Sunset 2021
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 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. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2019 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2019 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 4, 2019, as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments
Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

(1) not harmful to human health or the environment;
(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic handling.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with handling.

For Comments Addressing the Availability of Alternatives:
Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

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

For Comments on Nonorganic Agricultural Substances at Section 205.606.
For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 4, 2019, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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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 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:*

Acid, Alginic
Activated charcoal
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

Background from Subcommittee:
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 including baby food, breakfast cereals, frozen desserts, frozen entrees and certified organic personal care products. The remainder is 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 been approved for organic use under 205.605 if the citric acid used is produced by microbial fermentation of carbohydrate substances (non-synthetic). The NOSB in its initial request for public comment in 2017 did not ask for any specific information from stakeholders. While there were no specific questions asked of the public, the subcommittee did receive several comments from various stakeholders.
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. Alternate acids are not more natural and do not give the same flavor profile. It is used as a pH adjuster for organic fruit processing and spreads. There are no other alternatives to date that can replace citric acid.
While there were some public concerns from the 2015 sunset review about the relisting of this material, the majority of public comments from the 2015 sunset review stated that it is necessary in the organic industry for proper pH control in many foods. There are currently no allowed alternatives available to citric acid.
This material satisfies the OFPA Evaluation criteria.
Several commenters were in favor of relisting, stating citric acid is a naturally occurring substance but classified as a synthetic due to chemical processing through fermentation. One commenter suggested malic acid may work for lowering pH instead of citric acid but there are no studies that determine feasibility and the effect on product profiles. Comments from cut-fruit manufacturers stated no other alternatives provide the same shelf life extension as the fruit treated with citric acid.

Additional information requested by Subcommittee:
1. Are there any commercially available sources of citric acid derived from organically grown crops?

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

Background from subcommittee:

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). The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008). Other uses include mixing with sodium, potassium, and distilled water to form intravenous fluids commonly used after blood loss. It is sometimes used in the pharmaceutical industry to adjust acidity. 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 are 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 NOSB 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. A secondary manufacturing

process involves chemical synthesis of adding hydrogen cyanide to acetaldehyde, an organic chemical compound found in coffee, bread, ripe fruit, coal, or crude oil. This process only exists today in Japan. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation.

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.

Lactic acid is one of the most widely distributed acids and preservatives in nature. It is produced naturally by humans, animals, and microorganisms. Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with sour milk. It occurs naturally in two isomers (D) and (L). (D) is harmful to humans so (L) is the preferred isomer for food and pharmaceuticals. It functions as a flavor agent, preservative and acidity adjuster in foods.

There is no known organic alternative to lactic acid. Currently, it is not being produced organically. Since raw material sourcing for dextrose or sucrose could include corn and beet sugar, the TR (lines 569-572) stated the purification process would remove any traces of GMO DNA from the final product.

Past public comments for relisting were mostly in favor. Some comments expressed a concern that because of the chemical reactions in the purification process lactic acid should be considered synthetic.

Additional information requested by Subcommittee: None

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

Background from subcommittee:
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: None

Additional information requested by Subcommittee:

Is this material currently in use by the organic food processing industry and in what applications?

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

Background from subcommittee:
Use: 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.

Manufacture: 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.

International: According to the 2014 TR on microorganisms, there is widespread international acceptance of microorganisms and dairy cultures:

European Union: Article 19 states, "The following conditions shall apply to the composition of organic processed food: ...(b) only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes...may be used, and only in so far as they have been authorized for use in organic production in accordance with Article 21." "In addition, the products and substances referred to in Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market."

Canada - Canadian General Standards Board Permitted Substances List: Microorganisms are permitted in organic processed foods as nonorganic ingredients that are not classified as food additives. This appears in 32.311 Table 6.4 as follows: "Microorganisms (processing derivatives) derived from genetic engineering or with the addition of chemosynthetic substance are prohibited."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) Joint FAO/WHO Food Standards Programme: Microorganisms, probiotics, and enzymes are allowed for use as additives and processing aids. "Substances found in nature from biological/enzymatic processes and microbial processes (e.g., fermentation)" are allowed for use "as additives or processing aids in the preparation or preservation of food" (Section 5.1(c)). Any preparation of microorganisms can be used in food processing except those derived from genetic engineering (Table 3.4).

European Economic Community (EEC) Council Regulation: EC No. 834/2007 and 889/2008: Microorganisms and enzymes "normally found in food processing" are permitted for use (Article 2y(1)(b)).

Japan Agricultural Standard (JAS) for Organic Production: Microorganisms do not specifically appear in the JAS standard for Organic Processed Food (Article 3) nor they considered food additives (Table 1). However, the JAS Standard includes language that indicates that microorganisms are allowed (see the TR for more details).

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM standard, Section 7.2.5, states, "preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products.

Ancillary Substances: 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.

Discussion:
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.

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances not listed in the chart?
2. Is the dairy culture listing redundant and should it be combined with the microorganism listing?

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

Background from subcommittee:
Use: Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients. 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)

Manufacture: 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 nontoxigenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

International:

Canadian General Standards Board: Permits the use of egg white lysozyme and animal-derived rennet in organic food processing. Animal-derived rennet is described as a nonorganic ingredient that is not classified as a food additive… Animal-derived enzymes, including rennet, should be from an organic source unless no such source is commercially available. The Canadian General Standards Board also permits the use of any preparations of enzymes normally used in food processing derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria. Therefore, the Canadian organic standards allow the use of pectinase and bromelain in organic food processing.

The European Economic Community (EEC) Council: Regulation (EC) No 889/2008, Article 27, 1(b) indicates that the use of "enzymes normally used in food processing" is permitted in organic food processing practices (EC No 889/2008). This would include animal-derived rennet, egg white lysozyme, pectinase preparations from Aspergillus niger, and plant-based enzymes such as bromelain.

The Codex Alimentarius Commission: Organic food guidelines allow preparations of microorganisms and enzymes, specifically, "any preparations of micro-organisms and enzymes normally used in food processing, with the exception of micro-organisms genetically engineered/modified or enzymes derived from genetic engineering" (Codex Alimentarius Commission, 1999; USDA, 2000).

International Federation of Organic Agriculture Movements (IFOAM): Basic Standards considers enzymes acceptable for use in organic food processing provided they are based on the established Procedure to Evaluate Additives and Processing Aids for Organic Food Products (IFOAM, 2005; USDA, 2003). These standards are generally parallel to the OFPA criteria.

Ancillary substances: Explained in the Enzymes Technical Evaluation Report – Limited Scope, (NOP 2015):

"Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.

To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

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 acid, 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.

Discussion: 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 did 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 did 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).

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances to list for enzymes?

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: Malic Acid April 2003; *2019 TR pending (to be posted at https://www.ams.usda.gov/rules-regulations/organic/national-list/l)*
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

Background from Subcommittee:

Use:

There are two forms of Malic acid, D-Malic and L-Malic. D-Malic acid is not approved on the National List because a non-synthetic viable alternative is available. (TAP 2003). L-Malic acid is used as a flavor enhancer, flavoring agent and adjuvant, and as a pH control agent in a variety of foods to inhibit bacterial growth. Malic acid is more versatile for commercial black tea production and storage than citric acid. There are no alternatives to malic acid for this application.

Approximately 55% of all industrially produced L-Malic acid is used in beverages, and 20% is used in food.

GRAS: Title 21, Chapter 1, Part 184 of the Code of Federal Regulation Direct food substances affirmed as generally recognized as safe (GRAS), except for use in infant foods. Is approved for use as a Flavor enhancer, flavoring agent, adjuvant, and pH control agent (included in Appendix A, Exhibit 2).

OMRI: Organic Materials Review Institute includes malic acid on the January 2001 Processing and Handling Materials OMRI Generic Materials list as an allowed non-organic ingredient. (included in Appendix A, Exhibit 3)

Pennsylvania Certified Organic - approved use of Malic Acid by Honest Tea through 12/31/02, and during petitioning process until September 31, 2003 (letter of initial approval included in Appendix A, Exhibit 4)

Manufacture:

L-Malic acid is the natural form of malic acid occurring in fruits such as apples and cherries. It is produced by the fermentation of fumaric acid. Fumaric acid can be produced by fermentation from glucose.

International Acceptance:

CODEX: Malic Acid meets the specifications of the Food Chemicals Codex, 3rd Edition (1981)

pp. 183-184. Available from the National Academy Press, 2101 Constitution Ave., NW. Washington, D.C. 20418 (included in Appendix A, Exhibit 1).

Canada: CAN/CGSB-32-310 - National Standard of Canada Organic Agriculture - Malic acid is allowed without restriction in Appendix D, Permitted Substances List for Processing (Appendix 4) (included in Appendix B, Exhibit 1)

Australia: the Organic Federation of Australia Inc.'s guide to the Use of the National Standard for Organic Produce includes malic acid as a substance approved for post-harvest/ storage requirements.

Europe: EU 2092/91 - UKROFS Standards for Organic Food Production - Malic acid is approved as an allowed material for organic food processing in Annex VI, section A with no restrictions (included in Appendix B, Exhibit 2).

Japan: Japanese Agricultural Standard of Organic Agricultural Product Processed Foods - Malic acid is allowed to be used as a food additive without restriction in Article 5, Food Additives Table 1, Appendix B (included in Appendix B, Exhibit 3).

Environmental Issues:
Malic acid is sometimes combined with citric acid to make a mild pesticide. 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 listed on the EPA active chemical code report with no restrictions. Prolonged exposure can result in dermatitis.

Discussion:
The NOSB received public comment in 2014 from one certifier with 7 current clients using L-Malic acid in the wine, juice and bottled tea sectors. Another large producer gave comment confirming their current use and need for this substance. Two other commenters expressed concern that the original TAP review evaluated DL-malic acid, the synthetic form, rather than L-malic acid, the non-synthetic form currently listed. However, a review of the 2003 TAP shows that the reviewers very clearly accounted for the fact that there are two forms of this substance, and recommended that the synthetic form not be listed, and that L-malic acid be listed on 205.605(a).

L-Malic acid (CAS #97-67-6) was added to the National List (Federal Register Vol. 71, No. 175) §205.605(a) on September 11, 2006. This addition was based on a review of L-malic acid by the NOSB at its May 13-14, 2003 meeting. This material underwent its first sunset review at the Fall 2009 NOSB meeting and was relisted. The 2009 Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written).

In 2014 the Handling Subcommittee requested a TR, but one was not contracted. A TR was contracted in 2018 and is currently pending.

Additional information requested by Subcommittee: None

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

Background from subcommittee:

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. Natural nigari (derived from seawater) is a popular coagulant in Japan that contains magnesium sulfate and a number of other minerals. Nigari is predominantly magnesium chloride, with much smaller amount of magnesium sulfate, sodium chloride, potassium chloride, and other minerals. However, natural nigari is not approved by the FDA for use in the US and is not generally recognized as safe (GRAS). 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.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

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

Background from Subcommittee:
Use:
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.

Manufacture:
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.

International:
According to the 2014 TR on microorganisms, there is widespread international acceptance of microorganisms:

European Union: Article 19 states, "The following conditions shall apply to the composition of organic processed food: ...(b) only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes...may be used, and only in so far as they have been authorized for use in organic production in accordance with Article 21." "In addition, the products and substances referred to in

Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market."

Canada - Canadian General Standards Board Permitted Substances List: Microorganisms are permitted in organic processed foods as nonorganic ingredients that are not classified as food additives. This appears in 32.311 Table 6.4 as follows: "Microorganisms (processing derivatives) derived from genetic engineering or with the addition of chemosynthetic substance are prohibited."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) Joint FAO/WHO Food Standards Programme: Microorganisms, probiotics, and enzymes are allowed for use as additives and processing aids. "Substances found in nature from biological/enzymatic processes and microbial processes (e.g., fermentation)" are allowed for use "as additives or processing aids in the preparation or preservation of food" (Section 5.1(c)). Any preparation of microorganisms can be used in food processing except those derived from genetic engineering (Table 3.4).

European Economic Community (EEC) Council Regulation: EC No. 834/2007 and 889/2008: Microorganisms and enzymes "normally found in food processing" are permitted for use (Article 2y(1)(b)).

Japan Agricultural Standard (JAS) for Organic Production: Microorganisms do not specifically appear in the JAS standard for Organic Processed Food (Article 3) nor they considered food additives (Table 1). However, the JAS Standard includes language that indicates that microorganisms are allowed (see the TR for more details).

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM standard, Section 7.2.5, states, "preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products.

Ancillary Substances: 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 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.

Discussion:
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).

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.

In general, microorganisms are essential to the production of many organic foods and they are widely used in the industry.

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances not listed in the chart?

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

Background from Subcommittee:
Use:
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.

Additional information requested by NOSB:
Is this material still essential to organic production?

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

Background from subcommittee:
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 a 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 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: In the past public comment has been limited. It is unclear if potassium iodide is being used for sanitizing purposes or only as a dietary supplement.

Additional information requested by Subcommittee:

1. Is potassium iodide utilized as a sanitizing agent for food processing equipment? If so, in what applications?
2. If potassium iodide is used for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If so, should this separate listing be removed?
3. Are certifiers limiting the use of potassium iodide to non-synthetic forms even with the 205.605(b) synthetic allowance for Nutrient Vitamin and Mineral listing?

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

Background from subcommittee:

Use:

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.

Manufacture: 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.

International: According to the 2014 TR, yeast is listed separately as an allowed substance in Canada and the European Union whereas it is indirectly referred to by CODEX Alimentarius, Japan and IFOAM. Listed below are excerpts from the TR listings – refer to the TR for additional details.

> **Canadian General Standards Board:** Table 6.4, titled “Non-organic Ingredients Not Classified as Food Additives” of the Canadian Permitted Substance List states that only non-synthetic yeast is allowed in organic handling. The types of yeast include “autolysate, bakers’ (may contain lecithin, obtained without the use of bleaches and organic solvents), brewers’, nutritional, and smoked. Non-synthetic smoke flavouring process shall be documented. Growth petrochemical substrate and sulfite waste liquor are prohibited.”
>
> **CODEX Alimentarius:** Yeast in the CODEX Alimentarius does not appear separately as it does in the USDA organic regulations. Under Additives and Processing Aids, "probiotics, microorganisms and enzymes are allowed." GL 32-1999 section 3.4 states that “any preparations of microorganisms and enzymes normally used as processing aids in food processing” are permitted for use “with the exception of genetically engineered/modified organisms and enzymes derived from genetically engineered/modified organisms.”
>
> **European Economic Community Council:** Article 20 allows for the labeling of organically produced yeast as organic, and states that "only organically produced substrates are to be used for the production of organic yeast and organic yeast should not be present in organic food or feed together with non-organic yeast"
>
> **Japan Agricultural Standard (JAS):** The JAS Standard for Organic Processed Food does not specifically identify the allowance for yeast, in Table 1: Food Additives of the Japanese Agricultural Standard for Organic Processed Foods (Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606) 2005). However, the standard includes the following language that indicates that microorganisms, including yeasts, are allowed: “Only physical method or method using biological function (except for those produced by the recombinant DNA technology; hereafter the same) shall be used for the manufacturing or processing.”
>
> **International Federation of Organic Agriculture Movements (IFOAM):** Yeast is permitted in IFOAM per Section 7.2.5 which states that “preparations of micro-organisms and enzymes

commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products. Cultures that are prepared or multiplied in-house shall comply with the requirements for the organic production of microorganisms."

Ancillary Substances: 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 being problematic with regard to exposure.

Discussion: 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. 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 on the National List for the yeast.

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 being problematic with regard to 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).

Additional information requested by Subcommittee:

1. Are there still types or forms of organic yeast that are not available in sufficient quality or quantity for production of organic products? Specifically, have organic forms of torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast become available since the last sunset review in 2015?
2. Have there been changes in ancillary materials added to yeast compounds since the 2014 TR?

§205.605(b) Synthetics allowed:

Acid, Alginic

§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

Background from subcommittee:
Use:
Alginic acid is used in the food industry as an emulsifier, emulsifier salt, formulation aid, and thickening agent for soups and soup mixes. FDA limits the use of alginic acid as a stabilizer, emulsifier and thickener in 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 and because alginic acid is used primarily to enhance texture in foods it is therefore not "essential" according to OFPA criteria. The 2015 TR did not cite any evidence supporting those concerns.

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 of alginic acid. Those in favor of its relisting note 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 Board did recognize in October 2018 that further research may be needed on the sustainability of harvest practices. There was one public comment in October 2018 in favor of relisting alginic acid under 205.605(b) citing that harvesting practices of wild seaweed were safe and sustainable.
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)

Additional information requested by Subcommittee:

1. Is there a way to assess whether or not current brown seaweed harvesting practices are sustainable or damaging to local ecosystems?

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

Background from Subcommittee:
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.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

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

Background from Subcommittee:
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. Ascorbic acid is one of the most common sources of Vitamin C. 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.

Manufacture:
The majority of industrial production of ascorbic acid is synthesized using the Reichstein and Grussner process which is a six-step process developed in the 1930's that begins with D-glucose and involves hydrogenation, oxidizing, and treatment with acetone and then hydrogen chloride to yield L-ascorbic acid. Modern industrial production processes use fermentation with additional bio-oxidation steps adding a bio-catalyst which eliminates the need for the chemical steps. Synthetic ascorbic acid is

identical in molecular structure and in function to natural ascorbic acid. The majority of industrial production comes from China.

International Acceptance:
Ascorbic acid is GRAS as a chemical preservative (21CFR182.3013), a dietary supplement (21CFR182.5013), and nutrient (21CFR182.8013) when used in accordance with Good Manufacturing Practices. It is allowed by CODEX and the European Union.

Environmental Issues:
Ascorbic acid is considered non-toxic. The quantities needed to cause harm to humans are in the magnitude of one quart per 150 lbs. body weight. The potential for environmental pollution is slight (TR pp. 20).

Discussion:
Ascorbic acid is a vital nutrient necessary for humans and other primates. Humans cannot synthesize Vitamin C and must rely on dietary intake. It is added to many foods to restore Vitamin C lost during processing (Fall 2015 pp. 1146). Some FDA regulations require Vitamin C fortification, which is often achieved with ascorbic acid. It is manufactured using a culture process from dextrose.
Public comment for ascorbic acid was divided, with some comments remarking that ascorbic acid is being used as a preservative and therefore not consistent with organic agriculture. However, the majority of commenters strongly supported relisting of ascorbic acid, stating the ingredient to be critically essential to maintaining nutrients and freshness in their products (Ref: Transcript Fall 2015, pp.67-69). There is no known substitute in food processing.

Additional information requested by Subcommittee:
(*May be addressed in the pending TR*). Is the modern industrial manufacturing process which utilizes additional bio-oxidation an excluded method?

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

Background from Subcommittee:

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

Additional information requested by Subcommittee: None

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

Background from Subcommittee:
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: It appears this material is solely used is as a nutritional additive to address population-based iron deficiency.

Additional information requested by Subcommittee:

1. 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?

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

Background from Subcommittee:
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:
None. Inerts may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials including caprylic acid and mono-and di-potassium salts of phosphorous acid.

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 described 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.

Discussion:
Like peracetic acid, this material has received strong support and has been consistently relisted on the National List. Its overall profile is relatively safe, especially compared to many other sanitizers, such as chlorine compounds, and when used appropriately should not have adverse impacts on human health and the environment. In summary, hydrogen peroxide is an important tool for handling.

Additional information requested by Subcommittee:
Is this material still essential for the production and handling of organic products?

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

Background from Subcommittee:
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 to be fortified are listed in the chart below, as noted in 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 the 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.

Use of vitamins and minerals will depend on the application and the specific substances being used. 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 vitamins and minerals where required by law. The Canadian standards allow synthetic vitamins 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 the 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:

- 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 published in 2000 (65 FR 13512) included 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 vitamins 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 "nutrients" that were not in these CFR sections had to be petitioned individually for the National List because this listing did not include 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 for listing 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 noting the following 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

Additional information requested by Subcommittee:

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 currently dealing with non-synthetic nutrient vitamins and minerals?
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 that 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.

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

Background from Subcommittee:
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 generally been strong support for continued availability. 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. Furthermore, the annotation currently states "for use in wash and/or rinse water according to FDA limitation", which defines the permitted stabilizers.

Additional information requested by Subcommittee:

1) Is peracetic acid still essential for handling and processing of organic products?

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

Background from Subcommittee:
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.

Additional information requested by Subcommittee: none

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

Background from Subcommittee:
Use: 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 technical report (TR) noted that 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 review cycle, the NOSB received public comment 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; 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 are 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 are 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.

Additional information requested by Subcommittee:

1. Does industry still find the listing for potassium phosphate necessary? In what applications is this substance currently being used in products marketed as "made with organic."
2. 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?

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

Background from Subcommittee:
Use:
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-raising 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 and 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.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

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

Background from Subcommittee:
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.

Additional information requested by Subcommittee: None

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

Background from Subcommittee:
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.

Background from subcommittee:

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. Given past feedback on the commercial availability of non-synthetic tocopherols, 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:

1) Are there any additional ancillary substances not listed in the chart that should be considered?
2) Since the last sunset review, are new sources of non-synthetic tocopherols available that fulfill the needs of organic food processing?

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; *2018 TR pending*
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

Background from subcommittee:

Use:
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 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, 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. According to past information reviewed by the NOSB, meat preservation via natural nitrites/lactic acid is an ancient technology. Concerns have been raised during past reviews that production of high nitrate conventional nonorganic celery used for celery powder production requires enhanced use of synthetic nitrate fertilizers. According to the Kerry Inc. patent, other plants high in nitrate that could be used "include, but are not limited to, celery, beet, spinach, lettuce, cabbage, cucumber, eggplant, mushroom, green pepper, butternut squash, zucchini, mixed salad greens, carrot, artichoke, green bean, lima bean, broccoli, cauliflower, collard green, com, mustard, okra, onion, Chinese pea pod, black eyed pea, green pea, potato, turnip, sauerkraut, radish and the like. Other edible plant material containing nitrate, preferably at least about 50 ppm nitrate, also can be used. Any mixture or combination of plant materials can be

used to make the curing agent."

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, albeit with low potency, and the review committee was not unanimous. Nitrates and nitrites from celery powder may pose similar risks.

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 sausages. 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.

Celery powder was last reviewed by the NOSB in 2015, and there were extensive comments by celery powder manufacturers, trade groups, producers, and the larger organic community about the need for this material, as well as commitments by producers to address the lack of organically sourced material going forward to the next sunset review, which is occurring now. To address these concerns and in lieu of a technical report, the NOSB will be convening a panel discussion at the Spring 2019 NOSB meeting that will include agronomic specialists, celery powder manufactures, meat processors, and experts in meat science and nitrates and nitrites. This discussion will help flesh out the information needed for the Fall 2019 review and vote on whether to relist celery powder.

Additional information requested by Subcommittee:

1. Is nonorganic celery powder still essential for the production of processed meats?
2. Compared with growing celery for vegetable production, is increased use of synthetic nitrogen fertilizers required to produce source plants with enough nitrate for celery power production?
3. Since 2015, what progress has been made on the production of organic celery for powder production?
4. Are there strategies to produce organic celery powder that is standardized to consistently meet

safety and other requirements of the meat processing industry?

5. If not, enough organic celery is being produced to support the meat industry, why not?
6. Are there commercially available agriculturally produced alternatives to celery powder? What is your experience with them? Are they organic? Does their use vary by application? Are they more effective in one application compared to another?
7. What is the latest information on the human health risks of nitrate and nitrites present in processed meats from either synthetic or plant-based sources?

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

Background from subcommittee:

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 or TAP. The 2007 NOSB 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 on §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 which 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 states: "stabilized using only allowed ingredients on the National List." The Board considered this annotation to be 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 technical report (TR) which was received in March 2015. 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 that 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 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). 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 (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 dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 415 8) ppb (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 population's 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.

The NOSB and public were divided with regard to this substance during the 2015 review. . There was 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, 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. The NOSB received public comment about the essentiality of this substance, however, essentiality is not a criterion in OFPA or the Organic regulations used to review agricultural substances. . Essentiality is only a criterion applied to synthetic substances, adjuvants and processing aids. In the end the NOSB did not vote to remove fish oil and the substance was renewed.

Additional information requested by Subcommittee:

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 noted conservation concerns?

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

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

Background from subcommittee:

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 under §205.606.

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. For animal-based gelatin, public comment stated concern over gelatin sourced from conventional animal sources.

Additional information requested by Subcommittee:

1) Are there organic sources of collagen that preclude the listing of gelatin 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?

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

Background from subcommittee:
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 and 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 noted in the petition.

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 were received supporting relisting or addressing commercial unavailability of dried orange pulp. No organic handlers 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 listed organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp.

Additional information requested by Subcommittee:

1) Is there an organic supply of international orange pulp, dried?
2) Is there a domestic supply of organic orange pulp, dried?
3) Have manufacturers using this nonorganic orange pulp in organic products tried to develop an organic orange pulp?
4) Please describe any barriers to the production of organic orange pulp?
5) Are there other organic agricultural products or materials on the national list that have the same function and could replace the nonorganic orange pulp where it is currently used?
6) Are there any ancillary ingredients contained in dried organic pulp when sold commercially?

Seaweed, Pacific kombu

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(q) **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

Background from subcommittee:
Use:
Marine plants (seaweed) and algae are included in 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, 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; (q) Pacific kombu; and (u) 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 most Japanese traditional foods as stock.

Manufacture:
Kombu is harvested from the ocean. After the crop is harvested, it is sun-dried. In general, 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 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:
This material is discussed in the larger discussion document about marine algae and related materials.

Additional information requested by Subcommittee:

1. Are there any ancillary ingredients contained in Pacific Kombu seaweed when sold commercially?
2. Are there any organic seaweeds commercially available?

Wakame seaweed

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(u) **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

Background from subcommittee:
Use:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy. Marine plants (seaweed) and algae are included in 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; (q) Pacific kombu; and (u) 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:
This material is discussed in the larger discussion document about marine algae and related materials.

Additional information requested by Subcommittee:

1) Are there any ancillary ingredients contained in wakame seaweed when sold commercially?
2) Are there any organic seaweeds commercially available?