Sunset 2022
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 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 production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

Written public comments will be accepted through October 1, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2020

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
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

Subcommittee Review:
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

There were minimal comments about kaolin during the Spring 2020 Board meeting. Two certifiers commented that six entities list Kaolin in their organic system plan. The subcommittee felt this material was relatively benign with no significant environmental or health concerns.

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

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

Subcommittee Review:
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.

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.

The Subcommittee discussed the importance of sodium bicarbonate, its common usage, and general support for re-listing. Production from Trona deposits vs. the Solvay process was discussed, and the HS

strategized around how best to address developments in the manufacturing process. The question was raised as to whether requesting a work agenda item to annotate Sodium Bicarbonate to limit use to non-synthetic production forms and/or whether the decision tree could use some adjustment to capture updated manufacturing processes.

Written and oral comments support the re-listing of sodium bicarbonate. Stakeholders confirmed wide usage across many categories of products. A commonly used item, stakeholders did not report major environmental concerns; one cited sodium bicarbonate as a great example of a National List eligible substance due to its non-toxic, home kitchen use as a leavening agent.

Certifiers raised a classification question regarding the material produced from Trona deposits versus the use of the Solvay process for formulating Sodium Bicarbonate. Support was expressed for considering re-classifying and/or adding an annotation or some other guidance for clarifying the allowed process for Sodium Bicarbonate production.

Subcommittee Vote:
Motion to remove sodium bicarbonate from 205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Mindee Jeffery
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Waxes (Wood rosin) (sic. resin)

Reference: 205.605(a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR Carnauba Wax; 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

Subcommittee Review:
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)

Most commenters from the Spring 2020 meeting are in support of relisting wood rosin. Commenters also suggested the addition of an annotation to include 'not extracted using volatile synthetic solvents; contains only ancillary substances approved for organic production'. The Subcommittee supports the option of having multiple waxes which allows for more market share as some countries do not allow the use of certain formulations of waxes. The Subcommittee also recommends a technical correction to the listing - wood **rosin** is the accurate listing and **resin** should be removed.

Subcommittee Vote:
Motion to remove waxes (wood rosin) (sic. resin) from §205.605 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Kim Huseman
Seconded by: Scott Rice
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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

Subcommittee Review:
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.

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.

Stakeholders reflected mixed reviews on Ammonium Bicarbonate. Some certifiers reported little or no handlers known to be utilizing the substance. A trade association reported that it is essential as a leavening agent and alternatives have not been identified. Other certifiers support re-listing and reported common usage. An environmental group recommended delisting due to the emission of ammonia and carbon dioxide during manufacture or use.

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

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

Subcommittee Review:
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.

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.

The Handling Subcommittee discussed the material, noting that Ammonium Carbonate has low levels of concern in both environmental and human health areas.

An Environmental group supported delisting due to emissions of ammonia and carbon dioxide during manufacture and use. Certifiers listed little to no record of usage. One farm group supported relisting.

Subcommittee Vote:
Motion to remove Ammonium Carbonate from 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Mindee Jeffery
Seconded by: Steve Ela
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)
Technical Report: 1995 TAP; 2016 TR (Phosphates)
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

Subcommittee Review:
Use:
Calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminium 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 and 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.

Subcommittee Review:
The NOSB Subcommittee Review of Calcium Phosphates for the 11/27/2017 review process raised concerns regarding the cumulative effect on human health associated with the use of phosphorous additives in foods. These concerns were raised by stakeholders during both the oral and written comment process. However, some of the oral and written comments also refuted these same health concerns.

The Handling subcommittee was instructed to look into the concerns and come back to the full NOSB with further findings. This was done, and included a broader look at all phosphates with 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 the 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 no long term impacts are fully understood.

In reviewing all of the comments from the Spring 2020 meeting, no further concerns were expressed with the exception of the original concerns stated above. There were also several specific references to calcium phosphate as having a positive impact on bone health.

The Board is always concerned about allowing exceptions that could stifle innovation. However, it is our determination that calcium phosphates have no real substitute, particularly in baked products.

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

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

Subcommittee Review:
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 an 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 O_3. 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 O_2, breaking down in the lower atmosphere to O_2 (dioxygen). Ozone's odor is reminiscent of chlorine, and detectable by many people at concentrations as low 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 corona 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 use 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 U.S. Environmental Protection Agency, 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.

During its first review at the April 2020 meeting, the Board received comments voicing broad support for the continued listing of ozone. Comments from certifiers noted 51 operations list this material in their organic system plans (OSPs). Numerous comments pointed to ozone's importance as a disinfectant and sanitizer for food contact surfaces. Many noted the material's essentiality in reducing microbial loads on finished produce and grains.
One group acknowledged ozone's strong oxidizing properties and usage that does not leave toxic residues. However, they noted the potential risk to workers from leaks in irrigation water treatment when the material is not transferred to the water and is released as a gas. The group encouraged the Crop and Handling Subcommittees to review ozone in the context of all sanitizers.
The Handling Subcommittee considers that the positive attributes of ozone and its role in food safety programs outweigh the manageable risks to worker safety and supports relisting at this time.

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

Sodium hydroxide

Reference: 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.
Technical Report: 1995 TAP; 2020 TR IN PROGRESS
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

Subcommittee Review:
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.

The recent Technical Report states there are no alternatives that provide the desired browning properties of pretzels. Baking soda can be used but is not sufficiently alkaline 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 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. Each type of alkalizing agent results 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.

The Subcommittee discussed the wide usage of sodium hydroxide in organic systems. Several brands, certifiers, and a trade association listed wide usage of sodium hydroxide. A trade association further noted that alternatives are insufficient and, if removed, products would lose organic certification as reformulation is not an option.

Several commenters suggested an annotation to limit use solely for essential purposes. An environmental group noted that the current annotation only lists prohibitions and requested that the Board investigate essential uses of sodium hydroxide and move towards allowance of essential uses exclusively.

Subcommittee Vote:
Motion to remove sodium hydroxide from § 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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

Subcommittee Review:
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 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 it 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.

The Spring 2020 comment period presented arguments both for and against delisting carnauba wax at § 205.606. Some commenters referenced the sufficient availability of organically produced carnauba wax and therefore supported the delisting. Others suggested the organic form does not provide a satisfactory result when used as a processing aid. It was also mentioned through several comments that waxes in general are not always used, but they are important on those occasions when and where necessary; having alternative forms of waxes available allows for more export opportunities due to regulation differences at the respective destination.

The Subcommittee vote was split based on concerns about the use of volatiles in the production of carnauba wax, the possible availability of organic forms, and the issue of an unlabeled ingredient/additive used on produce. The Handling Subcommittee is seeking more information from stakeholders regarding the use of solvents in carnauba wax production.

Subcommittee Vote:
Motion to remove waxes (carnauba) from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of organically produced alternatives.
Motion by: Kim Huseman
Seconded by: Scott Rice
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

Colors Beet juice extract color, Beta Carotene, 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); 2011 (Beta carotene); 2012 Supplemental TR
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

Subcommittee Review:
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 as agricultural – 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.

Subcommittee Review:
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 powdered 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.

Should those stakeholders interested in maintaining a particular color on §205.606 not respond, the NOSB should take that as an indication that the color no longer needs to be listed on §205.606 and vote to remove it.

Public comment received during the Spring 2020 NOSB meeting addressed similar issues as the 2015 sunset review. Arguments were made for and against the renewal of all or some of the colors, but overall there was a dearth of comments given the number of companies that use colors. One commenter stated that the onus was on users of colors covered by this listing to make the case for relisting. If there were few or no comments in support of relisting, the NOSB should vote to remove the color. Several companies noted that they were able to source certain organic colors but there was insufficient supply of other colors. Other companies presented comments that there is sufficient supply of nearly all colors with a few exceptions. One comment came from a company that said they are a large manufacturer of organic colors

and can supply market demands, but that price may be a deterrent for some companies. If this is the case, then there is commercial availability and price should not be a reason for relisting. Based on these, often conflicting, comments, the Handling subcommittee has compiled a list of colors where there seems to be sufficient organic supply and should be delisted. The Handling Subcommittee has questions about supply of the remaining colors. In many cases the Subcommittee was split as to whether a color should be relisted or delisted, and would appreciate additional public comment for the Fall 2020 meeting. A listing of each color follows with comments specific to that color.

(1) Beet juice extract color (pigment CAS #7659-95-2)

Beet juice extract received conflicting public comments with one large supplier saying they had adequate organic supply and another supplier asking for it to be relisted. There was also a comment from an end user noting they had moved to nearly all organic colors, but this color should be relisted because of difficulties in using the organic color. The 2015 NOSB HS recommended this color be relisted. One commenter noted there were 47 listings for this color in the Organic Integrity Database. The HS recommends that this color should be relisted.

Motion to remove beet juice extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(2) Beta carotene extract color

Public comment, from both manufacturers and end users, from Spring 2020 for beta carotene extract recommended relisting of this color. Without adequate evidence that this color has adequate organic supply, the HS recommends relisting of this color.

Motion to remove beta carotene extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comment from Spring 2020 was mixed with several commenters recommending relisting and one manufacturer recommending that this color be delisted. One end user of this color commented that they had adequate supply of this color in organic forms. The 2015 NOSB HS review recommended relisting of this color. Given that one large manufacturer says they have adequate supply and that cost may be the limiting factor and that the only end user commenting on this color noted adequate supply, but that others comments recommended relisting, the HS had an even split vote as to relisting or delisting.

Motion to remove black currant juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comment from Spring 2020 was mixed. One end user and one manufacturer commented that this color should be relisted while another end user and manufacturer noted there was sufficient organic supply. The end user asking for relisting noted that they were using organic colors for other products but needed this color relisted for another product. Another commenter noted there were 47 listings for this color in the Organic Integrity Database. The 2015 NOSB HS recommended relisting this color. Given the mixed comments, the HS recommends relisting this color.

Motion to remove black/purple carrot juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting this material while another asked for delisting. One end user that uses mostly organic colors in other products asked for this color to be relisted. However, given increase in organic blueberry supply, the HS recommends this color be delisted.

Motion to remove blueberry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

(6) Carrot juice color (pigment CAS #1393-63-1)

Comments from the Spring 2020 meeting were mixed. One manufacturer asked for relisting while another asked for delisting. Similarly, one end user asked for relisting while another noted adequate organic supply. Given that there are commenters, both manufacturers and end users, that commented on adequate supply, HS recommends this color be delisted.

Motion to remove carrot juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability

Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color while another commenter noted 23 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting this color. The HS had an even split vote on whether this color be relisted.

Motion to remove cherry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove chokecherry – aronia juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 1 No: 5 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove elderberry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS had an even split vote as to whether this color should be relisted.

Motion to remove grape juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS had an even split vote as to whether this color should be relisted.

Motion to remove grape skin extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(12) Paprika color (CAS #68917-78-2) - dried, and oil extracted

Public comment from Spring 2020 were mixed but were more in favor of delisting. One end user and one manufacturer asked for relisting. However, two other manufacturers and one end user commented they had adequate supply. Without comments listing the exact reasons this color needs to be relisted and that there are several manufacturers noting they are able to provide adequate supply, the HS recommends delisting this color.

Motion to remove paprika color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

(13) Pumpkin juice color (pigment CAS #127-40-2)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. Another commenter noted 25 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting. With no other information, the HS had an even split vote

as to whether this color should be relisted.

Motion to remove pumpkin juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove purple potato juice extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. Another commenter noted 24 listings in the Organic Integrity Database. With no other information, the HS had an even split vote as to whether this color should be relisted.
Motion to remove red cabbage extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. The 2015 NOSB HS recommends relisting. With no other information, the HS recommends this color be relisted.
Motion to remove red radish extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela

Seconded by: Kim Huseman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(17) Saffron extract color (pigment CAS #1393-63-1).

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting noting they had adequate supply to meet market demands. Another manufacturer that also makes organic colors has asked for relisting on other colors due to difficulties in supply but did not ask for relisting of this color. One end user that uses organic colors in other products asked for relisting of this color. Given conflicting information, the HS recommends this color be relisted.

Motion to remove saffron extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(18) Turmeric extract

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. Two end users that use organic colors in other products asked for relisting of this color, while a third user says they have sufficient supply of organic product. Another commenter noted 40 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting at that time. With no other information and an apparent adequate supply based on comments from a manufacturer and end user, the HS recommends this color be delisted.

Motion to remove turmeric extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

Glycerin

Reference: 205.606(h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).

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

Subcommittee Review:

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 an 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 glycerin that would be classified as non-agricultural. 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.

In 2012 the NOSB received a petition to remove glycerin from §205.605(b), 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 rulemaking on the NOSB recommendation, moving glycerin from § 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)"

During the Spring 2020 NOSB meeting, held virtually from April 29 to May 1, 2020, and during subsequent Handling Subcommittee (HS) discussions, the issue of "commercial availability" was discussed and there was general agreement that, given the wide use of glycerin as a binder, humectant, solvent, and carrier, there is currently no suitable commercially available alternative. During this same time period, the HS addressed the question about the make-up of the remaining 1% left over from the "99% pure" claim attributed to glycerin? In reviewing the 2013 TR and through review of several stakeholder written comments, it is generally held that glycerin is at least 99% pure with the balance of the remaining material being water and fatty acids that, perhaps, support processing.

Subcommittee Vote:
Motion to remove glycerin from § 205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jerry D'Amore
Seconded by: Kim Huseman
Yes: 2 No: 3 Abstain: 1 Absent: 1 Recuse: 0

Inulin oligofructose enriched

Reference: 205.606(j) 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

Subcommittee Review:
Use:
Inulin-oligofructose enriched (IOE) is on the National List as a nonorganically produced agricultural product allowed 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, baby formulas, 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.

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, and were considered by the NOSB.

During the Spring 2020 public meeting the NOSB received about 25 public comments, mostly written, with about 75% in favor of relisting. Of the remaining 25% about 60% expressed strong opposition citing commercial availability, with 40% expressing some concern, again, centering around commercial availability. Many of the entities in favor of relisting provided compelling documentation regarding the widespread use of IOE as well as examples of its unique functionality. Most of those opposed to relisting referenced adequate supply with little or no supporting documentation.

Regarding the acceptability of using organic inulin + conventional FOS (already listed at §205 606), there were numerous public comments asserting that this alternative has a distinct lack of functionality, mostly concerning fiber and sweetness.

Subcommittee Vote:
Motion to remove inulin-oligofructose enriched from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jerry D'Amore
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Kelp

Reference: 205.606(k) Kelp—for use only as a thickener and dietary supplement.
Technical Report: 1995 TAP; 2016 TR (Marine Plants & Algae)
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

Subcommittee Review:
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:
Kelp is allowed in Canadian General Standards Board Organic Production Systems under aquatic plants and aquatic plant products, Table 4.2. It is also listed in the European Union Annex IX 1.1.3 Algae, including seaweed, permitted in non-organic foodstuffs preparation. It is also listed in the Japanese Agricultural Standard for Organic Plants-Dried Algae, including the powdered form.

Environmental Issues and Human Health Impacts:
Kelp is a renewable resource. It is also a keystone species, and there are concerns over responsible harvest 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 Committee would like more information on the impact of harvesting on kelp populations. There are also concerns over contamination of kelp from ocean radiation.

Subcommittee 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.

The NOSB asked several questions of the organic community. The questions were:

1. Are there organic supplies of kelp available? If so, are there enough organic supplies available to meet commercial demand?
2. How is organic kelp's use in livestock production different from uses for human consumption?
3. Are there 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 (human consumption) needs of kelp as a thickener and dietary supplement?

Several commenters requested the delisting of kelp because of the ambiguity of the listing and suggested a relisting of kelp under §205.607(b) - the wild crop certification. Other commenters suggested relisting with an annotation. The Subcommittee also discussed, in relation to the listing of kelp, the NOSB's discussion document regarding marine materials. Because the marine materials document will ultimately affect all marine materials, including kelp, there remains some uncertainty about how to proceed with kelp and other seaweeds that will have to be better defined, preferably at once, since many of the terms such as kelp can include other separate listings.

Subcommittee Vote:
Motion to remove kelp from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: A-dae Briones
Seconded by: Steve Ela
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Orange shellac

Reference: 205.606(o) 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

Subcommittee Review:
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 it is 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 option 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 provide a high gloss to some food products. For example, zein is a protein of the prolamine group occurring in maize and used

in food 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 handling purposes, including shine, permeability, cost, etc.

Limited public comments were presented during the Spring 2020 meeting; however, all the comments supported relisting orange shellac. Public commenters again suggested adding an annotation that would require labeling of fruits and vegetables that may have had orange shellac applied. As noted above, this would be a future work agenda item since annotations are not addressed during the sunset review. A petition is currently under review by the Board for corn zein, an alternative material to orange shellac that also provides a high gloss finish to some foods. The Subcommittee was split over relisting orange shellac. There is lack of information about whether its use in organic products is widespread or necessary as well as the absence of comments on this ingredient.

Subcommittee Vote:
Motion to remove orange shellac from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Alternatives, 7 U.S.C. 6518(m)(6)
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

Starches: cornstarch

Reference: 205.606(s) Starches.
(1) Cornstarch (native).
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

Subcommittee Review:
Use:
"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" (prior review).

Manufacture:
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 55 suppliers of "cornstarch" or "corn starch", including many in the United States. Cornstarch is listed under §205.606, so non-organic material should be used only when organic cornstarch is not available. The Handling Subcommittee requested public comment on the need to list cornstarch under §205.606.

During the Spring 2020 NOSB meeting, many certifiers, trade organizations, and food manufacturers supported relisting of cornstarch on §205.606. Although various forms of organic cornstarch are available and abundant, many commenters noted that some organic forms were not functional to manufacture their products or there was not enough specialized organic material available to meet their needs. Overall, certifiers and producers reported non-GMO derived cornstarch, albeit not organic, was readily available. Several organic cornstarch manufactures reported production of thousands of metric tons of organic cornstarch and also possible alternatives derived from pea starch or other products. One commenter recommended an annotation limiting cornstarch on §205.606 to specialized forms that are not available organically and thus encouraging broader use of available organic cornstarch when it meets production requirements. Note that an annotation is beyond the scope of the sunset review and would have to be considered as a separate work agenda item. The Subcommittee wanted to encourage policies that increase use of organically sourced cornstarch and there was debate about whether this could be accomplished by an annotation as described above or by removing cornstarch, as listed, from §205.606, and encouraging direct listing of any specialized forms that are not available organically. The Subcommittee ultimately voted to recommend removal of cornstarch from §205.606 because of an abundant supply of organic cornstarch.

Subcommittee Vote:
Motion to remove starches: cornstarch from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Asa Bradman
Seconded by: Scott Rice
Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Starches: sweet potato

Reference: 205.606(s) Starches.
(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

Subcommittee Review:
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 requested 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.

Public comment on sweet potato starch was very limited, with only a few reported users of this project. One organic starch manufacturer suggested pea starch provided a workable alternative to sweet potato starch, although this claim was not addressed by food producers currently using sweet potato starch. Another commenter noted that taking sweet potato starch off §205.606 would likely increase availability of organically sourced material. The Subcommittee wanted to encourage policies that increase use of organically sourced sweet potato starch and ultimately voted to recommend removal of sweet potato starch from §205.606 to encourage use of organically sourced material.

Subcommittee Vote:
Motion to remove starches: sweet potato starch from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Turkish bay leaves

Reference: 205.606(u) 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

Subcommittee Review:
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."

During its Spring 2020 review, the Handling Subcommittee heard overwhelming support to remove Turkish bay leaves from the National List. As noted above and attested to in public comments received, there appears to be a sufficient quantity of organic Turkish bay leaves in the market to support this removal. Of the certifiers that submitted comments on §205.606 sunset materials, only one noted the inclusion of nonorganic Turkish bay leaves in 4 organic system plans. One trade association noted one organic operation they surveyed used Turkish bay leaves in a wide range of canned soups but stated there is full availability of organic forms. The operation further noted there would be no impact from removal of this material because organic forms can be used and are available.

Based on these comments and the apparent wide availability of organic sources, the Handling Subcommittee recommends the removal of Turkish bay leaves from §205.606 of the National List.

Subcommittee Vote:
Motion to remove Turkish bay leaves from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

Whey protein concentrate

Reference: 205.606(w) 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

Subcommittee Review:
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 (TR lines 629-631).

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.

Subcommittee Review:
During the Board's previous review in 2015, the NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, and (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.

Public comments received during the Spring 2020 NOSB were overwhelmingly in support of removing whey protein concentrate from the National List. The Handling Subcommittee specifically requested information as to whether there were any forms of whey protein concentrate that were not available organically. In response to this explicit request, no public comments were received indicating that there were organic forms that were not available. Furthermore, several commenters replied that they had adequate supply of all forms and actually had so much supply that they were having to sell some organic product on the conventional market. These comments included:

> CROPP Cooperative: Organic Whey Protein is fully available in form and volume. The processing infrastructure has grown dramatically since whey protein concentrate was placed on the National List. Processors are established throughout the United States for both finished products and condensed whey. Roughly sixty percent of our whey is processed into whey powders, with future plans to utilize our entire whey stream. Our whey supply could produce 1.4 million pounds of WPC annually. Today there is an ample supply of organic whey protein concentrate on the market and the supply will continue to grow. In fact, our WPC supply is greater that market demand, where large volumes of our supply are sold on the conventional market.
>
> Western Organic Dairy Producers: We have more than adequate product available to meet the current demand for Organic Whey Protein Concentrate. Given this availability, there is no need to utilize a conventional product for products labeled as organic. The removal of the

conventional Whey Protein Concentrate further supports organic dairy producers and organic dairy product utilization.

Milk Specialties Global: As outlined in the petition, the decision to allow nonorganic whey in organic products may have been necessary in 2007, but no longer meets the threshold of necessity today. We urge the NOSB to remove Whey Protein Concentrate from the National List as part of the mandated sunset process.

Furthermore, at least one organic certifier notes that all of their handlers are currently using organic forms of whey protein concentrate and a number of suppliers were identified on the Organic Integrity Database. Another commenter also noted that organic whey-based products are also offered from international partners, making the supply chain quite robust.

As noted above, the NOSB has also received a petition to remove whey protein concentrate from the National List. The reasoning given in the petition is similar to the reasons listed above. There is adequate organic supply. Despite questions that have been directed towards identifying any forms that are not available organically, there has been no public comment received indicating that the organic supply is inadequate. In fact, there has been comment that at this point the supply exceeds the demand. For this reason the Handling Subcommittee recommends removing whey protein concentrate from the National List.

Subcommittee Vote:
Motion to remove whey protein concentrate from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Alternatives (availability of organic whey protein concentrate), 7 U.S.C. 6518(m)(6)
Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0