Sunset 2027
Meeting 1 - Request for Public Comment
Handling Substances §§ 205.605(a) 205.605(b) & 205.606
Spring 2025

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 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, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2025 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2025 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.605(a), §205.605(b), and/or §205.606, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments that do not support a substance on §205.605(a), §205.605(b), and/or §205.606, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

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

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

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

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

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'':

Kaolin
Sodium bicarbonate
Waxes-nonsynthetic (wood resin)

§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'':

Ammonium bicarbonate
Ammonium carbonate
Calcium phosphates (monobasic, dibasic, and tribasic)
Low-acyl gellan gum
Ozone
Sodium hydroxide

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

Carnauba wax
Colors:
(1) Beet juice extract color
(2) Beta-carotene extract color
(3) Black/purple carrot juice color
(4) Chokeberry, aronia juice color
(5) Elderberry juice color
(6) Grape skin extract color
(7) Purple sweet potato juice color
(8) Red cabbage extract color
(9) Red radish extract color
(10) Saffron extract color
Cornstarch (native)
Glycerin
Inulin-oligofructose enriched
Orange shellac

Kaolin

Reference: 205.605(a)(15)
Technical Report: 1995 TAP (kaolin, bentonite)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Kaolin is a filtration component in the manufacture of juices organic juices. It is also an ingredient in personal care products, used as a filler, additive, and functional ingredient. While past reviews have suggested that kaolin at one time was used as anti-caking agent in processed food (1995 TAP), there is no evidence this use continues.

The 2025 TR for kaolin identified several other relevant uses for kaolin: post-harvest pest control of stored grains; clarification of fruit wine; and filtration of seed oils.

Manufacture

Kaolin is a soft white clay consisting principally of the mineral kaolinite. Kaolin clays are formed by weathering and/or hydrothermal alteration of granites and rhyolites. It is found worldwide and commonly mined in many locations.

International Acceptance

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Kaolin is permitted as a clarifying agent (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165Kaolinitic clays, free of asbestos, are permitted (Binders and anti-caking agents, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Kaolin is permitted (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).
Kaolin is permitted in the extraction of propolis (For livestock and bee products, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Kaolin is permitted as a processing/post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production
Kaolin is permitted: limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Environmental Issues

Historically, kaolin has not been the focus of significant environmental concern beyond persistent questions related to global mining practices which can affect sensitive areas, habitats, and native soils, and both terrestrial and aquatic ecosystems. The mining process also results in significant waste byproducts (mostly sand and rock). The 2025 TR specifically mentions research that has been done in the Brazilian Amazon on the ecosystem impacts (forest canopy loss) from various industrial activities that include kaolin mining, as well as impacts in Chinese kaolin mining areas on soil bacterial and fungal communities. Larger organisms – including megafauna (mammals, birds, and fish) – appear to be more affected by the impacts of kaolin mining than smaller ones. This updated technical review also provided evidence of ecosystem resilience in various contexts where kaolin mining occurs.

The 2025 TR did indicate that heavy metals (particularly lead and cadmium) can be found in raw, whole kaolin materials, sometimes at levels of health concern. The TR included a limited survey that identified two kaolin materials that exceeded the specified tolerances for arsenic and lead.

Regulatory bodies overseeing various applications of kaolin relevant to this listing generally considered kaolin, when used responsibly, to be safe for use. Most concerns around health risk exposure from

consumption of kaolin relates to those who consume it specifically and intentionally, in which case it can be linked to iron-deficiency anemia; anemia during pregnancy; potassium deficiency; and bowel obstruction and perforation.

The TR also discusses the potential for nano-sized kaolin particles to appear in food-contact packaging, but also acknowledges that these considerations are outside the scope of this review.

Ancillary Substances

In the use of kaolin in clarification of fruit wines, the 2025 TR did indicate the following from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations: "Inert fibers, pulps, earths, or similar materials, may be used as filtering aids in the cellar treatment and finishing of wine. Agar-agar, carrageenan, cellulose, and diatomaceous earth are commonly employed as inert filtering and clarifying aids. In general, there is no limitation on the use of inert materials and no records need to be maintained concerning their use."

Discussion

There were minimal comments about kaolin during the previous sunset review period in 2020. Multiple certifiers conveyed that kaolin appeared in a number of Organic System Plans. The Handling Subcommittee, and ultimately the full Board, continued to view this material as relatively benign with no significant environmental or health concerns.

Given the updated review of kaolin in the form of the 2025 TR, the Handling Subcommittee looks forward to fresh insights from the community.

Questions to Our Stakeholders

1. Does kaolin appear in more Organic System Plans that it has during previous reviews? In other words, is the substance in growing or declining use?
2. Does the community have additional information about the presence of heavy metals in some kaolin products?

Sodium bicarbonate

Reference: 205.605(a)(26)
Technical Report: 1995 TAP (Baking powder, aluminum-free); 1995 TAP (Sodium carbonates)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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; that 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
The main source of sodium bicarbonate 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, after which the sodium bicarbonate then precipitates out.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Sodium bicarbonate (baking soda) is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Sodium bicarbonate (baking soda) is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- Sodium bicarbonate (baking soda) is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Sodium hydrogen carbonate is permitted in foods of both plant (confectionery, bakery wares) and animal (dairy products and analogues, excluding products of food category) origin (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

Japan Agricultural Standard (JAS) for Organic Production

- Sodium bicarbonate is permitted: limited to the use in confectionery, sugar, prepared legumes/beans, noodles, or bread; or as a neutralizer in dairy products (Table A.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted: limited to the use in confectionery, sugar, prepared legumes/beans, noodles, bread, beverages, processed vegetable products, or processed fruit products; or as a neutralizer in dairy products (Table A.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table B.1 - Agricultural chemicals, JAS for Organic Products of Plant Origin).

Ancillary Substances
None

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.

Human Health issues
None

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

The Handling Subcommittee was awaiting a new TR on sodium bicarbonate at the time of this review

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

Waxes (Wood rosin) (sic. resin)

Reference: 205.605(a)(29) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR waxes; 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; 10/2020 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 08/03/2021 (86 FR 41699); Technical correction: 11/14/2022 87 FR 68021
Sunset Date: 3/15/2027

Subcommittee Review

Use
According to the 2014 technical report (TR), wood rosin is used in organic processing and handling primarily as a component of fruit wax, most commonly applied to citrus fruit (2014 TR, line 86).

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 happens in two ways: the wax forms a physical barrier that the gas must permeate, and the coating also fills openings in the fruit peel. 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 comprises approximately 90% of the formula (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 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 considered ”food grade” and permitted as an ingredient in citrus fruit waxes. The manufacturing process may 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 Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Wood rosin is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Pine rosin extract is permitted for the processing of sugar only for antimicrobial purposes and must be from organic production, if available (Processing aids and other products, EC No. 2021/1165).
- Aleppo pine resin is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- Wood rosin is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Wood rosin is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Wood rosin is not explicitly mentioned in the regulations.

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 (2014 TR, lines 141-142).

Human Health and Environmental Issues

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 (2014 TR, lines 380-389).

The solvent extraction of wood rosin from wood chips has the 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 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/m^3. 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. For the second extraction step, methanol is considered to be environmentally preferable to other solvents of similar properties. 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. 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 (2014 TR, lines 392-414).

Discussion
The three main pine species in the southeast are Loblolly, Slash, and Longleaf. Wood rosin is derived primarily from Slash and Longleaf. Slash and Loblolly pine grow much faster than Longleaf and are, therefore, the predominate species planted for timber production. Stump removal after timber is harvested is very expensive but necessary cleanup for the land to be replanted or converted for other uses. With recent hurricanes in the Southeast, thousands of acres of pine timber tracts were damaged. Hurricane winds typically cause these trees to twist or snap, making them unmarketable. However, this material could be used to produce wood rosin. Previous Boards voted overwhelmingly in favor of keeping this material on the National List.

Questions to our Stakeholders
1. Could damaged trees from hurricanes be used to produce wood rosin?

Ammonium bicarbonate

Reference: 205.605(b)(4) - for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Handling)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Ammonium bicarbonate and carbonate are salts composed of ammonium and carbonate ions. Ammonium bicarbonate is the monoammonium salt of carbonic acid with the formula NH_4HCO_3 and a molecular weight of 79.06 g/mol.

Ammonium carbonates are used as leavening agents. Ammonium bicarbonate has critical functionality as a raising (leavening) agent in certain cookies and crackers. Compared to baking soda, it produces more gas, thus not leaving behind a salty or soapy taste in the finished baked goods, as it completely decomposes into water and gaseous products that evaporate during the baking process. It is used in baking where yeast is not used. Ammonium bicarbonate cannot be used for moist baked goods. It also helps provide certain characteristic textures (such as in crackers), as well as aids in controlling cookie spread.

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
The 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.

International Acceptance
Ammonium carbonates are approved for use in the following organic standards: They are considered GRAS by the FDA

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Ammonium bicarbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Ammonium bicarbonate is not explicitly mentioned in the regulations.
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ammonium hydrogen carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Ammonium bicarbonate is not explicitly mentioned in the regulations.
Japan Agricultural Standard (JAS) for Organic Production
Ammonium bicarbonate is permitted: limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances
None

Environmental Issues
The original 1995 TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. Subsequently, they have been looked at together during their previous two sunset reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review all found no environmental concerns, and no concerns have been brought to the subcommittee's attention during this current review.

Human Health Issues

Likewise, there were no human health concerns raised during the original TAP review or during the following two sunset reviews. The current sunset review and public comment periods (oral and written) have also not raised any environmental concerns, human health concerns, or any other reasons for why this material should not continue to be allowed for organic handling.

Discussion
During the previous public comment period, a stakeholder mentioned that this material was still critical for handlers, especially for baking crackers and similar baked goods. Other commenters supported its continued allowance on the National List. There were no comments against its relisting.

Questions
None

Ammonium carbonate

Reference: 205.605(b)(5) – for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Handling)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Past NOSB Review
The NOSB found no concerns regarding the continued listing of ammonium carbonate. This material still continues to satisfy all OFPA criteria, and public comments confirmed its current use and need.

Subcommittee Review
Use:
Ammonium bicarbonate and carbonate are salts composed of ammonium and carbonate ions. Ammonium carbonate is the diammonium salt of carbonic acid with the generalized formula $(NH_4)_2CO_3$ and a molecular weight of 96.09 g/mol.

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. The 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 the ammonium carbonates.

Manufacture
Ammonium carbonates are manufactured by the reaction of ammonia sourced from the synthetic Haber-Bosch process with carbon dioxide sourced from industrial processes like power generation, cement manufacturing, or fossil fuel processing. 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.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Ammonium carbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as an attractant in insect traps (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Ammonium carbonates are permitted in products of plant origin (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Ammonium carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Ammonium carbonates are permitted as additives only for cereal products, confectionery, cakes, and biscuits (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Ammonium carbonate is permitted (Table A.1 – Additives, JAS for Organic Processed Foods).
- Ammonium carbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

None

Discussion

The original 1995 TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. Subsequently, they have been looked at together during their previous two sunset reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review all found no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following two reviews.

According to 2024 TR (pg. 18)-Aquatic animals are especially susceptible to the toxic effects of ammonia because they have thin permeable skin surfaces; even very low concentrations of ammonia can cause fish mortality.

Questions

None

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)(9)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminum free). All three of the calcium phosphates are used as leavening agents: dough conditioner, yeast food, or as an expanding agent. Monobasic and dibasic calcium phosphate are often used for reduced sodium baking. Monobasic is also a buffer, firming agent, sequestering agent, and is popular in pancake mixes. It is the commonly used acid, along with sodium bicarbonate, used to make baking powder. It is also used in baked goods, such as cookies, cakes, and potato chips, and as a firming agent for canned fruits and vegetables. Dibasic is used in enriched flour, noodle products, and in both dry and cooked forms of breakfast cereals. It is often used as a dough conditioner. It also can be used as a thickening agent for various cheese products. Tribasic is an anti-caking agent 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 (2016 TR, lines 43-44).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Calcium phosphates (mono-, di-, and tribasic forms) are permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Dicalcium phosphate is permitted (Feed Materials of Mineral Origin, EC No. 2021/1165).
- Monocalcium phosphate is permitted (Feed Materials of Mineral Origin, EC No. 2021/1165).
- Monocalcium phosphate is permitted in self-rising flour as a raising agent (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Monocalcium orthophosphate is permitted in food of plant origin (flours) but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Monocalcium phosphate is permitted as an additive only for raising flour (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Limestone etc. are permitted: Limestone, shelly fossils, seashells, dolomite, phosphate rocks, and diatomaceous earth (Terms and definitions, JAS for Organic Feed).
- Limestone etc. and calcium carbonate, magnesium carbonate, phosphate hydrogen calcium, phosphate calcium, and silicic acid are permitted: derived from limestone and are not chemically treated, and to which no chemically synthesized substances are added (Ingredients, JAS for Organic Feed).
- Calcium dihydrogen phosphate is permitted: limited to the use in flour as a leavening agent (Table A.1 – Additives, JAS for Organic Processed Foods).
- Calcium dihydrogen phosphate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances
None

Human Health and Environmental Issues
During previous public comment, stakeholders raised concerns about the cumulative effects on human health associated with the use of phosphorous additives in foods. The NOSB review responded to the issue of human health concerns regarding cumulative phosphorous consumption by stating that no single phosphate additive or ingredient can be implicated as an isolated risk factor. Further information on each phosphate additive can be found in the TR (lines 438-687). The Board also determined that calcium phosphates have no viable organic substitute, particularly in baked products.

Discussion
During previous board discussions, it was determined that calcium phosphates have no viable organic substitute, particularly in baked products.

Calcium phosphates (monobasic, dibasic, and tribasic) are compliant with OFPA.

Questions to our Stakeholders

1. Should calcium phosphates be annotated in alignment with potassium phosphates to limit use to “made with” only?

Low acyl gellan gum

Reference: §205.605(b)(18)
Technical Report: 2018 TR (Gums)
Petition: 2019; 2020 Addendum
Past NOSB Actions: 10/2020 - recommendation to add

Recent Regulatory Background: Added to National List effective 11/14/2022 (87 FR 68021)
Sunset Date: 12/14/2027

Subcommittee Review

Use
Low acyl gellan gum is used in various food formulations, such as aspics; frostings; brownies and bakery fillings; gelatins and puddings; non-standardized jams and jellies; dairy drinks and soy milks; nutritional products; beverages (dairy alternative milks, dairy drinks, fruit drinks, drinking jellies, novelty drinks); beverage mixers; kefir; yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; marinades; pourable and spoonable dressings; and dairy desserts.

Gellan gum is approved in animal and pet food and is also used in personal care products such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. The typical amount of gellan gum in food for human consumption doesn't exceed 0.5%.

The mode of action is as a suspending or gelling agent with film-forming and texturizing attributes, forming gels in the presence of ions when heated and cooled.

Manufacture
The 2018 TR on gums and the 2019 petition note gellan gum is a high-molecular weight polysaccharide, produced by the pure-culture aerobic fermentation of a carbohydrate with Sphingomonas elodea (ATCC 31461), formerly known as Pseudomonas elodea. The carbohydrate fermentation substrate is comprised of glucose syrup derived from maize or wheat, inorganic nitrogen, an organic nitrogen source (protein) and trace elements. Pasteurization kills the bacteria. The structure of high acyl gellan gum consists of a 4-sugar repeating unit with acetate and glycerate side chains. Removing the acetate and glycerate groups results in a linear molecule with unique properties.

The petitioner provides the following detail specific to their manufacturing.

- The first step of producing the gum is by inoculating a carefully formulated fermentation medium with this organism.
- The medium contains a bio-based glucose syrup carbon source, phosphate, organic and inorganic nitrogen sources, and appropriate trace elements.
- The fermentation is carried out under sterile conditions with strict control of aeration, agitation, temperature, and pH.
- Deacylation of the gum develops the required functionality. A strong base is used to deacylate gellan gum. This additional step does not change the polysaccharide backbone of the molecule. After deacylation, acid is used to neutralize the gellan gum solution.
    - High acyl gellan gum is treated with potassium hydroxide and heated. This produces low acyl gellan gum and potassium acetate and potassium glycerate. The potassium acetate and potassium glycerate are removed from the low acyl gellan gum during the precipitation and recovery of the low acyl gellan gum with isopropyl alcohol.
- The gum is recovered by precipitation with isopropyl alcohol.
- The precipitate is then dried and milled to a fine powder.
- The powdered form of the product is packaged.

Low-acyl gellan gums (e.g. (KELCOGEL® [E], KELCOGEL® CG-LA [E], KELCOGEL® F[E])) produced by CP Kelco (the original petitioner) are Non-GMO Project certified.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Gums: The following gums are permitted: Arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum. Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Only high-acyl gellan gum is permitted in products of plant and animal origin, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Low-acyl gellan gum is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Additives and processing aids from biological sources, such as fermentation cultures, enzymes, flavors, and gums must be derived from naturally occurring organisms by the use of biological, mechanical, and physical methods. Nonorganic forms are allowed in organic products only if there are no organic sources (Processing and Handling Criteria, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Low-acyl gellan gum is not explicitly mentioned in the regulations.

Ancillary Substances

According to an internet search, it was noted that some ancillary substances could be present, such as calcium salts, residual sugars, pH adjusters, or carrier agents (like silicon dioxide). The 2018 TR for gums did not include this information as this was completed prior to the revision to the TR template, which now specifically asks about ancillaries.

Environmental and Human Health Issues

The two available technical reports (TRs) (2018 and 2006) did not list any notable human health or environmental concerns regarding the use of gellan gum. A 2018 study, in response to an NOSB request for an updated study of the safety of gellan gum as a food additive, found no adverse health impacts of gellan gum and did not recommend establishing an acceptable daily intake level.

Discussion

Low-acyl gellan gum was added to the National List in November 2022. This is its first sunset review. In 2010 gellan gum was annotated to limit its use to the high-acyl form only. It was indicated during that rulemaking process that since there were additional processing steps between high-acyl gellan gum and low-acyl gellan gum that only the high-acyl form could be classified as non-synthetic and that the low-acyl form would need to be petitioned separately as a synthetic substance.

The low acyl form of gellan gum is technically a synthetic substance as described above but is viewed from a regulatory and food safety perspective as identical to the high acyl form. The tenets of organic production tend to favor nonsynthetic options when available. However there do not appear to be significant differences between the nonsynthetic high acyl and synthetic low acyl forms of gellan gum.

There are several gums on the National list. Each has specific properties that may not be shared by other gums. Use of low-acyl gellan gum in hard and soft capsules gives a functionality that cannot be achieved with most materials currently on the National List. Carrageenan is the only material currently listed which offers producers of hard and soft capsules the necessary technical function/properties. Additionally, gellan gum is used at significantly lower levels (<20%) than other gums on the National List.

Low-acyl gellan gum is produced via a fermentation process. As with any substance that undergoes a fermentation step there are concerns pertaining to the use of excluded methods. All of the other gums on the National List were just reviewed in 2023. They were all unanimously relisted (13 yes, 2 absent).

Questions

1. What types of organic products is low-acyl gellan (synthetic) used in compared to high-acyl gellan gum (nonsynthetic)?
2. Are there additionally ancillaries present in low-acyl gellan gum that the board should be aware of?

Ozone

Reference: 205.605(b)(21)
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Ozone is a powerful oxidant with many industrial and consumer applications related to oxidation. The primary use of ozone globally is as a water treatment. In this capacity, ozone oxidizes organic and inorganic compounds, improving water quality when used as a broad-scope disinfectant. In food production, handlers also apply ozone directly to food as an antimicrobial treatment. Consequently, ozone is also a preservative (2024 TR, lines 119-122).

Manufacture
Ozone occurs naturally, mostly in the upper atmosphere. Naturally occurring ozone is often the product of ultraviolet radiation on atmospheric oxygen. Producers generate most ozone by applying a low-current electrical discharge (corona discharge) to atmospheric oxygen. Increasingly, producers generate ozone through the electrolysis of water. Ozone can also be manufactured photochemically by exposing oxygen in air or water to ultraviolet light (2024 TR, lines 54-61). Ozone is an unstable gas in the air and even more so in water, so it must be produced on site.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Teat dips and udder wash: Substances, such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and **ozone**, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's *Food and Drug Regulations* (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

- **Ozone** is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- With regard to disease prevention, ultraviolet light and **ozone** may only be used in hatcheries and nurseries (Production rules for algae and aquaculture animals, EC No. 2018/848).

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

- **Ozone** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- **Ozone** is permitted (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Ozone** is permitted: limited to the use only for the purpose of disinfecting meat or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS for Organic Livestock Products).
- **Ozone** is permitted: limited to the use for disinfecting processed meat products or cleaning of eggs (Table A.1 – Additives, JAS for Organic Processed Foods).
- **Ozone** is permitted (Table D.1 - Substances for preparation etc., JAS for Organic Products of Plant Origin).

Ancillary Substances
N/A

Environmental Issues and Human Health Impacts
The primary human health concern of ozone treatment for food and water is worker safety. Employees are exposed to higher levels than the general public. Ozone is an irritant to the eyes, nose, mouth, and upper respiratory system (2024 TR, lines 773-775). According to the U.S. Environmental Protection Agency (EPA), ozone exposure in the air we breathe can be harmful to human health and the environment. However, the application of ozone directly into water as a disinfectant minimizes this exposure. Once introduced into water, ozone decomposes into elemental oxygen in a brief amount of time. Exposure to atmospheric ozone generated from on-site production can be minimized through equipment maintenance. Ozone is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (FDA) without limitations other than current good manufacturing practice (2024 TR, lines 155-156). The impacts of ozone pollution on plant growth and health have received considerable attention from scientists world-wide with visible yellowing of the leaves and leaf death at higher levels (2024 TR, lines 704-708).

During the April 2020 meeting, the Board received comments voicing broad support for the continued listing of ozone. Comments from certifiers noted 51 operations listing 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.

Discussion
The Handling Subcommittee finds 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.

Questions to our Stakeholders
None

Sodium hydroxide

Reference: 205.605(b)(32) - prohibited for use in lye peeling of fruits and vegetables.
Technical Report: 1995 TAP; 2020 TR
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Sodium hydroxide is a highly caustic substance used as a processing aid in cocoa manufacturing, 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 the 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_2) 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
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Sodium hydroxide (lye or caustic soda) is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Sodium hydroxide (lye or caustic soda) is prohibited for use in lye peeling of fruits and vegetables (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- Sodium hydroxide (lye or caustic soda) is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Sodium hydroxide is permitted in 'Laugengebäck' flavourings for use as a surface treatment and acidity regulator (Section A1 – Food Additives including carriers, EC No. 2021/1165).
- Sodium hydroxide is permitted in the processing of sugar(s), oil from plant origin excluding olive oil, and plant protein extracts (Processing aids and other products, EC No. 2021/1165).

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

- Sodium hydroxide is permitted in food of plant origin (cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category; yeast-leavened breads and specialty breads), but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).
- Sodium hydroxide is permitted for pH adjustment in sugar production (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Sodium hydroxide is permitted as an additive and processing/post-harvest handling aid for sugar processing and for the surface treatment of traditional bakery products (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).
- Sodium hydroxide (caustic soda) is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Sodium hydroxide is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Sodium hydroxide is permitted: limited to the use in the processing of sugar (as a pH control agent) or pH adjustment in processed algae products or use in the production of edible fats & oils or in the production of processed grain products (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

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

Environmental Issues

Sodium hydroxide must be handled by personnel according to manufacturer guidelines because of its caustic nature. The 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 2020 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.

Questions to our Stakeholders
None

Carnauba Wax

Reference: 205.606 205.606 (a) Carnauba wax
Technical Report: 1996 TAP; 2014 TR
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Carnauba wax is 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. Its Generally Regarded as Safe (GRAS) listing doesn't provide any limitations on its use as an ingredient in food (2014 TR, lines 65-72).

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 (2014 TR, lines 114-116). 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 melted by steam or a solvent (2014 TR, lines 253-259). The wax is then cooled and filtered via a filter press or through filter cloth, and then cooled and dried (2014 TR, lines 263-265). The wax may also be clarified by centrifugation or with hydrogen peroxide.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Waxes, produce: Organic beeswax and organic **carnauba wax** may be used to wax produce. See 9.2.1 d) of CAN/CGSB-32.310 if organic wax is commercially unavailable (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- **Carnauba wax** is permitted in confectionery and citrus fruit for use as a glazing agent, mitigating method for mandatory extreme cold treatment of fruit as a mandatory quarantine measure against harmful organisms in accordance with Commission Implementing Directive (EU) 2017/1279, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).
- **Carnauba wax** is permitted in products of plant origin for use as a releasing agent and only from organic production (Processing aids and other products, EC No. 2021/1165).

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

- **Carnauba wax** is permitted as releasing agent (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- **Carnauba wax** is permitted as a processing/post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Carnauba wax** is permitted: limited to the use as a separating medium in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

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.

Human Health and Environmental Issues

It was stated in the 2014 TR that chronic toxicology or carcinogenicity studies have been done; however, the European Food Safety Authority does not consider carnauba wax a safety concern for human health.

Leaves harvested for the production of wax regrow every year, and the leaf remnants remaining after the wax extraction are used for making brooms and hats etc. There were no environmental concerns reported (2014 TR, lines 437-441).

Discussion

In previous sunset years, some commenters referenced the sufficient availability of organically produced carnauba wax and, therefore, supported 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 previous Board voted to retain carnauba wax on the list, with 11 votes in favor of relisting, and 3 to remove.

Questions to our Stakeholders

1. What is the current organic availability of carnauba wax?

Colors

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 derived from Beta vulgaris L., except must not be produced from sugar beets.
(2) Beta carotene extract color – derived from carrots (Daucus carota L.) or algae (Dunaliella salina).
(3) Black/Purple carrot juice color derived from *Daucus carota* L.
(4) Chokeberry, Aronia juice color - derived from *Aronia arbutifolia* (L.) Pers. Or *Aronia melanocarpa* (Michx.) Elliott.
(5) Elderberry juice color - derived from *Sambucus nigra* L.
(6) Grape skin extract color - derived from *Vitis vinifera* L.
(7) Purple sweet potato juice - derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
(8) Red cabbage extract color - derived from *Brassica oleracea* L.
(9) Red radish extract color - derived from *Raphanus sativus* L.
(10) Saffron extract color - derived from *Crocus sativus* L.

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; 10/2020 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 renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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, to protect light-susceptible vitamins, and to preserve flavor (2015 TR, lines 22-24). The natural colors market has grown dramatically since colors were added to the National List (2015 TR, lines 345-348).

The colors that remain on the National List fall into three categories (2015 TR, lines 17-22):

- Anthocyanin colors (chokeberry, black/purple carrot, red cabbage, elderberry, grape skin, purple sweet potato[1], red radish);
- Carotenoid colors (beta carotene, black/purple carrot, saffron); and
- Other colors (beet).

Anthocyanins are used in fruit products to add back reds, blues, purples, and oranges lost in processing (2015 TR, lines 33-35). They are composed of a pigment molecule, anthocyanidin, linked to a sugar molecule (2015 TR, lines 45-46). There are six main anthocyanidin pigments in colors covered by the 2015 TR, but there are about 25 known anthocyanidins in the world, which combine in various ways with sugars

[1] Note: The 2015 TR addresses “purple potato”, but it is presumed to mean purple sweet potato.

to make several hundred anthocyanins (2015 TR, lines 46-47, 139-141). They exist in varying concentrations and at varying pH, which affects their color and other properties (2015 TR, lines 46-61).

Carotenoids, the most widely distributed group of pigments, are used to give red, orange, or yellow colors to a wide range of products (2015 TR, lines 27-29, 145). They synthesized by microorganisms and plants, and about 600 carotenoid pigments have been identified (2015 TR, lines 149-153). Carrots contain significant amounts of beta-carotene (and black carrots also contain anthocyanins) (2015 TR, lines 64-68, 148-149). Saffron's major pigment is the water-soluble compound crocin (2015 TR, line 181). One other source of crocin, gardenia fruit, is not approved as a food colorant in the United States (2015 TR, 187-189).

Beet juice color is used in dairy, meat, baked, candy, and fruit products (2015 TR, lines 35-37). Beet juice contains red pigments called betalains or betacyanins, which are similar to anthocyanins (2015 TR, lines 112-113). While betalains occur in other plants, beets are the only allowed source of betalain colorant in the United States and European Union (2015 TR, lines 194-196). Beet color is more purple and brighter than anthocyanin pigments, and it has a more stable pH range; however, it has low heat stability (2015 TR, lines 198-200).

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 Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Colouring agents are permitted "from biological sources such as spices, annatto, juices made from plant sources, etc. derived using approved methods (see Table 11 B (1) & (2), Origin and mode of production of CAN/CGSB-32.310), and substances in Table 6.3 Extraction solvents and precipitation aids" and "May contain permitted carriers (see Table 6.3 & 6.4 Carriers)" (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Specific colors are not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Colours for stamping meat and eggshells pursuant to regulation (Processed food production rules, EC No. 2018/848).
- Natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention of placing them on the market at a given period of the year (Processed food production rules, EC No. 2018/848).
- Annatto for certain cheeses (Part A, Authorized food additives and processing aids, EC No. 2021/1165).
- Other specific colors are not explicitly mentioned.

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

- Specific colors are not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)

- A substance shall not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, **colors**, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law (IFOAM NORMS 2014, B.5.3).
- Specific colors are not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production

- Specific colors are not explicitly mentioned.

Ancillary Substances

The 2015 TR notes that additional ingredients may be added to stabilize or preserve pigments, and it identifies those ingredients by pigment group (2015 TR, lines 292-298). It notes that sulfur dioxide may be used to decrease browning in anthocyanin colors, in the presence of citric acid; however, it also notes the limitations on sulfur dioxide use (2015 TR, Table 5). Protective coatings or antioxidants may be used to protect carotenoid colors from degrading, and ascorbic acid may be used to prevent fading; the 2015 TR also specifically notes that green tea polyphenols may be used to prevent discoloration, but that they are not on the National List (2015 TR, Table 5). Citric acid may be used to extract beet juice extract color, and ascorbic acid may be used to stabilize it (2015 TR, Table 5). Purple (sweet) potato juice color may have water, invert sugar, and citric acid added, and saffron extract color may have moisture added for stability (2015 TR, Table 5).

Human Health and Environmental Issues

Color additives generally require Food and Drug Administration (FDA) approval before use in food, but certain pigments derived from fruits and vegetables are exempt from that requirement, including all those on the National List (2015 TR, lines 263-278). Many pigments have antioxidant or anti-inflammatory properties and may be helpful to health, and ingestion is unlikely to be harmful to human health (2015 TR, lines 649-651, Table 8, 752-759).

Nonorganic natural colors are products of conventional agriculture, and the 2015 TR identifies potential for contamination of natural colorants with aflatoxins, solvents used in processing (not an issue for listed colors because of the prohibition on solvent extraction), and pesticide and heavy metal residues (2015 TR, lines 656-660). Some colors are derived from agricultural waste products leftover from processing, and there may be environmental benefits to reducing that waste (2015 TR, lines 742-747).

Discussion

In the 2015 sunset review of colors, the NOSB documented the emerging presence of certified organic colors and recommended that future Boards carefully review the supply of individual colors, rather than renewing colors in whole on § 205.606. In the Fall 2020 NOSB sunset review, the NOSB voted to relist the 10 colors that are currently up for review. The NOSB also voted to sunset 8 that were subsequently removed due to findings that those colors were available in organic form (black current juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, and turmeric extract) (Fall 2020 NOSB Formal Recommendation re 2022 sunset reviews - handling). The following is a summary of the feedback the NOSB received for the 2020 review, for the colors that are currently listed:

(1) Beet juice extract color - derived from Beta vulgaris L., except must not be produced from sugar beets: Mixed information about whether organic forms were available in sufficient form or quantity

(2) Beta carotene extract color - derived from carrots (Daucus carota L.) or algae (Dunaliella salina): Strong concerns about supply

(3) Black/Purple carrot juice color - derived from *Daucus carota* L: Mixed information indicating organic supply may not be adequate or has too much color variation

(4) Chokeberry, Aronia juice color – derived from *Aronia arbutifolia* (L.) Pers. Or *Aronia melanocarpa* (Michx.) Elliott: Limited information indicating variable and inadequate organic supply

(5) Elderberry juice color – derived from *Sambucus nigra* L: Limited organic supply

(6) Grape skin extract color – derived from Vitis vinifera L: Supply tied to wine industry and impacted by limited organic wine production (grape skins and derivatives from wine labeled "made with organic grapes" would not qualify for an organic claim)

(7) Purple sweet potato juice – derived from Ipomoea batatas L. or Solanum tuberosum L: Inadequate supply

(8) Red cabbage extract color – derived from *Brassica oleracea* L: Inadequate supply

(9) Red radish extract color – derived from *Raphanus sativus* L: Mixed information on supply

(10) Saffron extract color – derived from *Crocus sativus* L.: Mixed information on supply

The 2015 TR (lines 834-844) identifies several potential alternatives to certain pigments, including:

- Organic palm fruit oil beta-carotene in place of beta-carotene from carrots
- Organic annatto for yellow to red carotenoids
- Organic marigold for the carotenoid lutein

The subcommittee discussed the value of colors in meeting consumer expectations, the colors that were removed in the last sunset cycle, and the impacts on market growth that 205.606 listings may have. As the most recent information available to the subcommittee is from the 2020 sunset review, the subcommittee seeks stakeholder input on the current commercial availability of the listed colors.

Questions to our Stakeholders

1. Which of these colors are now commercially available in organic form?
2. Where information about commercial availability is mixed (i.e. where some, but not all, commenters note that the organic color is available), should those colors be removed from the National List to ensure adequate market pressure to complete the transition to organic?
3. How essential are the colors that remain on the list? For example, could a different anthocyanin be substituted for red radish?
4. Are there any other specific barriers to organic transition for individual colors (e.g., grape skin extract supply is limited by constraints on organic winemaking)?

Cornstarch (native)

Reference: 205.606(e) Starches.

(1) Cornstarch (native).

Technical Report: 1995 TAP - Cornstarch; 2025 TR
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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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 (1995 TAP).

Manufacture
Cornstarch is obtained from the endosperm of the kernel (1995 TAP). 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.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Starch is permitted from rice and waxy maize—Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids, where applicable. Starch shall not be modified by chemicals. Starch may be modified using physical or enzymatic methods. Cornstarch—May contain substances that are plant derived or listed in Tables 6.3, 6.4, or 6.5 (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Cornstarch is not explicitly mentioned in the regulations.

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

- Cornstarch is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Cornstarch is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Cornstarch is not explicitly mentioned in the regulations.

Ancillary Substances
None noted

Human Health and Environmental Issues
Cornstarch poses no acute health hazards from ingestion or dermal absorption. Dust 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. Based on previous comment - Special strains of corn are grown to achieve the right ratio of the two glucose polymers (amylopectin and amylose) 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, but that non-GMO derived cornstarch was readily available. Others indicated that some organic forms were not functional to manufacture their products or there was not enough specialized organic material available to meet their needs.

A December 2024 search of the Organic Integrity Database identified 133 suppliers of "cornstarch" or "corn starch," located in the United States, China, and India. Cornstarch is listed under §205.606, so non-organic material should be used only when organic cornstarch is not available.

During the previous relisting, many certifiers, trade organizations, and food manufacturers supported relisting of cornstarch on §205.606. One commenter recommended an annotation limiting cornstarch on §205.606 to specialized forms that are not available organically, thus encouraging broader use of available organic cornstarch when it meets production requirements. In the previous review, the Subcommittee wanted to encourage policies that increase use of organically sourced cornstarch. 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.

Questions to our Stakeholders

1. In the past 5 years, the number of suppliers of organic cornstarch has nearly tripled. Does this mean that there is a sufficient supply of organic cornstarch?
2. Are there *any* barriers to using organic cornstarch instead of the non-GMO based conventional cornstarch? We are especially interested in understanding why there organic and conventionally produced cornstarch would not be completely interchangeable.
3. Is there sufficient supply of non-GMO based conventional cornstarch?

Glycerin

Reference: 205.606(i) 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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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 (2013 TR, lines 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 Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Glycerol (glycerine, glycerin) is permitted: Shall be from organic sources if commercially available. Shall be from vegetable oil or animal fat. Shall be produced using fermentation or by hydrolysis (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Glycerol (glycerine, glycerin) is permitted: Shall be from organic sources if commercially available. Shall be from vegetable oil or animal fat. Shall be produced using fermentation or by hydrolysis (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Collagen casings are permitted: Collagen shall be derived from animal sources. If derived from cattle, collagen shall be guaranteed free of Specified Risk Material (SRM). Other ingredients (such as, but not limited to; cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture that remain in the collagen casing when it is used shall respect the requirement provided in 1.4 a) of CAN/CGSB-32.310 (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Glycerol (glycerine, glycerin) is permitted: Shall be a) sourced from vegetable oil or animal fat; b) produced using fermentation or by hydrolysis (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Glycerol is permitted in plant extracts and flavourings with the following conditions: only from plant origin, solvent and carrier in plant extracts and flavourings, humectant in gel capsules, surface coating of tablets, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Glycerol is permitted when obtained from plant origin and allowed as a carrier for plant extracts and in untreated fresh fruit; surface-treated fresh fruit; processed fruit; surface-treated fresh vegetables; dried vegetables; vegetables; canned or bottled (pasteurized) or retort pouch vegetables; fermented vegetables; herbs, spices, seasonings, and condiments. **Glycerol** is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Glycerin is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Glycerin is not explicitly mentioned in the regulations.

Ancillary Substances
None mentioned in the TR.

Human Health and Environmental Issues
There are few, if any, potential human health concerns regarding glycerin exposure. The 2013 TR indicates that repeated oral exposure may cause GI irritation. Exposure to glycerin via inhaled aerosol shows local irritant effects at and above 662 mg/m^3, and no observable adverse limit is 167 mg/m^3. Evidence suggests that glycerin is not a skin sensitizer.

According to the 2013 TR, small amounts of glycerin may escape during the production process into either water or the atmosphere. Glycerin is biodegradable, and is not thought to bioaccumulate. Glycerin has low toxicity to fish and aquatic invertebrates. Overall, there is a low level of concern that glycerin is an environmental hazard. It is exempt from an EPA tolerance. Glycerin is manufactured from palm and coconut oils, so there is concern about its contribution to deforestation.

Discussion
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 previous sunset, the board and subcommittee discussed the issue of "commercial availability." There was general agreement that, given the wide use of glycerin as a binder, humectant, solvent, and carrier, there was 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.

Questions to our Stakeholders
None

Inulin oligofructose enriched

Reference: 205.606(k) 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; 10/2020 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 renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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 (2015 TR, lines 130-132). 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 (2015 TR, lines 294-296). If insufficient amounts of oligofructose are present, polymers ranging 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.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

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 (2015 TR, lines 208-209). 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, thereby limiting the amount of processing aids that remain (2015 TR, lines 335-338). 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.

Human Health and Environmental Issues
The 2015 TR was a limited TR and did not cover human health and environmental concerns.

Discussion
Public comments from the previous sunset received from stakeholders were mixed, however, a majority supported relisting citing the widespread use of this material, examples of its unique functionality, and that the alternative (fructooligosaccharides) has a lack of functionality in terms of fiber and sweetness in some applications. Due to the widespread use, these commenters expressed concern about the commercial availability of the organic forms. Those against relisting cited adequate organic supply but with little or no documentation.

Questions to our Stakeholders
1. Is there adequate supply of inulin derived from organic sources?
2. Are there technical or other barriers to using inulin derived from organic sources in place of inulin derived from conventional sources?

Orange shellac

Reference: 205.606(n) Orange shellac-unbleached (CAS # 9000-59-3).
Technical Report: 1999 TAP (Waxes); 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; 10/2020 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 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

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. Shellac dye is also 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 (2014 TR, lines 40-41). 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 (2014 TR, lines 45-49). The main areas of the world where it is produced are India, Thailand, and Myanmar (2014 TR, lines 55-56).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Orange shellac is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Orange shellac is not explicitly mentioned in the regulations.

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

- Orange shellac is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Orange shellac is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Orange shellac is not explicitly mentioned in the regulations.

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 (2014 TR, lines 159-164). 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 (2014 TR, lines 166-172). 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 (2014 TR, lines 432-437).

Human Health Issues
The TR states there are no reported adverse effects on human health due to orange shellac. The TR stated that some individuals may show allergic symptoms, and some vegetarians may consider it as animal product not suitable for their consumption (2014 TR, lines 445-446). The TR also indicated the allegoric reaction during processing is likely to stem from the solvents used in manufacturing vs the orange shellac itself (2014 TR, lines 452-456).

Orange shellac has an acceptable present use (as a coating, glazing, and surface-finishing agent externally applied to food) that is "not of toxicological concern" established at the 39th Joint Experts Committee for 460 Food Additives (1992) (2014 TR, lines 458-460).

Discussion
At the previous sunset review, there was a split vote out of subcommittee. The main concerns of the subcommittee in 2020 were largely due to a lack of information about whether its use in organic products is widespread or necessary as well as the absence of comments on this substance (historically).

Limited public comments were received during the last round. However, stakeholders that did submit comments were overwhelming supportive of relisting this material. There were several comments that suggested adding an annotation to require labeling of fruits and vegetables that had orange shellac applied. This is, in part, due to some individuals showing allergic symptoms and that some vegetarians may consider this material an animal product not suitable for consumption. Disclosing fruit coatings on labels is nuanced. The subcommittee discussed this and determined that this is an FDA labeling issue and is outside of NOP's jurisdiction.

Other commenters pointed out that while alternatives do exist (e.g. wood rosin, carnauba wax, beeswax, and candelilla wax), variability in shine and permeability may mean that certain waxes work better in some applications while others perform better in other applications. Only wood rosin and carnauba wax are currently listed as non-synthetics allowed on the National List. If beeswax, and candelilla wax would be used, they would be required to be organic. Additionally corn zein was petitioned for inclusion on the National List as a food coating and processing aid. The board narrowed the scope by adding an annotation for nutraceutical and pharmaceutical industries only. Despite the narrowed scope the NOSB voted to not add zein to the National List.

The lack of information about whether orange shellac's use in organic products is widespread or necessary as well as the dearth of public comments on this material led the Board to consider delisting, however, there was not adequate evidence demonstrating that non-synthetic substances are adequate alternatives. As such the board unanimously relisted orange shellac during the last sunset review.

Questions
1. Is orange shellac necessary for use in organic production (i.e. should it remain on §205.606)? Why?