the synthetic allowance as an allowance for non-synthetic usage and generally did not go into detail about how these materials are being manufactured. One certifier noted that non-synthetic versions were sometimes agricultural and would potentially require listing on 205.606. While clarification was supported by certifiers, no problematic or conflicting interpretations were raised.

In response to question 3: Commenters provided many suggestions on how to move forward on this topic, ranging from re-reviewing previous NOSB decisions on petitioned items, to supporting the 2012 proposed rulemaking to removing the categorical listing all together. Short of removing this listing in its entirety during a sunset review, recommendations on annotation changes would need to be considered as part of different work agenda item other than this sunset review.

Lastly, all commenters responded to the fourth question stating consumers were empowered with enough information to understand which products are fortified.

Overall there was strong support of this listing from industry and trade associations – noting the use of materials for reasons such as compliance with the law, to compete with conventional product, due to consumer expectations, or to make products for specific markets like infant food or enteral feeding products. Opposition to this listing came from interest groups who opposed the categorical listing of nutrient vitamins and minerals, that opposed a listing pointing to an incorrect FDA reference, and a reference to a list maintained by someone other than the NOSB. Concern was also raised over allowing the fortification of food in instances not required by law, and lastly about the categorical listing allowing for the continued usage of individual substances that had been reviewed but not recommended by the NOSB.

The public comment received in 2019 was similar to the public comment received in 2015 and no substantial new information was received supporting the removal of this listing.

Subcommittee Vote:
Motion to remove nutrient vitamins and minerals from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Peracetic acid

§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))."
Reference: 205.605(b) Synthetics allowed: **Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.**
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008 Petition
Past NOSB Actions: 11/2000 sunset recommendation; 04/2004 NODB meeting summary; 11/2009 NOSB formal recommendation
Recent Regulatory Background: Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Use:
Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products according to FDA limitations, and to sanitize food contact surfaces, including dairy-processing equipment and food-processing equipment and utensils. It is an important sanitizer used in organic handling. It is widely used as a sanitizer on food contact surfaces and as a disinfectant for fruits and vegetables. Peracetic acid/Peroxyacetic acid was added to the National List on September 12, 2006, with the annotation, "for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces." (It is also on the National List at §205.601 and §205.603 for use in Crops and

Livestock respectively). Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture:
According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Commercial grades are available in concentrations ranging from about 0.3 to 40 % by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide.

International:
Japan: Not listed
Codex: Not listed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary substances:
HEDP and dipicolinic acid (DPA) are added to peracetic acid solutions to chelate metals, especially iron, copper and manganese, because decomposition of peracetic acid and, thus, loss of sanitizing power is accelerated by these impurities. However, in past reviews, stakeholders did not declare the inclusion of ancillary substances (See below).

Human Health Environment:
peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

Discussion:
Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has been strong support for continued availability of this material. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds if not thousands of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. In particular, many processors identified the need for a "no-rinse" material as essential for treating equipment and other food contact surfaces. Overall, this material is considered effective and offers a less toxic profile then several other sanitizing materials, including many chlorine compounds. The TR does not offer new evidence of unacceptable adverse impacts on human health or the environment. During the last review, use of a synthetic stabilizer such as 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition were judged to be "inerts" for EPA registration as an antimicrobial and not subject to review as an ancillary substance.

However, comments submitted for the Spring 2019 meeting that at least "dipicolinic acid is a former List 3 "inert" and not allowed in products used in organic production" and identifies additional "inert" materials that warrant review. Only products with allowable "inert" ingredients should be used.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove peracetic acid from 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Potassium citrate

§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))."
Reference: 205.605(b) Synthetics allowed: **Potassium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses: Antioxidant, acidulant, pH control, flavoring agent, sequestrant, emulsifying salt, stabilizer, and as a dispersant in flavor or color additives. Commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat products. It is also used to wash processing equipment to remove off flavors.
Potassium citrate is used to replaced sodium citrate whenever a low sodium content is desired.

Manufacture:
Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization.
Potassium citrate is Generally Recognized as Safe (GRAS) as listed under 21 CFR 184.1625.

International:
Allowed by Canada and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including potassium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of potassium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: acidity regulator in the wine making process; buffer in confectionary products; when combined with citric acid the pair provides tartness without a significant drop in pH which is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin; offers an advantage over sodium citrate in that it does not add additional sodium to the product. One commenter would like to see all the citrates be restricted to uses that are in compliant with 205.600(b)(4), however that restriction only applies to processing aid and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove potassium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 4 Abstain: 3 Absent: 0 Recuse: 0

Potassium phosphate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s)),"** prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP, 2016 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Potassium phosphate can be used as a pH control in milk and dairy products, to make acidified milk products and in milk protein stabilization. It can also be used as a nutritional additive for a source of potassium and as a nutrient in yeast. Potassium phosphate can also be used in prepared meat applications

and liquid eggs. The initial Technical Advisory Panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled "organic," but was only approved for use in "made with" products.

Manufacture:
The initial TAP noted potassium phosphates are isolated from brines or salt deposits. However, the 2015 TR explained the manufacturing process to be as follows: All of the orthophosphate derivatives of potassium can be generated by neutralization of phosphoric acid with potassium hydroxide (Budavari 1996). Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate (Budavari 1996). Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm. [21 CFR 184.1631]. (2015 TR, pg 30-31)

International:
Potassium phosphate is not listed in CODEX, does not appear on the EU, JAS or IFOAM organic standards, but is listed in the Canadian organic standard for products in the 70%-95% category only.

Discussion:
During the 2017 sunset cycle public comment was received in support of potassium phosphate noting it is an efficient pH buffering substance with no organic alternatives. The industry indicated that potassium phosphate is used in non-dairy beverages; that it prevents precipitation and impaired mouthfeel; that the alternatives are not as good; and loss of this product would mean impaired quality and marketability. Other commenters noted a concern with the use of phosphates in production of processed foods and that phosphorus may not appear on the nutritional panel making it difficult to be informed about total phosphorous intake– although they would appear on the ingredient list. In particular there were concerns raised about the cumulative health impacts of phosphorous additives in food and in 2015 the NOSB requested a technical review and work agenda item to study this issue further. Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis, and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal renal function, from cumulative phosphorus. A daily limit of 70 mg/kg/day was recommended in one study. Populations at risk for bone health and kidney failure were especially impacted. In 2016 the NOSB Handling Subcommittee published a discussion document on the cumulative health impacts of phosphates and the NOSB decided to address phosphates individually during sunset reviews. Sodium phosphate was reviewed in 2017 and the NOSB came to the following conclusion:

> No single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population. Given the new information and research since last Sunset Review, the Handling Subcommittee requested a new Technical Report (TR) which it received in 2016. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long-term cumulative impacts are not fully understood.

During the 2019 public comment period we posed the following questions: Does industry still find the listing for potassium phosphate necessary – in what applications is this substance currently be used in products being marketed as "made with organic."; and if applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this listing be removed?

We heard from a certifier that noted at least 2 operations were using potassium phosphate for fortification purposes. Comments were also received from an industry trade association about the various possible uses

of phosphates and responses to the long term exposure risks to human health of phosphate products in general. It was not clear their comments were specifically about applications of phosphates in organic certified products. There was some support for removing this listing as redundant to the Nutrient Vitamins and Minerals listing but there was also opposition to the group listing of vitamins and minerals.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove potassium phosphate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Sodium acid pyrophosphate

§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))."
Reference: 205.605(b) Synthetics allowed: **Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.**
Technical Report: 2001 TAP (Sodium Phosphates); 2010 TR; 2016 TR
Petition(s): 10/2002 petition; 03/2007 petition for expand use
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation; 04/2011 sunset recommendation
Regulatory Background: Added to National List 09/12/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Uses
Sodium acid pyrophosphate is a common food additive for the purpose of a sequestrant/chelating agent in processed potatoes, an emulsifying agent in cheese, an inhibitor agent in canned tuna, and a curing accelerator in processed meats. This listing limits its use as a leavening agent. Sodium acid pyrophosphate is used as a leavening agent in baked goods, where it reacts with baking soda (sodium bicarbonate) to liberate carbon dioxide, 'leavening' the dough and creating the desired 'airy' texture that consumers expect of baked goods such as cakes and cookies. It is GRAS, listed at 21 CFR 182.1087.

Manufacture
Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220ºC to form sodium acid pyrophosphate. It is expressed by the formula Na2H2P2O7 and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

International
The Canadian General Standards Board Permitted Substances List (CAN/CGSB 32.311-2006) permits these phosphate salts with usage annotations identical to the NOP regulations.

CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (GL 32-1999)

These guidelines only permit monocalcium phosphate (341(i)) and “only for raising flour” (as a leavening agent).

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

ANNEX VIII, Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a), Section A – Food Additives, including Carriers, lists only monocalcium phosphate (341(i)) as a “Raising agent for self-rising flour” (as a leavening agent).

Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the Ministry of

Agriculture, Forestry and Fisheries of October 27, 2005)

Table 1, “Food Additives,” lists INS 341(i), Calcium dihydrogen phosphate (a.k.a. monocalcium phosphate), with the annotation “Limited to be used for powders as expanding agent” (as a leavening agent).

IFOAM – Organics International (IFOAM)

The IFOAM norms for Organic Production and Processing, Version 2014, list monocalcium phosphate, INS 341, as a food additive “Only for ‘raising flour’” (as a leavening agent).

Ancillary Substances
None identified.

Discussion
During the last sunset review, this material received positive support from stakeholders. While excess phosphates in wastewater contributed to environmental degradation in the past, this was largely due to its use in detergents. Its use in detergents has waned and in this use as a food additive, phosphates would have little environmental impact.

The 2016 technical report (TR) on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and completely bioavailable upon consumption whereas “food” phosphorous is much less available.

High blood phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

Yeast, a natural leavener used for time immemorial, is a common alternative to chemical leavening. However, yeast leavened baked goods have a different physical texture and require more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes such as found with muffins, pancakes and cookies.

During the first round of comments in the Spring of 2019, a number of food manufacturers and trade groups noted the essentiality of this material as it is the only chemical leavener available to the baking sector. One organization does not support relisting as the focus of the TR is on negative human health and environment effects is on the final product and not the primary manufacture of phosphoric acid.

Subcommittee Vote:
Motion to remove sodium acid pyrophosphate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Sodium citrate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Sodium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy. Also used as dispersants in flavor or color additives, and to wash processing equipment in order to eliminate off flavors.
During the last review of sodium citrate in 2015, public comment included these specific reasons for use:

- Potassium citrate is an option, but it has an unpleasant metallic taste. Sodium phosphates are another option, but they need to be used in higher quantities and are not as effective.
- We use sodium citrate as part of the process of preparing fresh fruit for use in our yogurts. We use sodium citrate primarily for its ability to buffer pH, neither citric acid nor potassium citrate would have the same buffering effect in our products.
- Sodium citrate is used in a personal care product (lubricant).

Manufacture:
Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization.
Sodium citrate is listed under 21 CFR 184.1751 as Generally Recognized as Safe (GRAS). The listing allows its production from citric acid and sodium hydroxide or sodium carbonate. It is allowed as an ingredient used in food with no limitation other than current good manufacturing practice.
The EPA lists citric acid and its salts in the 2004 List 4A (minimal risk inerts).

International:
Canada: Sodium citrate is allowed but restricted to use with sausages or milk products.

CODEX Alimentarius Commission: Sodium citrate is listed for sausages/pasteurization of egg whites/milk products.
European Economic Community (EEC): Sodium citrate is allowed as an ingredient in the preparation of foods of animal origin.
Japan Agricultural Standard (JAS): Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.
International Federation of Organic Agriculture Movements (IFOAM): allowed as an additive.

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including sodium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of sodium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: antioxidant, stabilizing salt, buffer, and when combined with citric acid the pair provides tartness without a significant drop in pH which is important for preventing degradation of sucrose in confectionary products and for achieving a consistent pH for the gelling of pectin. It's part of process of preparing fresh fruits for yogurt, neither citric acid or potassium citrate wouldn't have the same buffering affect. It's also found in Organic System Plans (OSPs) used for meat processing and in manufacturing dietary supplements and personal care products. One commenter would like to see all the citrates be restricted to uses that are compliant with 205.600(b)(4), however that restriction only applies to processing aids and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove sodium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Harriet Behar
Yes: 0 No: 4 Abstain: 3 Absent: 0 Recuse: 0

Tocopherols

§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)).")
Reference: 205.605(b) Synthetics allowed: **Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.**
Technical Report: 1995 TAP; 2015 limited scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review; 09/2016 Handling Subcommittee proposal additional listing of Tocopherol
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Synthetic tocopherols are currently permitted for use in organic agriculture handling/processing as an antioxidant ingredient in foods (2015 TR). Tocopherols are added to foods to help prevent oxidation of the fatty acids present in the lipid components of the food. Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" when rosemary extracts are not a suitable alternative (7 CFR 205.605[b]).

Manufacture:
Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables. As described in the 2015 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation. The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

International:
Japan: Listed for processed meats.
Codex: Allowed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary Substances:
Table 1 from the most recent technical review (TR) shows some of the more common formulations along with their ancillary substances.

Table 1. Commercially Available Tocopherols Products Used as Antioxidants in Foods

Manufacturer	Product Name	Formulation	Ancillary Substance(s)	Source(s)
Advanced Organic Technologies (Buenos Aires, Argentina)	Tocomix™	Liquid	Sunflower oil	AOM, 2014
Archer Daniels Midland Company (Decatur, IL)	Decanox™	Liquid	Unknown	ADM, 2014
		Powder	Unknown	
BASF (Germany)	Covi-ox®	Liquid	Soybean oil	Brenntag Specialties, Inc., date unknown; BASF, 2013
		Powder	Gum acacia	
BTSA (Madrid, Spain)	Tocobiol®	Liquid	Sterols, squalene, monodiglycerides*, soybean or sunflower oil	BTSA, 2014a; BTSA, 2013
		Powder	Calcium carbonate	
	Nutrabiol® T	Liquid	Soybean or sunflower oil	BTSA, 2014b; BTSA, 2012
		Powder	Silica	
DuPont Danisco (global)	Guardian® tocopherol extract	Unknown	Unknown	DuPont Nutrition and Health, 2014a
Kemin Industries, Inc. (Des Moines, IA)	Fortium® mixed tocopherols	Liquid	Sunflower oil	Kemin, 2014a; 2014b
		Powder	Rice maltodextrin	
Nutralliance (supplier) (Yorba Linda, CA)	Sunvitol™ MT	Powder	Unknown	Nutralliance, 2014
Organic Technologies (Coshocton, OH)	Natural mixed tocopherols	Liquid	Organic sunflower oil	Organic Technologies, 2013
		Powder	Tapioca starch	
Sigma-Aldrich (St. Louis, MO)	Mixed tocopherols	Liquid	Unknown	Sigma-Aldrich Co. LLC, 2014
The Scoular Company (Minneapolis, MN)	Natural source mixed tocopherols	Liquid	Unknown	The Scoular Company, 2014
		Powder	Unknown	
Vitablend (Wolvega, The Netherlands)	Tocoblend®	Liquid	Unknown	Vitablend, 2014
		Powder	Unknown	
VitaeNaturals (Toledo, Spain)	Vitapherole® T	Liquid	Unknown	Vitae Caps S.A., 2012
		Powder	Unknown	
Wilmar Spring Fruit Nutrition Products Co. (Jiangsu, China)	Natural mixed tocopherols	Liquid	Soybean or sunflower oil	Wilmar International Ltd., 2014
		Powder	Unknown	
ZMC-USA (The Woodlands, TX)	CarolE™ ET and PT	Liquid	Unknown	ZMC-USA, date unknown
		Powder	Unknown	

* Piñol del Olmo (date unknown) reports that sterols, squalene, and monodiglycerides are naturally present in Tocobiol® from the sou vegetable oil.

Discussion:

The NOSB has consistently relisted this material due to its essentiality for many processed food products. However, there has been extensive discussion about the need for synthetically derived tocopherols. Public comment has historically been divided on the relisting due to concerns that the

material's primary use is as a preservative and therefore inconsistent with organic production. Additionally, commenters have asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic. However, many past commenters have expressed strong support of relisting, stating that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers. Many comments were submitted during the April 2019 meeting and were uniformly supportive of relisting this material, including assertions that adequate non-synthetic sources were not available or that rosemary or other derived tocopherol product were not adequate. One comment recommended that the Handling Subcommittee investigate the availability of natural tocopherols manufactured without solvents, and, depending on availability, that they be removed from §205.605(b) and petitioned for §205.605(a). The Handling Subcommittee considered the possibility of reclassifying tocopherols to 205.605(a), or listing on both 205.605(a) and 205.605(b) with different uses annotated for each listing and/or an annotation about availability; however, as discussed at the Fall 2017 meeting, the Handling Subcommittee concluded to not move forward with the tocopherol annotation change. The meeting transcripts note that "if there is sufficient commercial availability of this material in another form, we encourage members of the public or industry to petition the NOSB to make this change, and we would take it up at that time".

Human Health and the Environment:
Tocopherols are one of the main sources of Vitamin E. No major impacts on human health or the environment are likely.

Additional information requested by Subcommittee: None

Subcommittee Vote:
Motion to remove tocopherols from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Reference: 7 CFR §205.606

Celery powder

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(c) **Celery powder.**
Technical Report: N/A
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Meat preservation via natural nitrites/lactic acid is an ancient technology. In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide "cured" meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage (as an antioxidant) and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled "uncured."

Manufacture:
Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, then heated and vacuum dried. According to the original petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf), "the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load." Celery powder is typically standardized to a specific nitrite content. See discussion below for more information about source material.

International:
There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Celery powder is not listed in the EU Organic Standards; however, sodium nitrate is allowed for meat products (an alternative to celery powder not currently listed on the National List).

Ancillary substances:
Possibly materials listed in the patent: "including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates."

Human Health and the Environment
Nonorganic celery is used to produce celery powder, with concomitant use of allowed conventional pesticides and fertilizers. These materials may pose risks to workers, consumers and the environment. Additionally, health concerns have been raised about the use of synthetic nitrates and nitrites in processed meats (allowed in the European Union). For example, the International Association for Research in Cancer (IARC) listed processed meats as carcinogenic to humans due to the formation of nitrosamines, albeit with low potency, and the review committee was not unanimous. In terms of human health risks from nitrates/nitrites in food, there is no difference between celery or other plant-based nitrate sources versus synthetic nitrates and nitrites used on non-organic meats. In summary, nitrates and nitrites from celery powder would pose similar risks. Nitrates in food may provide some health benefits. For example, formation of nitrous oxide may result in lowered blood pressure and better cardiovascular function.

Discussion (including OFPA criteria):
Celery powder was listed as a nonorganic handling material in response to a 2007 petition asserting the need for a uniform, agriculturally produced material necessary to produce organic processed meats such as bacon, hot dogs, and sausage. Several commenters argue that this material allowed substantial growth of the organic meat industry while complying with the "organic" or "made with organic" claims of processed foods. However, concerns were, and continue to be, raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to "supercharge" the product used for celery powder manufacture.

In lieu of a technical report, a celery powder expert panel was convened for the April 2019 NOSB meeting. Experts spoke to key questions addressing nitrate safety, organic celery powder production, processing and manufacture of celery powder, progress toward organically sources celery or other substrates that could be used process organic meats, and the scale of the organic processed meat industry. Presentations and discussion addressed concerns raised during past reviews that production of high nitrate conventional nonorganic celery used for celery powder production requires enhanced use of synthetic nitrate fertilizers. In summary:

- Celery powder remains an essential curing agent for organic cured meats. Alternative source material such as swiss chard or other crops do not fill the need for a uniform product;
- Currently, celery powder is the only option available to comply with FSIS food safety requirements;
- Organic cured meat products represent a multi-million dollar industry and have increased opportunities for organic agricultural production;
- Because celery powder is used in small amounts, it is difficult to leverage investment to develop alternative sources;
- In various trials, nitrate levels in organically produced celery were ~1,000 ppm and ranged from ~500 to ~2000, but there was very high variability between varieties, farms, and years. Overall, organic levels were not uniform and generally below thresholds needed for meat processing;
- Nitrate levels in mature conventional celery were much higher – in the range of ~2500 ppm;
- No information was available as to whether agronomic methods to produce conventional celery for celery powder production entailed the use of extra nitrate use;
- More research is needed to identify varieties and methods to produce organically produced celery

powder source material.

Overall, trade and industry members of the organic community supported relisting of celery powder at §205.606, with the caveat that more research is needed to produce a viable organic alternative. There was little opposition to relisting celery powder except one consumer group that reflected concerns about the direct dependence of the large organic processed meat industry on a conventionally grown agricultural product and whether its use is a direct violation of OFPA and organic regulations and artificially adding nitrate as a preservative at levels not possible to achieve through use of organic celery. Concerns were raised about the cancer health risks of nitrates and nitrites, but as noted above there are also potential health benefits to nitrate intake. Given the importance of the organic processed meat industry, public and NOSB comments encouraged the USDA to fund additional research to develop organic alternatives to conventionally produced celery powder.

Additional information requested by Subcommittee: None

Subcommittee Vote:
Motion to remove celery powder from the National List at §205.606(c) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Fish oil

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(e) **Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.**
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 sunset recommendation; 04/2010 sunset recommendation ; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Section 205.606 allows for use of non-organically produced ingredients to be used in processed products labeled "organic" when the ingredient is not commercially available in organic form.

The NOP does not presently have production standards for aquaculture, therefore organic fish cannot be commercially available as organic.

Uses: Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids - primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) - in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis (Chang et al., 2009; Lee et al., 2014). Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat

products, cookies, crackers, snack foods, condiments, sauces, and soup mixes (Rizliya and Mendis, 25 2014). (Technical Report 2015 lines 19-25).

In addition to aquaculture - estimated to use about 81% of the fish oil produced worldwide - fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture.

History: Fish oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a technical report (TR) or Technical Advisory Panel Report (TAP). The NOSB 2007 recommendation indicated that the OFPA criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the NOSB final recommendation from May 9, 2007 stated …"pursuant to the judgment in Harvey v. Johanns, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed at § 205.606. These criteria were finalized in the NOSB "Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606" of October 19, 2006. "That recommendation allows for pro-active listing on § 205.606 of materials that may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather, or trade-related issues. Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a § 205.606-listed material may be used, on a case by case basis. …" "…. After discussion, the Board decided to add an annotation to the recommendation to list fish oil to the National List. The annotation is "stabilized using only allowed ingredients on the National List." The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market." The NOSB (2007) further noted that "There were no public comments specifically opposing the listing of fish oil on §205.606…."

In its five-year review in April 2010 the NOSB received no public comment and fish oil remained on the List. In February 2015 the NOSB posed the following questions in the first posting of this material under the new Sunset procedure:

1. What are the primary geographic sources of fish oil and primary fish species harvested for the purpose of oil extraction?
2. Are there conservation and environmental issues surrounding harvest of wild caught fish for fish oil?
3. What is the manufacturing and purification process?
4. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB's for example? How is purity assessed?
5. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
6. What is the most current research on plant-derived alternatives such as flax and chia and how comparable
   are they to the Omega 3 in fish and algal oils?

In addition, in preparing for the 2017 Sunset Review the NOSB requested a full TR which was received in March 2015 after the posting of the initial sunset review. The 2015 TR provides a valuable in-depth analysis and provides up-to-date research and citations allowing the Subcommittee to re-evaluate fish oil comprehensively against the OFPA criteria. Sources: Fish oil is derived from a wide range of wild caught fish species including, tuna, mackerel, sardines, anchovy, halibut, (TR lines 69-79). NOTE: The TR also lists fish oil from whales and seal under fish, although these are mammals. (TR lines 75-76).

Fish oil is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil (TR lines 283-284). Farmed fish are not a source of fish oil; they are often fed fish oil supplements to boost their own levels of omega 3 fatty acids (TR 332-333). Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru

produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States (Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). (TR 90-110)

Manufacturing: Fish oil remains intact through the purification process and is not chemically modified (TR 338). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002) (TR 307320). There are also other purification methods, which are discussed in the TR.

International: Fish oil is not listed as allowed for organic processing in Canada, Japan, EU, or under IFOAM and is not listed in CODEX (TR 245-275). However, it should be noted that CODEX, IFOAM and JAS do not have discreet lists for non-organic agricultural substances. The EU does have a positive list and it does not list fish oil, but the EU Organic Standards also allow for organic certification of aquaculture. There are EU organic fish oil products being sold.

Discussion: Human Health: Fish oil is a naturally sourced product which appears to provide a multitude of health benefits (as listed above under "Uses"). It is one of the best sources of Omega 3 EPA and DHA fatty acids. Fish oil such as cod liver oil which has been given to children in many areas of the world for generations to promote healthy brain development and prevent inflammation. Fish oils are added to many foods and taken as dietary food supplements to promote heart health and reduce risk of atherosclerosis.

However, the health benefits from consumption of fish oil is currently a debated topic in the scientific community (TR 471) and some sources suggest that there are health risks from fish consumption that may outweigh the benefit of omega 3 fatty acids from fish oil (TR 489-494). However, this statement is contradicted by the FDA's *A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish*, which states "the assessment estimates that for each of the endpoints modeled, consumption of commercial fish during pregnancy is net beneficial for most children in the United States."[2] Fish bioaccumulate many contaminants (TR 503-507). A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (TR 403-408, LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). It should be noted however, that these tests were on fish oil supplements, not on fish oil used in food products which is controlled under different regulations than dietary supplements. The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012).

PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil

[2] https://www.fda.gov/media/88491/download

dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 415 8) ppb (TR 413-415, Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012). Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009).

The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively (GOED, 2012). There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. (TR 404-426). Note: The TR addresses the February 2015 NOSB Questions 1, 2, 3 and 6 listed above under History, and partially answers Question 4, but it is not clear if the Voluntary Standard for contaminant limits is still in effect (Question 5).

Conservation issues: There is a very high demand for fish oil. 81% of fish oil goes to aquaculture. Demands on fisheries may overburden the current supply of fish (TR 441-450). Fish oil used is from wild caught and not farmed fish. Overfishing may also lead to species extinctions and a decrease in biodiversity. There are more than 100 confirmed cases of extinctions in marine fish populations worldwide (Jenkins et al., 2009). Exploitation of fisheries is the largest contributor to marine extinctions, higher than habitat loss, climate change, invasive species, pollution, and disease (Dulvy et al., 2003) (TR 462-465). While some countries have highly regulated fisheries to prevent overfishing, many do not. According the Food and Agriculture Organization's (FAO) State of the World's Fisheries and Aquaculture, most of the pelagic fish stocks, globally, are considered either fully fished or overfished. Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department (2014). The State of the World Fisheries and Aquaculture. pp. 39. While many different species are used for fishmeal and fish oil, small pelagics are most commonly used due to their high oil content. Peruvian anchoveta, Japanese anchovy, and Atlantic herring are the most common pelagic species harvested for fishmeal and fish oil, with primary stocks in the Southeast Pacific, Northwest Pacific, and Northeast and Northwest Atlantic, respectively. In 2010, all of these were either fully exploited or depleted. (Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department. (2010) The State of the World Fisheries and Aquaculture. pp. 35. Available at: http://www.fao.org/docrep/013/i1820e/i1820e.pdf)

In the Mediterranean, sardine and anchovy stocks have been assessed as fully fished (FAO 2014, p 40). According to FAO, fisheries that target species of a specific trophic level, such as those that target pelagics for fishmeal and fish oil production, remove "one ecosystem component without considering cascading effects on the dependent species…Concerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems." (FAO 2014, p 136). Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds, serving as an important link in the transfer of energy from plankton to species higher in the marine food web, some of which are endangered (FAO 2014, p 137), such as humpback whales.

There was a divided opinion of the Board and public in the 2015 review of this substances. There was a high consumer demand and industry strongly supports continued listing, especially as there are no organic sources. Industry comments (April 2015) include the following: "Used in Gummy Confections, Gummy Nutritional Supplements, Panned Jelly Beans…. Fish Oil is used in our products as a natural source of DHA. An organic form is not available…. No alternative management practices that would eliminate the need for the specific substance. This ingredient is essential to our organic products." Other Industry comments: "Fish oil provides nutritional benefits which our consumers are seeking"; "Peru fisheries are well regulated"; "specification sheets indicate levels of PCB's, arsenic, cadmium and lead are tested 3 times a year to meet

very strict guidelines; plant sources of omega 3 are not as complete as found in fish oil". On the other hand, conservation groups are concerned about impact on word fisheries, and NGO's are concerned about the cumulative risk impact of fish oil on human health recommend removing fish oil as it fails to meet OFPA criteria relating to human health, environmental conservation and compatibility with a sustainable system of agriculture. Public comment was also received about the essentiality of this substance however, essentiality is not a criterion used to review agricultural substances in OFPA/NOP regulations. Essentiality is only a criterion applied to synthetic substances, adjuvants, and processing aids. In the end the NOSB voted to not remove fish oil and the substance was renewed.

During the 2019 sunset cycle we posed four questions at the spring meeting:

1. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB's for example? How is purity assessed?
2. How is industry controlling for the risk of contaminants such as heavy metals and PCBs?
3. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
4. How can the annotation be modified to control for the note conservation concerns?

Public comment indicated there was no mandatory standard for fish oil purity limits but that the GOED, a trade association representing the 85-90% of the fish oil industry, requires members to comply with a monograph for fish oils. As of this review limits were as follows:

- PCBs: Maximum 0.09 mg/kg
- PCDDs and PCDFs: Maximum 1.75 pg WHO-PCDD/F-TEQ/g
- Dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Total Dioxins, Furans and dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Lead (Pb): Less than 0.05 mg/kg
- Cadmium (Cd): Less than 0.1 mg/kg
- Mercury (Hg): Less than 0.1 mg/kg
- In-organic Arsenic (As): Less than 0.1 mg/kg[3]

The organization states control is established via randomized testing but no details on this program were provided. The same organization noted that the CRN monograph and its Omega-3 Working Group were the foundations for the GOED trade association. The current GOED monograph is the successor to the CRN monograph.

Support was received from several commenters, including the GOED trade association, for annotations that further address conservation concerns. The NOSB has submitted a separate work agenda request on this topic, however, annotation changes are handled separately from sunset reviews.

Support was received from organic dairies and industry that speak to the consumer demand for omega-3 enriched products and having an opportunity to compete with conventional products that market themselves similarly. Opposition was received from several interest groups who questioned the environmental impact from overfishing, human health impact from heavy metal exposure, and compatibility due to its usage as a supplement. Comments are consistent with previous comments received by the Board during earlier reviews and did not provide new information on fish oil. Furthermore, there is no relevant criteria in OFPA or the Organic regulations for delisting this material based on its use as a nutritional supplement.

No new information was received by the NOSB supporting removal of this substance.

[3] https://goedomega3.com/storage/app/media/Governance%20docs/goedmonograph-2019-03-01-r.pdf.

Subcommittee Vote:
Motion to remove fish oil from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Gelatin

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(g) **Gelatin (CAS # 9000-70-8).**
Technical Report: 2002 TAP; 2019 TR Gelatin, collagen gel, and casings
Petition(s): 2001 Petition ; 2007 Petition
Past NOSB Actions: 05/2002 NOSB Recommendation; 05/2007 Recommendation to add to the national list; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Gelatin is used in a wide range of products as a clarification or fining agent in teas, juice, and wine, as a stabilizer, texturizer, thickener, and in capsules. It may either be an ingredient or a processing aid in candies (gummy bears), desserts (puddings, jello, marshmallows), dairy products (yogurt, sour cream, ice cream), cereals and cosmetics. Fish gelatin is widely preferred for uses in kosher foods. Collagen gel has recently been petitioned for inclusion on the National List at §205.606. Collagen is the native form of gelatin and chemically the two are indistinguishable.

Manufacture:
Gelatin can be made from many different sources of collagen. Cattle bones, hides, pigskin, and fish are the principle commercial sources. Gelatin may be prepared in a way that is more like cooking and could be considered nonsynthetic. However, gelatin may also be processed in ways that would render it synthetic. All manufacturing operations extract and hydrolyze collagen found in fish skins, bovine bone, and porcine skin with subsequent purification, concentration, and drying operations. These can be either simple or complicated operations.

International:
EU 2092/91 — Annex VI — Gelatin is listed under "Processing aids and other products which may be used for processing of ingredients of agricultural origin" in Section B and under "Ingredients of Agricultural Origin Which Have Not Been Produced Organically" in Section C.
Codex Alimentarius — Guideline for the Production, Processing, Labelling, and Marketing of Organically Produced Foods CAC/GL 32-1999, Table 2 Substance for Plant Pest and Disease Control, 1. Plant and Animal: listed. Table 4: Listed under "processing aids which may be used for the preparation of products of agricultural origin."

IFOAM — Basic Standards for Organic Production and Processing, September 2000, Appendix 4 List of Approved Ingredients of Non Agricultural Origin and Processing Aids Used in Food Processing, Processing Aids and Other Products: listed for use in fruit & vegetable products and wine.
Ministry of Agricultural, Forestry and Fisheries of Japan (MAFF) — Japan Agricultural Standard, Notification #60, Table 2 of food additives: allowed, with no annotation.
Canada — Canadian General Standards Board National Standard for Organic Agriculture (CAN/CGSB-32.310-99), June 1999: permitted as a clarifying agent.
Certified Organic Associations of British Columbia (COABC) — British Columbia Certified Organic Production Operation Policies and Farm Management Standards, Section 9.14 Processing and Handling Materials List, March 2001: non hydrolyzed or hydrolyzed, regulated as a processing production aid; Either form of gelatin maybe used as a product processing aid, for now, but the producer must submit to the certifying agency written details of their search to replace the hydrolyzed gelatin format with a non-hydrolyzed gelatin or a completely different product. Allowed for fruits and vegetables and in winemaking.
Naturland, Germany — Listed in the August 1999 General Processing Standards in the "List of Permitted Ingredients, Additives, and Auxiliary Products" as "food gelatin without additives (exclusively for cream-like masses)."

Ancillary Substances:
It does not appear that there are any ancillary ingredients used regularly for gelatin, such as anti-caking agents, preservatives, colorings etc.

Discussion:
There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. Public comment stated concern over gelatin sourced from conventional animal sources. The Subcommittee briefly discussed gelatin in relation to collagen gel, currently being petitioned, because gelatin is derived from processing collagen.

During the review period, the Subcommittee posted the following questions:

1) Are there organic sources of collagen that preclude the listing as a non-organically produced agricultural product allowed as ingredients in or on processed products labeled as 'organic'?
2) Are there any ancillary ingredients typically found in commercially available gelatin?

In response to the questions, several commenters said that the organic meat market has not sufficiently reached the "magnitude of mass" needed to produce organic gelatin and that the industry is currently working on the supply chain for future development of the organic gelatin market. However, detailed information about what the barriers are to organic gelatin development were not specified. Several commenters mentioned other alternatives to gelatin such as organic pea starch and pectin. However, in discussions with organic gummy manufacturers, it was noted that pectin and pea starch may add a flavor residue that is undesirable. The 2019 TR did not have any new information indicating that organic gelatin would be commercially available in the near future. The Handling Subcommittee hopes that at the next sunset review, the barriers to production of organic gelatin will no longer be present.

Subcommittee Vote:
Motion to remove gelatin from §205.606(f) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Orange pulp, dried

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

Reference: 205.606(n) **Orange pulp, dried.**

Technical Report: N/A

Petition(s): 2008 Petition

Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National List; 10/2015 NOSB Final Review

Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
According to the petitioner, dried orange pulp is a fiber with about 33.3% soluble fiber and 34.9% insoluble fiber. It is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use, but is self-limiting after that point due to loss of desirable eating qualities.

Manufacture:
Dried orange pulp is a byproduct of the orange juice industry and is manufactured from the washed orange peel, core and rag (membrane) remaining after juicing. The pulp is then mechanically dewatered, stabilized with heat, dried, and mill-ground to a powder. The only processing aid used is water. No chemicals are used to process the product. The petitioner notes, due to food safety and economics, dried orange pulp manufacture must be co-located with orange juice processing facilities.

International:
There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list dried orange pulp.

Ancillary substances:
No ancillary substances were provided.

Discussion:
The 2015 NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments supported relisting or addressed commercial availability of dried orange pulp. No organic handler commented in favor of the material. While the NOSB could not find organic dried orange pulp during a search of publicly available sourcing resources in February 2015, there were several listings for organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp. During the review period, the Subcommittee asked the following questions:

1) Is there an organic supply of international orange pulp, dried?
2) Is there a domestic supply of organic orange pulp, dried?
3) Is it essential?

There were no commenters who listed orange pulp, dried, as an ingredient in their products nor any certifiers who listed it in their review of materials in organic products. However, orange peel and orange pulp were listed as ingredients in organic products. During the Spring 2019 public subcommittee discussion, the Handling Subcommittee noted that this listing also has a patent which may limit its use in organic products. Other commenters requested that the Board consider the use of conventional pesticides in conventional orange production that may leave residue in the final product of orange pulp, dried.
The Handling Subcommittee has voted to remove this item from the National List because orange pulp dried does not seem to be necessary for or consistent with organic handling (failing OFPA criteria at 7 U.S.C. § 6517(c)(ii)–(iii)), and alternatives exist (failing OFPA criteria at § 6518(m)(6)). There were no comments that supported it use, nor no known organic products that include it as an ingredient. There is sufficient supply of organic oranges to produce dried orange pulp, and those wishing to purchase this product organically could work with manufacturers to source organic raw material. It is inconsistent with organic farming and handling to use a nonorganic product in organic foods, when an organic ingredient could be produced.

Subcommittee Vote:
Motion to remove orange pulp, dried from §205.606(n) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Not necessary for, or consistent with, organic handling and alternatives exist (§§ 6517 and 6518)
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 4 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Seaweed, Pacific kombu

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(r) **Seaweed, Pacific kombu.**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Added to NL effective 03/15/12 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

Uses:
Marine plants (seaweed) and algae are included on the National List in several sections and allowed for use in organic production and handling:

1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar, carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as

''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.

3) At §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (r) Pacific kombu; and (v) Wakame seaweed (*Undaria pinnatifida*).
4) In addition, calcium used for fortification may be derived from marine plants. In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production, also known as wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).

Currently, Kombu is used as an ingredient to make stock for instant miso soup and Yuzu Ponzu. Kombu is integral to the preparation of many Japanese traditional foods such as stock.

Manufacture:

Kombu is harvested from the ocean. After the crop is harvested, it is sun-dried. In general, for the preparation of stock for Japanese traditional food, dried Kombu is boiled in water.

International:

Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted as a medium for mushroom spawn production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.

Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan and alginates are allowed as food additives (IFOAM, 2014).

Ancillary substances:

It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of Pacific Kombu products.

Discussion:

As a marine material, use of Kombu seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials (see https://www.ams.usda.gov/sites/default/files/media/Marine%20Plants%20and%20Algae%20TR.pdf; and https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsDiscDocOct2018Web.pdf) and whether standards preventing overharvesting are needed to protect ocean environments. No written or oral comments were submitted for the April 2019 NOSB meeting by users of Kombu seaweed. Written comments addressed environmental concerns about overharvesting and also the potential for Kombu seaweed to concentrate heavy metals and/or radioactive isotopes of iodine which may be present in contaminated waters. Annotations were recommended for risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. One commenter suggested that certification as a wild-crafted organic product could prevent overharvesting and contamination, and in the absence of such standards, the material should not be relisted.

Additional information requested by Subcommittee: None

Subcommittee Vote:

Motion to remove seaweed, Pacific kombu from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Wakame seaweed

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(v) **Wakame seaweed (*Undaria pinnatifida*).**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy. Marine plants (seaweed) and algae are included on the National List in several sections and allowed for use in organic production and handling:

1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the 46-extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar and carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.
3) In §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (r) Pacific kombu; and (v) Wakame seaweed (*Undaria pinnatifida*).
4) In addition, calcium used for fortification may be derived from marine plants

In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production or wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).

Wakame seaweed is a traditional accompaniment to Miso Soup in Japanese cuisine.

Manufacture:
Wakame is naturally occurring in the ocean. It is harvested and sun dried. It is often cut into smaller pieces and salted for shelf life.

International:
Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted a medium for mushroom spawn production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to

consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.

Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in Appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan and alginates are allowed as additives (IFOAM, 2014).

Ancillary substances:

It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of wakame products, other than salt.

Discussion:

As a marine material, use of Wakame seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials (see https://www.ams.usda.gov/sites/default/files/media/Marine%20Plants%20and%20Algae%20TR.pdf; and https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsDiscDocOct2018Web.pdf) and whether standards preventing overharvesting are needed to protect ocean environments. Among written and oral comments submitted for the April 2019 NOSB, only one user of this materials was noted. Written comments addressed environmental concerns about overharvesting and also the potential for Wakame seaweed to concentrate heavy metals and/or other contaminants which may be present in polluted waters. Annotations were recommended for risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. As with Kombu seaweed, one commenter suggested that certification as a wild-crafted organic product could prevent overharvesting and contamination, and in the absence of such standards, the material should not be relisted.

Additional information requested by Subcommittee: None

Subcommittee Vote:

Motion to remove seaweed, wakame (*Undaria pinnatifida*) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0