Sunset 2022
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 2020

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 2020 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2020 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 3, 2020 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 3, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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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:
Kaolin
Sodium bicarbonate
Waxes (Wood resin)

§205.605(b) Synthetics allowed:
Ammonium bicarbonate
Ammonium carbonate
Calcium phosphates: monobasic, dibasic, tribasic
Ozone
Sodium hydroxide

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”
Carnauba Wax
Colors (18)
Glycerin 606
Inulin-oligofructose enriched
Kelp
Orange Shellac - unbleached
Starches: Cornstarch (native)
Starches: Sweet potato starch for bean thread production only.
Turkish bay leaves
Whey protein concentrate

Kaolin

Reference: 205.605(a)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Filtering of organic juices, and for personal care products

Manufacture:
Kaolin is a soft white clay consisting principally of the mineral kaolinite.

International:
Allowed by Canadian Standards, CODEX, European Economic Community (EEC), Japan Agricultural Standards (JAS), and International Federation of Organic Agriculture Movements (IFOAM).

Ancillary Substances:
Unknown

Discussion:
There is no technical report (TR) or technical advisory panel report (TAP) available for this material. Public comment from the 2015 sunset review was limited to a trade association representing the juice industry, a certifier, and a manufacturer who stated that Kaolin was essential for filtering organic juices. No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by Subcommittee:
1. Is this material essential to organic production?
2. Are there possible alternative materials?

Sodium bicarbonate

Reference: 205.605(a)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Sodium carbonates are used as raising (leavening) agents in food processing. Sodium bicarbonate (baking soda) is a common compound in baking powder; helps to regulate acidity for things like tomato soup, or in pastes and beverages. It can be used as an anti-caking agent or as a stabilizer helping to maintain the appearance and consistency of foods. Sodium bicarbonate is often used in pancakes, biscuits, muffins, crackers, and in cookies. It often is used in self-rising flour and confections. It may also be used as a neutralizer for use in butter, cream, and ice cream.

Manufacture:
Sodium bicarbonate (baking soda) – its main source is from natural deposits of trona ore. It can also come from natural brine found in Searles Lake, California. Trona ore (sodium sesquicarbonate) is heated and then mixed with water to dissolve the soda ash and separate out the impurities. Then it is allowed to evaporate to crystallization. Carbon dioxide is added to the kiln gas to a saturated pure sodium carbonate solution, the sodium bicarbonate then precipitates out.

International Acceptance:
Sodium bicarbonate is approved for use in the following organic standards:

Canadian General Standards Board Permitted Substances List: allowed

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999): not specifically mentioned but sodium sesquicarbonate is allowed

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: may be grouped under “sodium carbonates” and if so is allowed

Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, beverages, vegetable products, processed fruits or for dairy products as neutralizing substance.

International Federation of Organic Agriculture Movements (IFOAM): may be grouped with “sodium carbonates” and if so is allowed

Environmental Issues:
Since sodium bicarbonate is derived from sodium sesquicarbonate, a mined material, and the usual environmental issues of mining would be present. However, no major issues have been raised in past reviews.

Discussion:
The original Technical Advisory Panel Report (TAP) combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. The original TAP, previous Subcommittee reviews, public comments, historical information, and current review indicate no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that sodium bicarbonate is a primary component of baking powder and is still widely used in a variety of baked goods, and that it is an essential leavening agent.

Additional information or questions requested by Subcommittee:

Is there any new information related to environmental concerns, human health, or use that would cause this substance to be considered for delisting?

Waxes (Wood rosin) (sic. resin)

Reference: (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR - Wood Rosin
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation: 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Uses:
According to the 2014 TR, wood rosin is used in organic processing and handling primarily as a component of fruit wax, most commonly applied to citrus fruit.
At the most basic level, wood rosin, when formulated as part of a fruit wax, reduces the gas exchange between the surface of the fruit and the atmosphere, which in turn reduces the respiration rate and resulting weight loss. The reduced gas exchange is considered to happen in two different ways: the wax forms a physical barrier that the gas must permeate, and the coating also fills openings in the fruit peel (Hagenmaier and Baker 1993). Hagenmeier and Baker (1993) found that some factors such as thickness of coating, and the waxiness vs. resinous qualities of the coating, also affect the action of fruit waxes. For example, coating thickness is as important as type of coating for resistance to water vapor. Wood rosin, when formulated with carnauba wax at differing percentages, only offers limited resistance to water vapor unless carnauba wax consists of approximately 90% of the formula (Hagenmaeier and Baker 1994) (2014 TR, Lines 120-128).

Manufacture:
Wood chips are passed through a series of extractors where each batch of new chips is extracted with several portions of solvent in succession. Each portion of solvent is used on several different batches of chips. This is a counter-current process where fresh solvent is used on the final extraction of the wood chips, and then it is successively used on the chips that receive one, two or three more extractions. Thus, the oldest solvent is used on the freshest wood chips. After the wood chips have received the final solvent extraction wash, the solvent is drained, and the chips are pressure-steamed to recover any residual solvent. The solvent from the terpene oil-rosin solutions leaving the extractors is recovered by vacuum-distillation separation and reused for subsequent extraction processes. The resulting terpene oils are separated by fractional distillation into refined terpentine, dipentene, and pine oil. The remaining residue is the non-volatile extract and is considered to be crude wood rosin (not food grade). The crude wood rosin is further refined and purified by a liquid fractionation process. It is placed into refining towers where a proprietary polar solvent (Merck 2013) is used to extract the darker

components. According to the EPA Toxic Release Inventory (2013), methanol is the likely solvent used in this process step. The solvent is evaporated off, recovered and reused. The resulting lighter wood rosin is called Vinsol and the remaining, darker grade (Grade K) wood rosin is that which is considered 'food grade' and permitted as an ingredient in citrus fruit waxes (Merck 2013). The manufacturing process may only differ by the solvents used, but this is the only known method for manufacturing wood rosin. No chemical changes occur during the extraction and refinement of wood rosin. (2014 TR, Lines 230-248)

International:
Allowed under the Canadian Organic Standards

Ancillary substances:
Raw wood rosin is sold directly to further formulators of fruit wax and other products without any additional ingredients such as stabilizers or preservatives (Pinova 2013) (2014 TR, lines 141-142)

Discussion:
According to the 2014 TR, wood rosin is erroneously listed at 205.605(a) as "wood resin". FDA regulations clearly permit and define only wood rosin and do not define or permit wood resin as a direct or indirect food additive. Wood resin is the raw material produced by coniferous trees prior to distillation of any terpene, tall oil, and other components.

In terms of harm to the environment, wood rosin is derived from two pine species including Longleaf pine which is categorized as endangered by the IUCN Red List of Threatened Species (2013). While wood rosin is considered a by-product of the timber industry (derived from the remaining tree stumps) the conversion of farmland for timber use has contributed to the decline of Longleaf pine which due to its slow growth cannot economically compete with other pine species for replanting.

The solvent extraction of wood rosin from the wood chips has potential to negatively affect human health. Although the specific solvents used by Pinova, Inc. are proprietary, the EPA Toxic Release Inventory (2013) suggests that methyl isobutyl ketone (MIBK) is the likely solvent used for the initial extraction, and methanol for the further refinement. According to the EPA (2003), human studies of acute inhalation exposures to MIBK indicated "transient sensory irritation, neurological effects, and/or strong odor sensation during exposure". Another study showed some nose and throat irritation at an exposure rate of 100-200 mg/m3. A study by the National Institute for Occupational Safety and Health on the other hand did not find any changes in neurological or irritation systems after a 2-hour exposure to MIBK at 100ppm (EPA 2003). For the second extraction step, methanol is considered to be environmentally preferable to other solvents of similar properties (Capello, Fischer and Hungerbuhler 2007). However, workers repeatedly exposed to methanol have experienced headaches, sleep disorders, gastrointestinal problems and optic nerve damage. Exposure to large amounts of methanol can result in death or severe abdominal, leg and back pain (EPA 1994). No information is available on the carcinogenic, reproductive, and developmental effects of methanol in humans, but birth defects have been observed in the offspring of rats and mice exposed to methanol by inhalation (EPA 2000) (TR 2014, Lines 393-414)

Additional information requested by subcommittee:
1. Is this material essential to organic production?
2. Are there possible alternative materials?

Ammonium bicarbonate

Reference: 205.605(b) - for use only as a leavening agent
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Ammonium carbonates are used as leavening agents, and may be used in baking where yeast is not used. Ammonium bicarbonate has critical functionality as a raising (leavening) agent in certain cookies and crackers. Compared to baking soda it produces more gas and in the finished baked goods, ammonium bicarbonate completely decomposes into water and gaseous products that evaporate during the baking process. It does not leave behind the salty or soapy taste that sodium bicarbonate may leave when used at higher concentrations. Since ammonium bicarbonate completely breaks down in heat it has no effect on the pH of the baked product. Ammonium bicarbonate cannot be used for moist baked goods since if there is more than 5% moisture in the baked good, the ammonia gas will dissolve in the water and give an ammoniacal flavor to the baked good. Ammonium carbonate may also help provide certain characteristic textures (such as in crackers), as well as aids in controlling cookie spread.

Since this is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process, there are no organic alternatives to replace ammonium bicarbonate.

Manufacture:
Ammonium carbonates are made from ammonia and carbon dioxide. Ammonium bicarbonate is made when carbon dioxide is bubbled through an ammonia solution. Crystals of ammonium bicarbonate precipitate from this saturated solution. It is a component of what was formerly known as sal volatile and salt of hartshorn. The ammonium carbonates are considered Generally Regarded as Safe (GRAS) by the FDA.

International Acceptance:
Ammonium bicarbonate is approved for use in the following organic standards:

Canadian General Standards Board Permitted Substances List: Allowed as a leavening agent

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999): Not specifically mentioned but “ammonium carbonates” are allowed for food of plant origin

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: May be grouped under “ammonium carbonates” and if so is allowed for food of plant origin

Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for processed foods of plant origin

International Federation of Organic Agriculture Movements (IFOAM): May be grouped with "ammonium carbonates" and if so is allowed only for cereal products, confectionary, cakes and biscuits

Environmental Issues:
The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Ammonium bicarbonate can be an irritant to the skin, eyes, and respiratory system. There may be short term health effects after exposure and long term exposure may cause lung damage.

Discussion:
The original TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. These two substances have been reviewed together during their subsequent two sunset reviews. The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that this material is still critical for organic food processing, especially for baking crackers and similar baked goods.

Additional information or questions requested by Subcommittee:

1. Is there any new information related to environmental concerns, human health, or use that would cause this substance to be considered for delisting?

2. Are there any other organic uses that, in the future, should be considered for listing beyond the annotation for leavening?

Ammonium carbonate

Reference: 205.605(b) –for use only as a leavening agent
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Ammonium carbonates are used as leavening agents. Ammonium carbonate is used as a raising (leavening) agent for flat baked goods, such as cookies and crackers. It is often referred to as "*Bakers Ammonia"* in cooking recipes and by chefs. Ammonium carbonate is also used to make breadsticks, cookies, and crackers because it helps to make them both lighter and crispier. It is also used in many traditional Greek cooking recipes. Ammonium carbonates are heat activated, so baked goods will not rise until whatever is being baked actually goes into the oven, thus helping with food preparation and time requirements. This is the only leavening agent (ammonium carbonates) that is completely

eliminated through the baking process. There are no organic alternatives to replace ammonium carbonates.

Manufacture:
Ammonium carbonates are made from ammonia and carbon dioxide. Ammonium carbonate is made when carbon dioxide is passed through an ammonia solution and by then allowing the vapors to distill, thus the resulting solid is ammonium carbonate. It is a component of what was formerly known as sal volatile and salt of hartshorn. Ammonium carbonates are considered Generally Regarded as Safe (GRAS) by the FDA.

International Acceptance:
Ammonium carbonate is approved for use in the following organic standards:

Canadian General Standards Board Permitted Substances List: allowed as a leavening agent

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

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: allowed for food of plant origin

Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for processed foods of plant origin

International Federation of Organic Agriculture Movements (IFOAM): allowed only for cereal products, confectionary, cakes and biscuits

Environmental Issues:
The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Ammonium carbonate can be an irritant to the skin, eyes and respiratory system. There may be short term health effects after exposure and long term exposure may cause lung damage.

Discussion:
The original TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. These two substances have been reviewed together during their subsequent two sunset reviews. The original TAP, previous subcommittee review, public comments, and historical information indicated few environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that this material is still critical for organic food processing, especially for baking crackers and similar baked goods.

Additional information or questions requested by Subcommittee:

1. Is there any new information related to environmental concerns, human health or use that would cause this substance to be considered for delisting?

2. Are there any other organic uses that, in the future, should be considered for listing beyond the annotation for leavening?

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminum free). All three of the calcium phosphates are used as leavening agents: dough conditioner, yeast food, or as an expanding agent. Monobasic and dibasic calcium phosphate are often used for reduced sodium baking. Monobasic is also a buffer, firming agent, sequestering agent, and is popular in pancake mixes. It is the commonly used acid along with sodium bicarbonate used to make baking powder. It is also used in baked goods, such as cookies, cakes, and potato chips, and as a firming agent for canned fruits and vegetables. Dibasic is used in enriched flour, noodle products, and in both dry and cooked forms of breakfast cereals. It is often used as a dough conditioner. It also can be used as a thickening agent for various cheese products. Tribasic is an anti-caking agent, buffering agent. It also provides a very critical function as a free flow aid in finely powdered salt used in baking. Additionally, it is used as a food source for yeast in bread making, as an anti-caking agent in dry powders, such as in spices, and as a thickener, stabilizer and sequestering agent for some dairy products. Calcium is derived from either mined limestone or from oyster shells.

Manufacture:
Calcium and phosphorus are sourced from limestone and phosphate rock, respectively. The food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides (TR 2016 43-44).

International:
Calcium phosphates are allowed for use in Canada, IFOAM and JAS.

Discussion:
All phosphates were reviewed in 2016. public commenters noted 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, although phosphates would appear on the ingredient list. In particular there were concerns 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 contributed 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 or questions requested by Subcommittee:
Is calcium phosphate still in use and in what applications?

Ozone

Reference: 205.605(b)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Ozone is a powerful oxidant with many industrial and consumer applications related to oxidation. Ozone, which has approximately 150% of the oxidizing potential of chlorine, is used as an equipment and food disinfectant and in post-harvest treatment for produce to retard spoilage in cold storage or in wash water. It is effective and environmentally benign substance used to reduce and control microorganisms for food safety purposes.

Manufacture:
Ozone, or trioxygen, is an inorganic molecule with the chemical formula O3. It is a pale blue gas with a distinctively pungent smell. It is an allotrope of oxygen that is much less stable than the diatomic allotrope O2, breaking down in the lower atmosphere to O2 (dioxygen). Ozone's odor is reminiscent of chlorine, and detectable by many people at concentrations of as little as 0.1 ppm in air.
Ozone is an unstable gas in the air and even more so in water. Because of this, it must be produced onsite. To do so, typically an oxygen supply is fed to a carona discharge system which uses ambient air to produce ozonated water that is used as a liquid disinfectant.

International:
Canadian General Standards Board Permitted Substances List
Included as an ingredient classified as a food additive, and as a processing aid, as a food-grade cleaner, disinfectant and sanitizer.

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

While section 5 outlines criteria for the inclusion of substances, the guidelines do not include a permitted substance list.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The regulation does not specifically address the use of ozone.

Japan Agricultural Standard (JAS) for Organic Production
The standard limits ozone uses to processed foods of plant origin, animal intestine disinfection, or as egg cleansing.

International Federation of Organic Agriculture Movements (IFOAM) Norms for Organic Production and Processing
The norms allow ozone as an equipment cleanser and disinfectant.

Ancillary Substances:
N/A

Environmental Issues and Human Health Impacts:
According to the EPA, ozone exposure in the air we breathe can be harmful to human health and the environment. However, the application of ozone directly into water as a disinfectant minimizes this exposure. Once introduced into water, ozone decomposes into elemental oxygen in a brief amount of time. Exposure to atmospheric ozone generated from on-site production can be minimized through equipment maintenance.

Discussion:
The most recent Technical Advisory Panel report (TAP) dates to 1995 and does not include the degree of detail of more recent Technical Reports (TR). The Subcommittee suggests that NOP contract an updated ozone TR in advance of the next sunset review.

Additional information or questions requested by Subcommittee:
Are there any commercially available alternatives to ozone that warrant its removal from the National List?

Sodium hydroxide

Reference: 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Sodium hydroxide is a highly caustic substance, used as a processing aid in cocoa manufacture, as a

caustic bath for pretzels that makes the pretzel surface smooth and helps it to develop brown color during baking and for removing bitterness from olives. It is also used as an alkali to peel fruits and vegetables, but this use is specifically prohibited in organic foods by an annotation. Sodium hydroxide is used to manufacture soaps, oral care products and detergents, and can be used as an ingredient in food preservatives to prevent the growth of mold and bacteria. Soda ash ($NaCO_3$), Magnesium Oxide (MgO) or Sodium Hydroxide can be used in the production of sugar to increase the pH and alkalinity of the sugar cane juice. It is highly soluble in water.

Manufacture:
Sodium hydroxide is derived from saltwater brine, and manufactured by the electrolysis of this salt brine solution. During the electrolysis process, the water (H_20) is reduced to a hydrogen gas (H) and a hydroxide ion (OH). The hydroxide ion bonds with the sodium to form sodium hydroxide (NaOH). Chlorine is also produced during this process.

International Acceptance:
Sodium Hydroxide is listed on the Canadian General Standards Board Permitted Substances List as an approved food additive. It is approved for use in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) for bakery wares within the food category. It is approved on the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 for the production of sugar, for the production of rape seed and for the surface treatment on pretzels and pretzel breads. It is not listed in the Japan Agricultural Standard (JAS) for Organic Production. It is listed as approved by International Federation of Organic Agriculture Movements (IFOAM) for sugar processing and the surface treatment of traditional bakery products. IFOAM also has sodium hydroxide on its list of allowed cleansers and disinfectants, with the annotation that an intervening event or action must occur after this type of use, to eliminate risks of contamination.

Ancillary Substances:
It does not appear there are any ancillary substances associated with this material.

Environmental Issues:
Must be handled by personnel according to manufacturer guidelines because of caustic nature. Concentration of sodium hydroxide is routinely monitored in pretzel production to verify complete conversion to sodium bicarbonate during baking. The EPA allows sodium hydroxide for use in treating sewage systems to control tree roots, and as a fungicide and algicide on water well casings. Effluent containing sodium hydroxide is not to be discharged into lakes, streams and other public waters without a NPDES (National Pollutant Discharge Elimination System) permit. Well water casing treatment would result in minimal exposure of birds, mammals and other organisms. The EPA states that current product labeling helps to protect wildlife from undue exposure to sodium hydroxide.

Discussion:
The TR states there are no alternatives which provide the desired browning properties of pretzels. Baking soda can be used, but is not sufficiently alkaline enough to result in distinctive crust and flavor. Certain varieties of olives rely on sodium hydroxide to remove bitterness, as salt or water curing does not result in an acceptable product. Potassium carbonate, potassium bicarbonate, sodium carbonate, sodium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium hydroxide, magnesium carbonate and magnesium oxide, as well as sodium hydroxide can be used to alkalize cocoa, with each type of alkalizing agent resulting in different flavors and functional attributes. The label claim “processed with alkali” is used when these alkalis are used in cocoa production. It appears sodium hydroxide is the only alkali in use when an alkali is needed in sugar processing.

Additional information or questions requested by Subcommittee:

1. Is this product still needed in the processing of organic products?
2. Are there any nonsynthetic alternatives to this material with the same functionality?

Waxes (Carnauba)

Reference: 205.606 Waxes – nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR - Carnauba Wax
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Used as a component in fresh fruit coatings, as a candy coating, and as component of an edible coating for nuts. Other uses include as a base for chewing gum and in soft drinks. It can also be used as a processing aid as a releasing agent and in defoamers. It's Generally Regarded as Safe (GRAS) listing doesn't provide any limitations on its use as an ingredient in food.
When formulated as part of a fruit coating, carnauba wax functions to reduce gas exchange between the surface of the fruit and the atmosphere, thereby reducing the respiration rate and weight loss of the fruit. It also has antifungal properties beyond the creation of a gas barrier.

Manufacture:
The production of carnauba wax begins with leaves cut from the carnauba palm tree during Brazil's dry season. They are dried in the sun and then beat or scraped until the wax falls off as a fine powder. The wax is collected and then either melted via steam or a solvent. The wax is then cooled and filtered via a filter press or through filter cloth, and then cooled and dried. The wax may also be clarified by centrifugation or with hydrogen peroxide.

International:
Allowed by Canadian Standards, CODEX, European Economic Community (EEC), Japan Agricultural Standards (JAS), and International Federation of Organic Agriculture Movements (IFOAM).

Ancillary substances:
According to the 2014 TR, raw carnauba is sold to formulators without any additional ingredients such as stabilizers or preservatives. While formulations containing carnauba as the only wax are available, it is more common to combine it with other waxes and coasting materials, such as beeswax, candelilla wax, wood rosin, or shellac.

Discussion:
Carnauba wax was originally listed at §205.605(a) of the National List. In October 2015 the NOSB passed a recommendation to reclassify the substance as agricultural and move to §205.606.

The 2014 TR did not find the manufacture or use of carnauba wax to be harmful to the environment or human health.

Unlike other fruit coating materials like orange shellac and wood rosin, carnauba wax is available organically. There are 19 listings in the USDA's Organic Integrity Database.

Additional information requested by subcommittee:

1. Since this material is available organically, does it need to remain on the National List?
2. Are there barriers to obtaining organic carnauba wax in the needed form or quantity?

Colors - Beet juice extract color, Black Currant juice color, Black/Purple Carrot Juice color, Blueberry Juice color, Carrot Juice color, Cherry Juice color, Chokeberry/Aronia Juice color, Elderberry Juice color, Grape Juice color, Grape Skin Extract color, Paprika color, Pumpkin Juice color, Purple Potato juice color, Red Cabbage Extract color, Red radish Extract color, Saffron Extract color, Turmeric Extract color

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

(1) Beet juice extract color (pigment CAS #7659-95-2)
(2) Beta carotene extract color
(3) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(4) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(5) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(6) Carrot juice color (pigment CAS #1393-63-1)
(7) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(9) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(10) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(11) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(12) Paprika color (CAS #68917-78-2)—dried, and oil extracted
(13) Pumpkin juice color (pigment CAS #127-40-2)
(14) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134- 04-3)
(15) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7,

and 134-04-3)
(16) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3
(17) Saffron extract color (pigment CAS #1393-63-1).
(18) Turmeric extract color (CAS #458-37-7)

Technical Report: 2015 TR - Colors (all)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Added to NL effective 06/21/07 (72 FR 35137); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date (All except beta carotene): 3/15/2022
Sunset Date: Beta carotene extract color: 5/29/2023

Background from Subcommittee:

Use:
Colors are added to food products to enhance the attractiveness of the food, to assure uniformity of color, to add back color lost during processing, to intensify existing colors. (TR 12-25)

Manufacture:
Colors can be produced via a number of production methodologies that vary by individual crop and pigment. While most sources have common agricultural crop names, those used for color extraction are often specific varieties that are grown in specific geographical regions using specific production techniques to produce the specific pigments for coloring purposes. Since these items are listed on the agricultural lists – processing is restricted to physical or biological means. The most common types of extraction will be water extraction, milling, pressing, drying, distillation, enzyme treatment, ethanol extraction, or oil extraction. The annotation prohibits the use of synthetic solvents, carrier systems and artificial preservatives.

International:
Colors are allowed on the Canadian, Codex and EU lists but are not listed on the Japanese (JAS) or IFOAM lists.

Discussion:
It should be noted that §205.600(b)(4), which states "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law," is only applicable to synthetic substances used as a processing aid or adjuvant per §205.600(b). Citing this section is not a reason to delist colors as they are only listed as agricultural, nor are they considered a processing aid or adjuvant.

During the Fall 2015 NOSB sunset review the NOSB ultimately supported relisting all colors. However, the initial Subcommittee review, as well as a statement from the lead reviewer recommended removing all colors but beet, black currant, black/purple carrot, cherry, pumpkin, red cabbage and turmeric juices. The lack of complete information about availability and whether some were available in powder form was a factor in the Board's decision to relist. The Board noted the emerging presence of certified organic colors and recommended future NOSBs do not renew colors in whole on §205.606. Because of differences in supply of the various colors it is important to review each color individually rather than lumping them as a group. It is also worth noting that since these colors are on §205.606 they are currently subject to commercial availability of organic forms.

Additional information or questions requested by Subcommittee:

1. Why types of organic products are currently using each color listed, and are powdered or liquid forms used?
2. Going color by color, have you been able to source organic forms of each color - if not, what has been the barrier?
3. Manufactures of colors: What colors can be readily produced organically today? For those that cannot, what are the barriers?
4. On a color by color basis, are both powdered and liquid forms of each color available organically if both forms are needed by processors?
5. Which colors are not available in sufficient organic quality or quantity and should be relisted?

Glycerin

Reference: 205.606 - produced by hydrolysis of fats and oils.

Technical Report: 1995 TAP; 2013 TR

Petition(s): 1995 N/A**,** Glycerin (2012 Petition to remove)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Glycerin is used in food as a binder, humectant, solvent, and carrier. It is widely used in natural flavors. It is used in alcohol free applications as an alternative to ethanol (as a carrier or solvent). It is also used in cosmetic and personal care products as a emollient, carrier, lubricant and filler. It has a neutral to sweet taste. (TR 24-25)

Manufacture:
Glycerin can be manufactured from a variety of sources using a variety of means. Glycerin exists in nature as part of triglycerides as a backbone glycerin molecule with three fatty acid chains. The product must undergo processing to break the fatty acids from the glycerin. The processing of glycerin will determine if it is agricultural or non-agricultural and the organic certification status of the raw materials, processing plant, and compliance with the national list would determine if the product could be organic or not. It should be noted that it is possible to produce an organic non-agricultural form of glycerin. Common practices are high pressure hydrolysis (considered agricultural), saponification (considered synthetic but possible to be certified organic if origin materials are organic and the caustic material is on the national list), methyl esterification (product of biodiesel, considered synthetic), and fermentation of carbohydrates, (considered agricultural, but uncommon). Common feedstocks to produce glycerin are palm oil, Soy oil, tallow, canola oil and rapeseed oil. Fermented glycerin is produced from carbohydrates with the common source being corn. When produced from a fat, the glycerin yield is generally 1:10 glycerin to fatty acid.

International:
Glycerin is allowed in the EU (from vegetable sources), Canada (From hydrolysis of fats and oils) and CODEX. It is not on the Japanese (JAS) or IFOAM lists.

Discussion:
In 2012 the NOSB received a petition to remove Glycerin from §205.605(b) and reclassify it as agricultural, and move its listing to §205.606. The petitioner stated as follows: "….An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used "only when the product is not commercially available in organic form." Certified organic glycerin is currently available, but there is no "commercial availability" requirement to incentivize processors to use it or certifiers to require it. Consequently, glycerin should be removed from the National List in order to encourage organic agricultural production." ….

This matter was discussed at length by the NOSB and received considerable public comment over a period of two years, including presentation at the NOSB meetings in Spring and Fall 2014 and Spring of 2015.

The NOSB proposal dated October 21, 2014, included the following:

"….Because of the confusion around classification of glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced glycerin, the Handling Subcommittee, after significant discussion, is proposing the listing of glycerin at §205.606 and removal of glycerin from §205.605(b). …"

In April 2015 the NOSB voted to remove Glycerin –produced by hydrolysis of fats and oils- from 205.605(b)

In December 2018 the NOP finalized rule making on the NOSB recommendation, moving Glycerin form 205.605(b) to 205.606 and changing the annotation to read "produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a)"

Additional information or questions requested by Subcommittee:

1. What are the barriers to sourcing organic glycerin?

2. Glycerin is often labeled as 99% pure. What is the 1%? Are ancillary substances present in glycerin? If so, what are they?

Inulin-oligofructose enriched

Reference: 205.606 Inulin-oligofructose enriched (CAS # 9005-80-5)
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 recommendation; 2010 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)

Sunset Date: 6/27/2022

Background from Subcommittee:

Use:
Inulin-oligofructose enriched (IOE) is on the National List as a nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." IOE is a non-digestible carbohydrate that is used to increase calcium bioavailability and absorption, as a soluble dietary fiber, as a noncaloric sweetener, and for functional effects on the texture/consistency of food. It is used in many foods including yogurt, baked goods, candies, jams, and other dairy products.

Manufacture:
IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin, however, the most common commercial method to produce oligofructose for use in IOE production is from inulin. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), agave, and other plants. Chicory inulin is the most commercially available inulin, however in organic production, inulin is generally derived from Agave (Mexico) and Jerusalem artichokes (China). Chicory inulin is produced by shredding chicory roots, which are treated with hot water, juiced, and filtered to remove the raw inulin. The raw inulin is purified by treatment with calcium hydroxide, carbonated, and filtered and spray-dried. The resulting inulin polymers range in chain length from 2–60 units. The shortest polymers range from 2–10 fructose units and are called oligofructose. The longer polymers range from 10–60 units. If insufficient amounts of oligofructose are present, polymers range from 10–60 units are treated with inulinase enzyme from *Aspergillus niger* to create more oligofructose and is mixed back in with the original inulin.

Ancillary substances:
The 2015 TR indicated no ancillary substances but noted that IOE could contain up to 20% glucose, fructose, and sucrose left over from the chicory source material or enzymatic conversion. Further the TR noted processing aids are removed in favor of a pure IOE product. The amounts of these remaining substances may vary, but the general approach in producing IOE is to purify the IOE solution and thereby limit the amount of processing aids that remain. The TR for fructooligosaccharides (FOS) noted the following residuals: glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol. There are no ancillary substances to list for IOE.

International:
IOE is not specifically listed in the CODEX, EU, or Japanese organic standards, however, non-organic agricultural products are not listed in these standards. IOE is not specifically listed on the Canadian standards.

Discussion:
In the Fall of 2015 the NOSB voted to sunset IOE based on the availability of alternatives like inulin derived from organic agave and the continued listing of conventional FOS. However, in the public comment period for the proposed rule a processor and trade association asserted that IOE from chicory was still needed. The USDA decided to renew the listing for IOE even though these same comments were received in the Fall 2015 meeting during oral comment.

Additional information or questions requested by Subcommittee:

1. Is inulin-oligofructose, enriched still in use in certified organic products, and if so what types of products?
2. Are alternative organic forms available?
3. Is organic inulin + conventional FOS (already listed at §205.606) an acceptable alternative in product formulations? If not, why?

Kelp

Reference: 205.606(m) Kelp—for use only as a thickener and dietary supplement.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Kelp is a term used for seaweeds belonging to the brown algae (Phaeophyceae) class in the order Laminariales. There are about 30 genera and many species. Kelp is dark green or brown in color and has a salty, characteristic taste. Through the 19th century, the word "kelp" was closely associated with seaweeds that could be burned to obtain soda ash (primarily sodium carbonate). The seaweeds used included species from both the orders Laminariales and Fucales. The word "kelp" was also used directly to refer to these processed ashes. Used for centuries in traditional Japanese food, kelp provides a unique flavor profile and can be used as a thickening agent or as a base for broth. Kelp can also be used as a source of iodine within maximum daily iodine intake limits.

Manufacture:
Kelp is harvested, dried and then ground or chopped for use in food. Giant kelp can be harvested fairly easily because of its surface canopy and growth habit of staying in deeper water.

International:
Allowed in *Canadian General Standards Board Organic Production Systems* under aquatic plants and aquatic plant products, Table 4.2.
European Union Annex IX 1.1.3 Algae, including seaweed, permitted in non-organic foodstuffs preparation.
Japanese Agricultural Standard (JAS) for Organic Plants-Dried Algae, including the powdered form.

Ancillary Substances:
N/A

Environmental Issues and Human Health Impacts:
Kelp is a renewable resource. It is also a keystone species, and there are concerns over responsible harvesting of kelp beds. Climate change is also impacting the distribution of kelp populations. For example, Northern California populations of kelp have been reduced by 90% due to sea urchin populations that exploded after disease killed local sea stars, which are natural predators of the urchins. The bacteria affecting sea stars may be increasing due to warmer water temperatures resulting from global warming. The impact of the loss of kelp on the California coastal marine ecosystem is potentially catastrophic, and the Handling Subcommittee would like more information on the impact of harvesting on kelp populations. There are also concerns over contamination of kelp from ocean radiation.
Discussion

While the term “kelp” generally refers to seaweeds belonging to the brown algae in the order Laminariales, by tradition some forms of kelp have more specific names, for instance, wakame or kombu. Most kombu is from the species *Saccharina japonica* (*Laminaria japonica*). However, some edible kelps in the family Laminariaceae are not always called kombu, such as arame, kurome (*Ecklonia kurome*) or *Macrocystis pyrifera*. The name "wakame" was derived from the Japanese name wakame. Starting in the 1960s, the word "wakame" started to be used widely in the United States, and the product (imported in dried form from Japan) became widely available at natural food stores and Asian-American grocery stores. There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds.

Additional information or questions requested by Subcommittee:

1. Are there organic supplies of kelp available? If so, is there enough organic supply available to meet commercial demand?
2. How is the use of organic kelp in livestock production different from uses for human consumption?
3. Are there sufficient organic supplies of kelp available for human consumption?
4. Is the availability of organic kelp enough to supply both livestock and human consumption demand in handling?
5. What are the handling needs of kelp as a thickener and dietary supplement?

Orange shellac

Reference: 205.606(r) Orange shellac-unbleached (CAS # 9000-59-3).
Technical Report: 2002 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Orange shellac is used to coat fruits and vegetables to reduce water loss and retain firmness. It is an ingredient in lozenges, capsules and tablets, and is a part of confectionary glazes on candy, chocolate and coffee beans. A dye from shellac is used as a food color. It is a natural bio-adhesive polymer that is soluble in alkaline solutions such as ammonia and in solvents such as ethanol. Shellac is water insoluble. There are also numerous non-food uses: on wood, in cosmetics, in clothing, on seeds, and in adhesives, varnish, and polishes.

Manufacture:
Orange shellac or “shellac” as it is commonly known is the purified product of the natural resin lac, which is the hardened secretion of the small, parasitic insect Kerria lacca, popularly known as the lac insect. These insects suck the sap of certain host trees, and when digested by the insects the sap undergoes a chemical transformation and is eventually secreted through the pores of the insect. When this secretion comes into contact with the air, if forms a hard shell-like coating over the larger swarm of insects. The main areas of the world where is it produced are India, Thailand, and Myanmar.

International Acceptance:
Orange shellac is not listed on the Canadian General Standards Board Permitted Substances List, on the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999), on the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, on the Japan Agricultural Standard (JAS) for Organic Production, nor by International Federation of Organic Agriculture Movements (IFOAM). Therefore, these international organic standard bodies do not allow this substance in or on organic foods.

Ancillary Substances:
From the 2014 Technical Report (TR), there are a number of substances that are used to process the orange shellac for use in fruit coatings. Some are allowed in organic production and some are not, they include: isopropyl alcohol, morpholine, oleic acid, candelilla wax, fatty acid soaps and fast drying solvents, wood rosins, paraffin wax, petroleum wax, carnauba wax, sugar cane wax, polyethylene emulsions, castor oil, triethanolamine, ammonia, sodium o-phenyl phenate, stearic acid, alkyl naphthalene sulfonates, sodium hydroxide, bentonite, borax, potassium hydroxide, glycerol, palmitic acid, luric acid, and stearic acid. Fungicides, growth regulators, and preservatives could be added as well as plasticizers such as castor oil, vegetable oils (corn, soy, etc.), acetylated monoglycerides, fatty acids, etc. that are not soluble in water can be used in formulating shellac products. Plasticizers are additives that increase the plasticity or fluidity of material. Coloring agents such as dyes, titanium dioxide, iron oxide, natural colors and other materials such as talc, calcium carbonate and alumina may be used. Only items allowed on the National List can be included in orange shellac used in or on organic products.

Environmental Issues:
The TR states there are no major adverse environmental effects on the production and processing of orange shellac. However, wash-water originating from processing units contain water soluble dye, fragments from insect bodies, proteinaceous matter, vegetable glue, and some sugars. These effluents collect in a pit outside factories and putrefy, generating an offensive smell. This may be a potential environmental hazard for which further studies are required. During washing of sticklac to seedlac, the effluents of lac factories are allowed to flow and collect in reservoirs. This accumulated water is treated with acid, precipitating all solid matter called lac-mud. Lac-mud is also a source of lac dye and lac wax (Baboo and Goswammi 437 2010).

Discussion:
At the previous sunset review, public commenters expressed the desire to add an annotation that would require labeling of fruits and vegetables that may have had orange shellac applied. This would be a future work agenda item, since annotations are not changed at sunset. The TR states: “There have been no reports showing adverse effects on human health due to orange shellac. Some individuals may show allergic symptoms and some vegetarians may consider it an animal product not suitable for their consumption. Corn zein and starch are alternative materials for shellac that give high gloss. Zein is a protein of the prolamine group occurring in maize and used in fruit coating. Carnauba wax has been used commercially to coat apples but has less gloss than shellac. There are primarily four different non-synthetic substances that may be used in place of orange shellac as a component of citrus fruit waxes: wood rosin, carnauba wax, beeswax, and candelilla wax. Each has their own positives and negatives for various factors, including shine, permeability, cost, etc.

Additional information or questions requested by Subcommittee:

1. Please provide any information on ancillary substances that may be part of organic shellac formulations used in organic products.
2. Is this product still needed in the processing of organic products?
3. What are the barriers to producing this agricultural product as organic?

Starches: cornstarch

Reference: 205.606(v) Starches.
(1) Cornstarch (native).
(2) Sweet potato starch - for bean thread production only.
Technical Report: 1995 TAP - Cornstarch
Petition(s): N/A – Cornstarch; 2007 Petition - Sweet Potato Starch
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset recommendation on cornstarch; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420);
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
From the 2017 review: "Starches are used in many foods as thickeners, formulation aids, to make corn syrup, and as bulking agents and moisture adsorption agents. Cornstarch is made from special strains of corn that are high in amylose and amylopectin."

Manufacture:
As described in Wikipedia, cornstarch is obtained from the endosperm of the kernel. The corn is steeped for 30 to 48 hours, which ferments it slightly. The germ is separated from the endosperm and those two components are ground separately (still soaked). The starch is then removed by washing. The starch is separated from the corn steep liquor, the cereal germ, the fibers and the corn gluten mostly in hydrocyclones and centrifuges, and then dried. This process is called wet milling. Finally, the starch may be modified for specific uses.

Ancillary substances:
None noted.

International acceptance:
Canada: Yes, with restrictions on materials used for manufacture.
Codex: Not listed.
EU: From corn, not chemically modified.
Japan: Not listed.
IFOAM: Not listed

Environmental/Health Issues:
Cornstarch poses no acute health hazards from ingestion or dermal absorption. Dusts produced during production may pose inhalation risks, and potentially a fire hazard if levels in air reach critical combustion concentrations. Cornstarch that is not organic may be produced from conventional corn that was grown with synthetic fertilizers and pesticides that pose risks to human health and the environment.

Discussion:

There are organic starches on the market, but they are not necessarily suitable for all uses. "Cornstarches are described by the relative content of two glucose polymers: amylopectin and amylose. Special strains of corn are grown to achieve the right ratio of the polymers and these special varieties are all identity preserved to maintain their amylose ratio and so are never genetically engineered". During the 2017 review, public commenters indicated that some types of organic cornstarch are not available. A recent search of the Organic Integrity Database identified 13 suppliers of "cornstarch", including 12 in the United States. Cornstarch is listed under §205.606, so non-organic material can be used only when organic cornstarch is not available. The Handling Subcommittee requests public comment on the need to list cornstarch under §205.606.

Additional information or questions requested by Subcommittee:

The Handling Subcommittee requests public comment addressing the following questions:

1. Are there adequate organic sources of all types of cornstarch for food processing and production so this material can be removed from §205.606?
2. If not, please identify which types of cornstarch are not available organically and describe their use and the impact of removal from §205.606?
3. If any types of essential cornstarch are not available organically, please describe barriers to producing this material and any steps to promote organically sourced product.
4. Is there a risk of cornstarch derived from GMO corn contaminating materials used for producing organic products?

Starches: sweet potato

Reference: 205.606(v) Starches.

(1) Cornstarch (native).

(2) Sweet potato starch - for bean thread production only.

Technical Report: 1995 TAP - Cornstarch

Petition(s): N/A – Cornstarch; 2007 Petition - Sweet Potato Starch

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset review Sweet potato starch; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Use:

Sweet potato starch is specifically used as a formulation aid for bean thread production.

Manufacture:

The sweet potatoes are crushed, and the starch is washed out and dried to a powder.

Ancillary substances:

None noted.

International acceptance:

Canada: Not listed.

Codex: Not listed.

EU: Not listed.

Japan: Not listed.

IFOAM: Not listed

Environmental/Health Issues:
Sweet potato starch poses no acute health hazards from ingestion or dermal absorption. Dusts produced during production may pose inhalation risks. Sweet potato starch that is not organic may be produced from conventional sweet potatoes that were grown with synthetic fertilizers and pesticides that pose risks to human health and the environment.

Discussion:
A recent search of the Organic Integrity Database identified two suppliers of "sweet potato starch", including one in the United States and one in China. Sweet potato starch is listed under §205.606, so non-organic forms can be used only when organic cornstarch is not available. The Handling Subcommittee requests public comment on the need to list cornstarch under §205.606 and whether current supplies are adequate to meet demand for organic bean thread products.

Additional information or questions requested by Subcommittee:

1. Please provide more detail on the manufacturing steps to produce sweet potato starch.
2. What organic products is this material being used in?
3. Are there adequate sources of organic sweet potato starch to meet existing market demands?
4. What are the barriers to obtaining organic sweet potato starch and how can these barriers be overcome?

Turkish bay leaves

Reference: 205.606(x) Turkish bay leaves.
Technical Report: N/A
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)
Sunset Date: 6/27/2022

Background from Subcommittee:

Use:
Turkish bay leaves are an herb that has been used traditionally to flavor food.

Manufacture:
Turkish bay leaves (*Laurus nobilis*) are widely cultivated in the Mediterranean and Asia. Leaves are harvested, sorted and then sold fresh or dried.

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 Turkish bay leaves.

Ancillary Substances:
None noted

Discussion:
During the review of 2017 sunset materials conducted in 2015, the NOSB requested information from the public to assess commercial demand, commercial availability, alternatives, necessity and use in organic production. At that time, the original petitioner noted a source of Turkish bay leaves but believed the supply was too fragile to have the listing removed. Searches of publicly available organic sourcing pages by the NOSB in June of 2015 resulted in 85 NOP organic certificate holders of bay leaves with 12 specifying *Laurus nobilis*. Additionally three spice companies were contacted, and all had sources of Turkish bay leaves from Turkey, India or both.

One commenter noted concern regarding impacts of pesticide use and residue when a conventional agricultural ingredient is used. Products certified to the "made with organic…" may use non-organic agricultural ingredients that are not listed on §205.606 and have not undergone a review for compliance with OFPA criteria. However, these ingredients are still required to comply with §205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or with excluded methods. Additionally, the commenter provided no data specifically on pesticide usage and residues on Turkish bay leaves and just cited EPA tolerance levels for pesticides on herbs subgroup 19A.

Based on the availability of organic sources, the NOSB recommended at its October 2015 meeting to remove Turkish bay leaves from 205.606. In an August 7, 2017 final rule, USDA noted it received public comments opposing the remove of Turkish bay leaves from the National List. These extensive comments stated that Turkish bay leaves are not available in the quantity or quality needed to meet organic handling needs. Comments explained that while organic whole bay leaf may be commercially available, ground organic bay leaves provide a different flavor profile, are not presently commercially available, and removal of Turkish bay leaves from the National List would negatively impact finished products containing ground bay leaves. Comments requested that USDA maintain the allowance for nonorganic Turkish bay leaves while suppliers pursue sources of ground organic Turkish bay leaves in sufficient quality and quantity to meet industry needs.

In response to these comments, USDA determined that nonorganic forms of Turkish bay leaves are essential to organic production and handling and should remain on the National List. At the time of this decision, USDA noted that organic handlers are permitted to use the nonorganic substance only if the organic substance is not commercially available. Handlers need to demonstrate, and certifiers need to verify, that the organic substance is not available in the form, quality or quantity needed.

In a December 2019 review of the Organic Integrity Database, the Handling Subcommittee found 62 records of certified handlers and crop producers listing "bay leaf," 86 records listing "bay leaves," and four records listing "Turkish bay leaves."

Additional information or questions requested by Subcommittee:

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for Turkish bay leaves in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.

2. Has the industry made progress in its efforts to locate organic sources of whole and ground Turkish bay leaves? What specific efforts have been made and what degree of success has the industry had?

3. Are there other ingredients with suitable flavor profiles that could be used in place of Turkish bay leaves, given adequate transition time for ingredient inventory and label depletion?

4. In what organic products is non-organic Turkish bay leaves currently used, and what are the specific reasons for its necessity in these products?

Whey protein concentrate

Reference: 205.606(z) Whey protein concentrate.
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 05/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)
Sunset Date: 6/27/2022

Background from Subcommittee:

Use:
Whey protein concentrate is used in dairy products, protein bars, and infant formulas. Whey protein concentrate is used as a source of protein, as a fat replacer, and as a texturizer.

Manufacture:
Whey protein concentrate is a soluble fraction of bovine milk composed of protein, minerals and lactose and is a byproduct of cheese manufacturing. The primary method of production mixes milk with rennet to coagulate the casein to make cheese curds, the resulting liquid is whey. Another method of production is via microbiological fermentation or direct addition of lactic acid that acts to reduce the pH and coagulate the casein. The whey undergoes an ultra-filtration process to remove a large portion of the lactose and minerals. Low temperature processing ensures retention of both nutritional and functional properties. Whey protein concentrate is evaporated then spray-dried and sold as a dry ingredient. The whey protein concentrate may also be bleached with hydrogen peroxide or benzoyl peroxide. Whey protein concentrate can be concentrated to different protein levels (i.e., 35%) but max out around 80%. Concentrations higher than 90% are considered whey protein isolate.

International:
Whey protein concentrate is not specifically listed in the CODEX, Canadian, or Japanese organic standards. “Whey powder ‘herasuola’” is listed on the EU Organic Standards.

Ancillary Substances:
Soy lecithin may be added as an "instantizing" ancillary substance.

Environmental Issues and Human Health Impacts:
In most jurisdictions, environmental regulations now prevent disposal of untreated whey on agricultural land or discharging in municipal sewage system or surface water. Whey composition (high solids, lactose and salt content) makes disposal practices a problem. Rodenberg, 1998 reported that the five day biochemical oxygen demand (BOD5) is a measure of the organic pollutant concentration in the wastewater, and is proportional to the amount of milk or whey lost to the sewer. Normal dairy production plant wastewater is in the range of 2000 to 3000 mg/l which is 10 times the strength of domestic sewage. The BOD5 can go much higher if a milk spill occurs and the pH can fluctuate widely if spent cleaning in place chemicals are discharged as well. Dairies manage their wastewater discharge to avoid upsetting their biological treatment process or a publicly owned treatment system. With recent advances in technology, as well as increasing awareness of the environmental and financial costs of whey disposal, the dairy industry has found it profitable to process whey into high value added protein products for use as ingredients in food systems. Whey proteins are generally recognized as safe (GRAS) and are considered a label-friendly ingredient. A large portion of the energy used at a typical cheese making operation is devoted to processing whey powder or concentrate. Falling-film type evaporation systems are used to concentrate whey liquid. To fully dry the whey to a powder form, condensed whey from an evaporator is fed to a spray dryer. Both of these processes are highly energy intensive due to the thermal energy required.

Discussion:
During the last review, the NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, (5) use in the industry. In the past, one public comment was received from a certifier on the use of soy lecithin as an ancillary substance. No information was provided on commercial demand, alternatives or its use in the industry. One trade association commented on its essentiality and lack of supply but provided no detailed information on why the supply identified by the NOSB was insufficient. One certifier noted they have clients producing and selling organic whey protein concentrate. Given the availability of organic whey protein concentrate and the absence of information on continued commercial unavailability from industry, the Handling Subcommittee recommended this item be removed from the National List in 2015 (2015/Fall - Rec to Remove). To date, NOP has not removed WPC from the National List. A petition to remove whey protein concentrate from the National List (https://www.ams.usda.gov/sites/default/files/media/Addendum1_PetitionforRemovalofWheyProteinConcentrate_2019.pdf) is currently under review by the Handling Subcommittee, and review of the Organic Integrity Database indicates several suppliers of whey protein concentrate.

Additional information or questions requested by Subcommittee:

1. Are there any forms of whey protein concentrate that are not available organically beyond what has been found in the NOP Organic Integrity Database?

2. If yes, what are the barriers to producing that whey protein concentrate or other whey products in an organic form, since it appears there are many manufacturers of raw liquid whey from both cow and goat suppliers and numerous manufacturers are currently certified and capable of making a variety of organic whey products?