Sunset 2027
Meeting 2 - Review
Handling Substances § 205.605(a), § 205.605(b) & § 205.606
Fall 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
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); 2025 Limited Scope 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 06/06/2012 (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 (2025 TR, lines 44-46, 54-56). While past reviews have suggested that kaolin, at one time, was used as an anti-caking agent in processed food (1995 TAP), there is no evidence that 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 (2025 TR, lines 84-87).

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 (2025 TR, lines 103-105).

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 2021/1165

- Kaolinitic 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 (2025 TR, lines 206-212, .226-231).

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 (2025 TR, lines 363-364). The TR included a limited survey that identified two kaolin materials that exceeded the specified tolerances for arsenic and lead (2025 TR, lines 170-172).

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 (2025 TR, lines 376-380).

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 (2025 TR, lines 346-354).

Ancillary Substances

For the use of kaolin in clarification of fruit wines, the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations state that 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 (2025 TR, lines 323-328).

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.

Spring 2025 commenters were supportive of relisting kaolin, and the 2025 limited-scope TR didn't add any new information that would contradict that support. Given the updated review of kaolin in the form of the 2025 TR that was posted just before the Spring meeting, the Handling Subcommittee looks forward to fresh insights from the community.

Questions to our Stakeholders
1. Does kaolin appear in more organic system plans than it has during previous reviews? In other words, is the substance growing or declining in use?
2. Does the community have additional information about the presence of heavy metals in some kaolin products?

Justification for Vote
The Subcommittee finds kaolin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

S**ubcommittee Vote**
Motion to remove kaolin from the National List
Motion by: Kathryn Deschenes
Seconded by: Amanda Felder
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Sodium bicarbonate

Reference: §205.605(a)(26)
Technical Report: 1995 TAP (Baking powder, aluminum-free); 1995 TAP (Sodium carbonates); 2025 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 06/06/2012 (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 bicarbonate's food processing and handling uses are varied. It is primarily used in meat products, baked goods, baking mixes, cocoa processing, and as a surface cleaner. Sodium bicarbonate (baking soda) is a common compound in baking powder; helps to regulate acidity for things like tomato soup, or in pastes and beverages. It can be used as an anti-caking agent or as a stabilizer helping to maintain the appearance

and consistency of foods. Sodium bicarbonate is often used in pancakes, biscuits, muffins, crackers, and in cookies. It often is used in self-rising flour and confections. It may also be used as a neutralizer for use in butter, cream, and ice cream.

Manufacture

According to the 2025 TR, food-grade sodium bicarbonate is primarily derived from the carbonation of a refined sodium carbonate precursor. The sodium carbonate precursor can be obtained from a naturally occurring mineral source (sesquicarbonate – aka trona or nahcolite extraction) or from the Solvay process (a chemical synthesis reaction producing sodium carbonate from sodium chloride, ammonia, and calcium carbonate). While sodium bicarbonate can be directly extracted from a mineral (nahcolite), this source is not as common as other sources. Most sodium bicarbonate is produced from sodium carbonate, which is then converted to sodium carbonate (2025 TR lines 60-70).

Sodium bicarbonate extraction from nahcolite deposits

Nahcolite deposits of sodium bicarbonate are recovered through solution mining operations in the Green River area of Colorado. Hot, pressurized water is pumped into wells, and the saturated solution is cooled to precipitate sodium bicarbonate. This is the only common process to generate sodium bicarbonate directly from a mineral, without further chemical reactions (2025 TR, lines 547-551). According to evaluation question #1C in the 2025 TR, sodium bicarbonate extracted from nahcolite bed solution mining is nonsynthetic (2025 TR, lines 773-781).

Sodium bicarbonate production from sodium carbonate

Sodium bicarbonate may also be produced using sodium carbonate as a precursor. There are two primary ways to produce sodium bicarbonate from sodium carbonate: the Solvay process or from trona ore. Regardless of whether sodium carbonate originates from the Solvay or trona/brine processes, sodium bicarbonate is commonly manufactured by percolating carbon dioxide gas through a carbonation tower that contains a saturated solution of refined sodium carbonate. Carbon dioxide reacts with sodium carbonate to produce sodium bicarbonate, which precipitates and is then collected through filtration, centrifugation, drying, screening, and packaging. The carbon dioxide used in sodium bicarbonate production can come from limestone calcination or other sources, such as the petrochemical industry (2025 TR, lines 553-560).

1. **Solvay process** (2025 TR, lines 783-789)

The Solvay process utilizes ammonia, a synthetic reactant produced through the Haber-Bosch process. The Solvay process involves a displacement reaction between sodium chloride and ammonia, which takes place in the presence of carbon dioxide, derived from calcium carbonate. This reaction facilitates the formation of sodium bicarbonate. Due to this, the material is synthetic because it is not manufactured from a natural source.

2. **Sodium carbonate precursor production: Trona processing** (2025 TR, lines 791-813)

The substance (sodium bicarbonate) is manufactured through carbonation using two precursors (sodium carbonate and carbon dioxide). The sodium carbonate precursor is produced by calcining (heating) sodium sesquicarbonate, which is mined. Sodium sesquicarbonate is a double salt of sodium carbonate and sodium bicarbonate. The calcination process decomposes sodium sesquicarbonate, ultimately releasing carbon dioxide and water. This converts the double salt into the single salt, sodium carbonate.

The carbon dioxide precursor may be derived from the calcination of lime, from carbon dioxide wells, from fermentation processes, from calcination of sodium sesquicarbonate, or from other sources.

Sodium carbonate is combined with carbon dioxide and water to produce sodium bicarbonate.

According to the decision tree, a chemical change caused by heating a mineral results in a synthetic material. Furthermore, to create sodium bicarbonate, the material undergoes another chemical reaction to transform sodium carbonate into sodium bicarbonate via carbonation.

International Acceptance
Internationally, sodium bicarbonate is sometimes referred to as sodium hydrogen carbonate, and is sometimes included under the term "sodium carbonates." It is generally allowed under other international standards (see below).

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as an ingredient and processing aid without further annotation.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Grouped under "sodium carbonates" and is allowed as a food additive in products of plant and animal origin without further annotation.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
It is allowed for any *function* in organic food production under CODEX guidelines but is limited for use in confectionary products and bakery wares. It is also allowed in dairy products and analogs, but excludes "products of food category 02.0" (fats and oils, and fat emulsions).

International Federation of Organic Agriculture Movements (IFOAM)
It is allowed as an additive or a processing and post-harvest handling additive without limitation.

Japan Agricultural Standard (JAS) for Organic Production
Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, beverages, vegetable products, processed fruits or for dairy products as neutralizing substance. It is also allowed for use as an additive in alcohol beverages, without further annotation.

Korea Republic of Korea (ROK) Korean Organic Act
Limited to use as a food additive in cakes, confectionery and liquid tea.

Switzerland Federal Office for Agriculture (FOAG), Switzerland Organic Ordinances, Organic Farming Ordinance (SR 910.18), EAER Ordinance on Organic Farming (SR 910.181), FOAG Ordinance on Organic Farming (SR 910.184)
It is allowed for use for the preparation of foodstuffs of plant origin, as well as milk jam (*Dulce de leche*), sour cream butter and sour milk cheese. Sodium carbonates (again, assuming this includes sodium bicarbonate) are listed as permitted for the regulating the pH-value of primary yeast and yeast preparations/formulations.

Taiwan Organic Agriculture Regulations
It is limited to the use as a leavening agent. Nonsynthetic sodium carbonate might be allowed under this standard for purposes other than leavening and harmful organism control.

United Kingdom Organic Products Regulations (2009), Retained Council Regulations (EC) (834/2007, 889/2008, and 1235/2008)

It is allowed as a food additive in products of plant and animal origin, for use in dulce de leche, soured-cream butter, and sour milk cheese.

Ancillary Substances
According to the 2025 TR, sodium bicarbonate is generally sold as a single material and does not contain ancillary substances. However, a tortilla blend mix was identified that contained a sodium bicarbonate mixed with less than 1% silica to improve its handling characteristics (2025 TR, lines 835-837).

Environmental Issues
According to 2025 TR, the industries involved with sodium bicarbonate manufacturing have a more significant environmental impact than food production operations. At the concentrations used in the food industry, sodium bicarbonate and its breakdown products are unlikely to represent an environmental hazard.

Since sodium bicarbonate is derived from mined materials, and the usual environmental issues of mining would be present (as described below). However, no major issues have been raised in past reviews or in comparison to other materials on the National List that are derived from mined minerals.

The Solvay process requires significant amounts of limestone and rock salt. Extraction of these deposits from quarries or mines results in dust and fine particle emissions. These emissions can lead to respiratory diseases and harm agricultural land in the surrounding areas. Additionally, there are several effluents produced as a result of this manufacturing process. These effluents are directed to sedimentation ponds where the solids settle and the liquids are disposed of in local waterways or deep underground wells. The Solvay process also relies on the calcination of limestone, releasing large amounts of carbon dioxide and carbon monoxide, significantly contributing to the greenhouse gas effect (2025 TR, lines 960-998).

Trona mining and processing can produce methane emissions and "fugitive dust" (sodium carbonate powder) that blows off the tailings ponds and during transport. This dust can be seen as white clouds from a distance, and environmental protection measures are in place to collect it. The trona process expels carbon dioxide. Part of the expelled carbon dioxide may be used for the carbonation step, while the rest is released into the atmosphere or compressed and stored to be used for other purposes. Additionally, trona processing requires constant liquor purges to prevent the buildup of impurities on the equipment and final product. These purges are disposed of in evaporative ponds, which are toxic to vegetation due to their high salinity and can cause problems for wildlife, particularly waterfowl (2025 TR, lines 1000-1039).

Per the 2025 TR no studies were found that specifically measured the environmental impact of nahcolite extraction using solution mining. In general, solution mining can result in land subsidence if the extraction wells are not managed correctly. Due to advances in solution mining technologies, incidents of surface sinks and collapses are uncommon today. Nahcolite solution mining facilities do require the creation of tailings ponds. As mentioned earlier, these ponds pose a risk to migrating bird populations, particularly grebes, that are protected by the federal Migratory Bird Treaty Act (2025 TR, lines 1065-1072).

Human Health issues
The 2025 TR indicated no negative impacts to human health when consumed as part of a normal diet (i.e. rates observed on processed foods).

Discussion
During the 2020 sunset review commenters were generally in support the re-listing of sodium bicarbonate. A commonly used item across many categories of products, stakeholders did not report major

environmental concerns. Certifiers raised a classification question regarding the material produced from Trona deposits versus the use of the Solvay process for formulating sodium bicarbonate. Support was expressed for considering re-classifying and/or adding an annotation or some other guidance for clarifying the allowed process for sodium bicarbonate production. Based on the Subcommittee review and public comment, the NOSB found sodium bicarbonate compliant with OFPA criteria and did not recommend its removal from the National List.

This substance had a Technical Advisory Panel Report (TAP) from 1995. The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. Due to the age of the information and the concerns raised during the previous sunset review regarding the manufacturing process and reclassification, the Handling Subcommittee requested a TR.

The 2025 TR explains the historical classification of sodium bicarbonate:
During the 1995 NOSB meeting in Orlando, Florida, the NOSB voted to classify sodium bicarbonate as nonsynthetic. Prior to the board's vote, a TAP report was conducted that briefly described the manufacturing process for sodium bicarbonate. Publicly available notes from the NOSB meeting do not contain any further details regarding the decision to classify sodium bicarbonate as nonsynthetic, or which forms are nonsynthetic. The classification recommended by the NOSB in 1995 was not based on the decision tree in Guidance NOP 5033-1 Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, which was not published until 2016. The 1995 TAP review only discussed two manufacturing processes, neither of them the direct method from nahcolite. Based on the NOSB recommendation and the listing of sodium bicarbonate on 7 CFR 205.605(a) as nonsynthetic, many certifiers and material review organizations consider sodium bicarbonate from trona ore as nonsynthetic, and sodium bicarbonate from the Solvay process as synthetic (2025 TR, lines 757-769).

At the time of the spring meeting the 2025 TR was not available. In addition, the incorrect document was initially included in the meeting packet. The correct version was posted in advance of the meeting. Most (if not all) were in favor of relisting due to essentiality. However, this is couched with the acknowledgement of stakeholders not having full information to evaluate.

Due to the information represented in the 2025 TR the Handling Subcommittee proposes to retain the listing of sodium bicarbonate as nonsynthetic as presented in this sunset review. The Handling Subcommittee also plans to pursue a reclassification of sodium bicarbonate production from sodium carbonate (e.g. Solvay and trona ore) as synthetic. This may result in listing both as nonsynthetic and synthetic. The subcommittee will evaluate the various synthetic processes and whether an annotation is needed to comply with OFPA criteria. In the meantime, the subcommittee acknowledges the historical allowance of sodium bicarbonate manufactured via the trona process and does not intend for this review to limit or exclude sodium bicarbonate currently in use manufactured using this process.

Justification for Vote
The Subcommittee finds sodium bicarbonate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove sodium bicarbonate from the National List
Motion by: Kyla Smith
Seconded by: Amanda Felder
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Waxes (Wood rosin)

Reference: §205.605(a)(29) Waxes—nonsynthetic (Wood rosin).
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 06/06/2012 (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. In Spring 2025 the Subcommittee asked if damaged trees from hurricanes could be used to produce wood rosin and didn't receive any answers indicating this was the case.

Justification for Vote
The Subcommittee finds wood rosin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove wood rosin from the National List
Motion by: Logan Petrey
Seconded by: Amanda Felder
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Ammonium bicarbonate

Reference: §205.605(b)(4) - for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Ammonium bicarbonate, Ammonium carbonate)
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 06/06/2012 (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 (2025 TR, line 65). Ammonium bicarbonate is the monoammonium salt of carbonic acid with the formula NH_4HCO_3 and a molecular weight of 79.06 g/mol (2025 TR, lines 82-83).

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 (1995 TAP, page 5). 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 (1995 TAP, page 5).

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 (1995 TAP, page 5).

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

It is considered GRAS by the Food and Drug Administration (FDA), without limitations other than current good manufacturing practice (2025 TR, lines 188-189).

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 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.

According to 2025 TR, aquatic animals are especially susceptible to the toxic effects of ammonia because they have thin permeable skin surfaces, and even very low concentrations of ammonia can cause fish mortality (2025 TR, lines 810-812).

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.

The 2025 TR did not find reports of negative effects directly caused by ammonium carbonates when used as leavening agents, nor explicit safety considerations that need to be taken when using them as leavening agents (2025 TR, lines 857-859).

Discussion
The original 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 found no environmental concerns, and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two reviews.

Public comments supported continued listing of ammonium bicarbonate on the National List. A stakeholder mentioned that this material was still critical for handlers, especially for baking crackers and similar baked goods. Other stakeholders recommended relisting due to the lack of availability of natural alternatives. There were no comments against its relisting.

Justification for Vote
The Subcommittee finds ammonium bicarbonate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ammonium bicarbonate from the National List
Motion by: Dilip Nandwani
Seconded by: Andrea Hatziyannis
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 0

Ammonium carbonate

Reference: §205.605(b)(5) – for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Ammonium bicarbonate, Ammonium carbonate)
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 06/06/2012 (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 (2025 TR, line 65). 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 (2025 TR, lines 89-90).

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 (1995 TAP, page 5).

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 (2025 TR, lines 115-117). Ammonium carbonate is made when carbon dioxide is passed through an ammonia solution and then allowing the vapors to distill, resulting in solid ammonium carbonate (1995 TAP, page 5).

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 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 found no environmental concerns, and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two reviews.

According to 2025 TR, 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 (2025 TR, lines 810-812).

Public comments supported continue listing of ammonium carbonate on the National List. There were no comments against its relisting.

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.

Justification for Vote
The Subcommittee finds ammonium carbonate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ammonium carbonate from the National List
Motion by: Dilip Nandwani
Seconded by: Andrea Hatziyannis
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 0

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 06/06/2012 (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 in aluminum-free baking powder. 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 (2025 TR, lines 75-84, 325-326). 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 periods, stakeholders raised concerns about the cumulative effects on human health associated with the use of phosphorous additives in foods. NOSB responded to this issue 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 (2016 TR, lines 438-687).

Discussion
All three calcium phosphates (monobasic, dibasic, and tribasic) are compliant with OFPA criteria and were all unanimously relisted by the NOSB during the last review in 2020. During Subcommittee discussions, it was determined that calcium phosphates have no viable organic substitute, particularly in baked products. Additionally, it is an alternative to sodium phosphate. During the 2015 sunset review, NOSB received comments including new research that indicates potential serious human health impacts from the cumulative effects of phosphates that are added to processed foods. Of particular concern is not just one substance, but the cumulative effect of the phosphates overall in the human diet. It was recommended that all phosphate-containing compounds should be under sunset review together and that calcium phosphate should be reviewed against the same standards for other phosphate compounds for consistency.

Some public comments called for calcium phosphate use to be limited by type and application. Outside the US and Canada, the only phosphate additive allowed in organically-processed food is monocalcium phosphate, and only as a leavening agent. The international standards follow the guidance allowing only the monocalcium variety for use in foods for consumption and some other allowances for animal feed. Traditionally, calcium phosphates are used as leavening agents, dough conditioners, and yeast food. Monobasic calcium phosphate is also used as a buffer, sequestrant, and firming agent, while tribasic calcium phosphate is also used as an anti-caking agent and a buffer. The NOSB may recommend increased restrictions through annotations or removal of phosphate food additives in the future. Because the health effects come from the cumulative impact, rather than any one specific phosphate alone, NOSB was reluctant to remove any one phosphate from the National List.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds calcium phosphates compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove calcium phosphates from the National List
Motion by: Andrea Hatziyannis
Seconded by: Amanda Felder
Yes: 1 No: 5 Abstain: 0 Recuse: 0 Absent: 2

Low-acyl gellan gum

Reference: §205.605(b)(18)
Technical Report: 2006 TR (Gellan gum); 2018 TR (Gums)
Petition: 2019 Petition; 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. The typical amount of gellan gum in food for human consumption doesn't exceed 0.5% (2019 Petition, page 6).

Gellan gum is approved for use in animal and pet food and in personal care products such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash (2019 Petition, page 6).

Gellan gum is used as a suspending or gelling agent with film-forming and texturizing attributes, forming gels in the presence of ions when heated and cooled. The gum is stable under normal storage conditions (2019 Petition, page 6).

Manufacture
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 (2018 TR, lines 648-652). In gellan gum, thickness and hardness is determined by acetyl groups present. With acetyl groups present, the gel is soft and elastic. Firmer gels are obtained by reducing the number of acetyl groups by adding potassium, magnesium, calcium, and/or sodium salts (2018 TR, lines 253-255). Therefore, low acyl forms are hard, non-elastic, brittle gels, while high acyl forms are soft, very elastic, non-brittle gels (2018 TR, lines 260-261).

The petitioner provides the following detail specific to their manufacturing (2019 Petition, page 7):

- 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.

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

An internet search 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 (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 on 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. During that rulemaking process, it was noted that there were additional processing steps in the low-acyl form compared to the high-acyl form. Therefore, only the high-acyl form could be classified as nonsynthetic, while the low-acyl form would need to be petitioned separately as a synthetic substance (75 FR 77521).

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 (2019 Petition, page 19).

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 votes to relist, 2 absent).

During the Spring 2025 meeting most commenters were in favor of relisting, noting its essentiality. Specifically, commenters noted the following in support of relisting:

- Creates gels without requiring high sugar content or high ionic concentrations.
- Offers a healthier choice in dietary considerations such as fat replacers, replacements in products suitable for celiacs, or replacements for other thickeners to meet socio-cultural dietary needs (even when used in very small amounts).
- Forms firm and brittle gels, making it an excellent gelatin replacement for vegan/vegetarian products and improving the quality of jams, jellies, and some dairy desserts.
- Provides optimal heat stability, making it especially suitable for foods undergoing heat treatment, such as bakery products with fillings.
- Offers clarity (high-acyl gellan gum is not available in a clarified form).
- Carageenan replacement: Heat stable in acid systems unlike carrageenan (nonsynthetic list), which breaks down under acid conditions, therefore can be used in fruit fillings, retorted gels, or low pH beverages.
- Provides processing flexibility for food manufacturers because it can be used in standard processing without additional steps (pectin requires special handling such as preparation of concentrated gum solutions.
- Used in hard and soft capsules (functionality that cannot be achieved with most materials currently on the National List).

Some certifiers indicated that they didn't have any operations using this material.

There were also a few comments received that were in opposition, which also cited essentiality. They called into question essentiality due to the fact that there are several gums on the National List. These stakeholders specifically stated that the essential uses of each gum should be listed in an annotation. Another comment in opposition indicated that manufacturers are dictating use of this material due to equipment functionality rather than making equipment to support the product (and use a different gum).

The Handling Subcommittee asked two questions during the Spring 2025 comment period. One question was related to the types of organic products that use low-acyl gellan gum (synthetic) compared to high-acyl gellan gum (nonsynthetic). The Subcommittee received a few comments in response to this question. One stated, "organic food manufacturers rely on low-acyl gellan gum to achieve desirable product consistency and stability, particularly in dairy alternatives, plant-based beverages, and organic fruit-based products." Also, as specified above, low-acyl gellan gum provides clarity in the final product which cannot be achieved by high-acyl gellan gum and has several specific functions identified. In some instances, it was unclear if these were able to be achieved by high-acyl gellan gum or other gums on the National List. The second

question asked about additional ancillaries present in low-acyl gellan gum that the Board should be aware of. We did not receive any comments regarding ancillaries.

Low-acyl gellan gum doesn't seem to be widely used. That said, this material is relatively new to the National List (added in 2020). Additionally, it does seem to be essential as it performs unique functions that other gums do not provide.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds low-acyl gellan gum compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove low-acyl gellan gum from the National List
Motion by: Kyla Smith
Seconded by: Kathryn Deschenes
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 0

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 06/06/2012 (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
During the April 2025 meeting, the Board heard widespread support from commenters advocating for the continued listing of ozone. Comments from certifiers noted 55 operations listing this material in their organic system plans (OSPs). Stakeholders emphasized ozone's critical role as a disinfectant and sanitizer for food contact surfaces, especially those composed of porous materials, such as wine barrels. Numerous stakeholders underscored the material's critical function in reducing microbial contamination on finished produce and grains, cautioning that while alternative sanitizers are available, they may not provide equivalent effectiveness or serve as direct replacements. An environmental group opposing the relisting of the material cited concerns about potential worker exposure to harmful ozone levels and recommended assessing the extent of ozone release during use and corresponding worker exposure levels.

The Board discussed public comments expressing concern about potential health risks to workers from exposure to ozone. The Board acknowledged these concerns and noted that, when properly maintained and managed, ozone systems significantly limit worker exposure and should not pose a health risk under normal operating conditions.

Justification for Vote
The Subcommittee finds ozone compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ozone from the National List
Motion by: Amanda Felder
Seconded by: Dilip Nandwani
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

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 06/06/2012 (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 Environmental Protection Agency (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.

Discussion
The Subcommittee discussed the wide usage of sodium hydroxide in organic systems. Several certifiers and a trade association listed wide usage of sodium hydroxide. All public comments supported the relisting of sodium hydroxide. Three commentors noted that the current annotation only lists prohibitions and requested that the Board investigate essential uses of sodium hydroxide and move towards allowance of essential uses exclusively. The Board reviewed the request but found no viable alternative to the existing prohibition on lye peeling.

Justification for Vote
The Subcommittee finds sodium hydroxide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove sodium hydroxide from the National List

Motion by: Amanda Felder
Seconded by: Kathryn Deschenes
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent:2

Carnauba Wax

Reference: §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 06/06/2012 (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 coating 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?

Justification for Vote

The Subcommittee finds carnauba wax compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove carnauba wax from the National List
Motion by: Logan Petrey
Seconded by: Andrea Hatziyannis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

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 sugarbeets.
(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 color – 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: 2011 (Beta carotene); 2012 Supplemental TR; 2015 TR - Colors (all)
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 06/21/2007 (72 FR 35137); Sunset renewal notice published 06/06/2012 (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 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).

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

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 are 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 extract 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 crops and pigments. 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 are 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 as a 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 listings 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 sugarbeets: 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 color – 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.

Public comments received in Spring 2025 ran the spectrum from support for delisting all colors (to protect the environment and health and because the origin crops all exist in organic form) to relisting all colors (because they are important for consumer acceptance, may be needed in varying forms, and production has not kept pace with consumer demand for organic products). Comments on particular colors included:

- Beta carotene has had strong support for relisting in the past.
- Organic production of grape skin extract color may be stunted by the annotation limiting use of sulfur dioxide to wine labeled "made with organic grapes."
- Beet juice extract color, red radish extract color, and purple sweet potato juice color do not appear to be available in commercial quantities.
- There may be sufficient supply for black/purple carrot juice color.
- One certifier noted that they have members who use all the listed colors except chokeberry, aronia juice color and saffron extract color; another certifier reported that they have members who use all but chokeberry, aronia juice color, saffron extract color, and elderberry juice color. Certifiers reported relatively high use of black/purple carrot juice color and beta carotene extract color.

It was noted that an updated TR that addresses particular barriers to production of the remaining individual colors may be helpful for the next sunset review.

Public comments and the NOSB discussed the extent to which existing production of organic crops could be directed to organic color production. A commenter noted that the Organic Integrity Database includes listings for all of the crops used as raw materials for the listed colors, and several commenters noted that excess crops could be directed to color production. However, other commenters noted that crops grown for pigment differ from crops grown for other purposes – just because a category of crop is grown organically doesn't mean it has high enough pigment content for use in color production. A commenter noted that organic food manufacturers typically have relationships with color manufacturers to create bespoke colors that fit particular product needs, and they are often not interchangeable. Season and region also impact the availability of particular colors.

The NOSB discussion noted that aronia berry has been introduced into the Midwest and Washington and has limited market options; there were questions about whether it could be a candidate for organic color production. It was also observed that FDA is looking closely at artificial colors, which may spur more demand for organic colors and could strain supply availability. The technology for color production is widely available, but it is not clear how much flexibility manufacturers have in sourcing raw materials. Smaller quantities may also be less available than large quantities, which may pose particular challenges to smaller operations.

The Subcommittee proposes sunsetting the remaining colors that were not specifically named as not commercially available in public comments and for which no specific technical barriers have been identified. A listing vote for each color follows.

Questions to our Stakeholders
None

Justification for Vote
(1) Beet juice extract color – derived from *Beta vulgaris* L., except must not be produced from sugarbeets.

The Subcommittee finds beet juice extract color compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove beet juice extract color from the National List
Motion by: Allison Johnson
Seconded by: Amanda Felder
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Justification for Vote
(2) Beta-carotene extract color – derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).

The Subcommittee finds beta-carotene extract color compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove beta-carotene extract color from the National List

Motion by: Allison Johnson
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Justification for Vote
(3) Black/purple carrot juice color – derived from *Daucus carota* L.

The Subcommittee is divided regarding whether black/purple carrot juice color is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient supply of organic black/purple carrot juice color to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove black/purple carrot juice color from the National List
Motion by: Allison Johnson
Seconded by: Amanda Felder
Yes: 2 No: 5 Abstain: 0 Recuse: 0 Absent: 1

(4) Chokeberry, aronia juice color – derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.

The Subcommittee is divided regarding whether chokeberry, aronia juice color is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient supply of organic chokeberry, aronia juice color to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove chokeberry, aronia juice color from the National List
Motion by: Allison Johnson
Seconded by: Kathryn Deschenes
Yes: 3 No: 4 Abstain: 0 Recuse: 0 Absent: 1

(5) Elderberry juice color – derived from *Sambucus nigra* L.

The Subcommittee is divided regarding whether elderberry juice color is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient supply of organic elderberry juice color to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove elderberry juice color from the National List
Motion by: Allison Johnson
Seconded by: Dilip Nandwani
Yes: 3 No: 4 Abstain: 0 Recuse: 0 Absent: 1

(6) Grape skin extract color – derived from *Vitis vinifera* L.

The Subcommittee finds grape skin extract color compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove grape skin extract color from the National List

Motion by: Allison Johnson
Seconded by: Amanda Felder
Yes: 1 No: 5 Abstain: 0 Recuse: 0 Absent: 2

(7) Purple sweet potato juice color – derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.

The Subcommittee finds purple sweet potato juice color compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove purple sweet potato juice color from the National List
Motion by: Allison Johnson
Seconded by: Kathryn Deschenes
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

(8) Red cabbage extract color derived from *Brassica oleracea* L.

The Subcommittee is divided regarding whether red cabbage extract color is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient organic supply to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove red cabbage extract color from the National List
Motion by: Allison Johnson
Seconded by: Kyla Smith
Yes: 1 No: 5 Abstain: 0 Recuse: 0 Absent: 2

(9) Red radish extract color – derived from *Raphanus sativus* L.

The Subcommittee finds red radish extract color compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove red radish extract color from the National List
Motion by: Allison Johnson
Seconded by: Kyla Smith
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

(10) Saffron extract color – derived from *Crocus sativus* L.

The Subcommittee is divided regarding whether saffron extract color is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient supply of organic saffron extract color to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove saffron extract color from the National List
Motion by: Allison Johnson
Seconded by: Dilip Nandwani
Yes: 1 No: 4 Abstain: 1 Recuse: 0 Absent: 2

Cornstarch (native)

Reference: §205.606(e) Cornstarch (native).
Technical Report: 1995 TAP; 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 06/06/2012 (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 (2025 TR, lines 366-384). 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
Cornstarch is listed under §205.606, so non-organic material should be used only when organic cornstarch is not commercially available. The availability of organic cornstarch has been increasing. During the 2020 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. During the 2020 review, many certifiers, trade organizations, and food manufacturers supported relisting of cornstarch on §205.606 due to the supply inconsistency. 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 2020 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, but the vote at the full Board meeting was split, with 6 in favor of removing and 9 in favor of relisting.

Since the previous sunset review, organic cornstarch has become widely and consistently available. 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. Nearly all public comments at the Spring 2025 meeting supported delisting cornstarch, given that there is a sufficient supply of organic cornstarch. A representative comment states, "the inclusion of corn starch under § 205.606 is no longer necessary because organic corn starch is now fully commercially available, in appropriate form, quality and quantity, to support the organic industry's cornstarch demands." Another commenter wrote, "Overall, the organic corn starch market is well-supplied, offering a diverse portfolio suitable for a broad range of applications. The transition from conventional to organic is technologically feasible, requiring only modest adjustments while maintaining product integrity and meeting clean label and organic certification standards." In addition, public commenters noted that there is a need for more market opportunities for organic corn producers. Board discussion at the Spring 2025 meeting was supportive of removing cornstarch from the National List, given the abundant supply of organic corn and organic cornstarch.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee proposes removal of cornstarch from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): there is sufficient supply of organic corn and organic cornstarch.

Subcommittee Vote
Motion to remove cornstarch from the National List
Motion by: Carolyn Dimitri
Seconded by: Dilip Nandwani
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 0

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 06/06/2012 (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 and 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 24-29).

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 certified organic or not. It should be noted that it is possible to produce 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 (2013 TR, lines 609-616).

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 (2013 TR, lines 563-565, 568-570, 582-585-591).

Discussion
In December 2018 the National Organic Program finalized rulemaking on the April 2015 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 were no suitable commercially available alternatives. During this same time period, the Subcommittee 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 several stakeholder written comments, it is generally held that glycerin is at least 99% pure, with the remaining balance of material being water and fatty acids that, perhaps, support processing.

The 2025 Spring public comments centered on three themes: (1) glycerin is synthetic, with commenters suggesting reclassification, (2) there is a robust supply of organic glycerin, so delist it, and (3) there was some support for keeping the listing as is.

Public commenters suggested that few handlers had nonorganic glycerin on their organic system plan: one certifier mentioned 34 handlers listed organic glycerin, and 11 listed nonorganic glycerin. A trade association reported that a member commented that less than 10 percent of the current supply of organic glycerin is being utilized, and another indicated that there is sufficient raw material to meet demand for organic glycerin production. A May 2025 search of the Organic Integrity Database revealed that there were 94 certified organic handlers with glycerin listed in the category of certified products under the handling scope.

Other concerns include the type of oil used to make organic and nonorganic glycerin: one commenter mentioned that nonorganic glycerin is derived from palm oil or upcycled oils, while organic glycerin is made from soy, flax or sesame. In other words, nonorganic glycerin production contributes to deforestation, while organic glycerin creates new markets for organic farmers.

Subcommittee discussion centered on whether there is a sufficient supply of organic glycerin and whether there is a sufficient number of suppliers.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee is divided regarding whether glycerin is compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, including whether there is sufficient supply of organic glycerin to meet the needs of organic handlers.

Subcommittee Vote
Motion to remove glycerin from the National List
Motion by: Carolyn Dimitri
Seconded by: Kyla Smith
Yes: 4 No: 4 Abstain: 0 Recuse: 0 Absent: 0

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 06/06/2012 (77 FR 33290); Sunset renewal notice published 07/06/2017 (82 FR 31241); NOP Proposed Rule to remove 01/18/2017 (82 FR 5431); NOP Final Rule to renew 07/06/2017 (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.

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

Discussion
Public comments from stakeholders during the previous sunset 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 of IOE. Those against relisting cited adequate organic supply but with little to no documentation.

This substance has an interesting history. During the 2015 Fall Board meeting, the Board unanimously voted to remove the substance from the National List. The National Organic Program (NOP) acted on the recommendation and published a proposed rule in January 2017, proposing to remove the substance from the National List. During public comment during the rulemaking process, several handlers pointed out that inulin-oligofructose() is a long-chain inulin from the root of the chicory plant, and was not the product the Board believed it was voting on (organic agave inulin). The two substances had different properties. Consequently, during final rulemaking in 2017 the substance was relisted. At the time of the next sunset in 2020, the Board did not propose removing this substance.

A 2025 search of the Organic Integrity Database yielded very few handlers with this specific substance included in the list of the certified products under the handling scope.

One Board member reported that a USDA-certified facility in Germany does not allow EU-certified organic inulin-oligofructose enriched to be used in infant formula because all components of infant formula need to be specifically approved for this use by the Food and Drug Administration (FDA).

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds inulin-oligofructose enriched compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove inulin-oligofructose enriched from the National List
Motion by: Carolyn Dimitri
Seconded by: Dilip Nandwani
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 0

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 06/06/2012 (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 (2014 TR, lines 6-9, 113-118). 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, the sap is digested by the insects and undergoes a chemical transformation, and is eventually secreted through the pores of the insect. When this secretion comes into contact with the air, it forms a hard shell-like coating over the larger swarm of insects (2014 TR, lines 45-49). The main areas of the world where shellac 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 orange shellac for use in fruit coatings. Some are allowed in organic production and some are not, and 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 dyes, 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. Some individuals may show allergic symptoms, and some vegetarians may consider it as an animal product not suitable for their consumption (2014 TR, lines 445-446). The TR also indicated that allergic reactions during processing is likely to stem from the solvents used in manufacturing as opposed to 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 in the 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 overwhelmingly 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 that is not suitable for consumption. Disclosing fruit coatings on labels is nuanced. The Subcommittee discussed this and determined that this is an Food and Drug Administration (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 are 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 corn zein to the National List.

The lack of information about whether orange shellac 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.

During the 2025 Spring meeting most commenters were in favor of relisting, noting its essentiality and lack of alternatives. One commenter in support noted the importance of orange shellac to be used in rotation with other fruit coatings.

Some commenters didn't state a position but instead urged the NOSB to consider and address the following concerns:

- Use of pesticides on the host trees. Orange shellac is produced from the secretions of the lac insect (*Kerria lacca*), which sucks the sap of several host trees. One commenter stated that there appears to be few pests that harm the host trees, so fewer pesticides are likely to be used in shellac production. That said, this commenter encouraged further exploration by the Board regarding this topic of pesticide use on the host trees.
- Consumer expectations that organic products would not be waxed, especially without notifying consumers of the use of wax.
- Labeling to ensure that vegan consumers were aware that the organic product contained a material that came from an insect.
- Clarification on which ancillaries are allowed in organic production.

To solve these concerns, commenters suggested a proposed annotation: "Contains only ancillary substances approved for organic production; presence must be labeled on individual items; label must include 'produced from excretions of the lac insect.'"

The Subcommittee discussed these concerns.

1. Use of pesticides: The Subcommittee agreed that the use of a pesticide is low. This is something that can be evaluated in future TRs.
2. Consumer expectations/labeling: As stated above, the Subcommittee believes that the identification of waxes on fruit would be the purview of the FDA. We also discussed the potential negative impact to organic producers if they are required to label while nonorganic producers are not. This could mislead consumers to think that the nonorganic product does not use orange shellac (or another wax), when in all likelihood that would be untrue.

3. Ancillaries: The TR identifies several substances that are used to produce orange shellac. The TR also states, “although many substances not permitted on organic food are used in combination with shellac in fruit coatings, there are also commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations (2014 TR, lines 181-183). The Subcommittee agreed that this is an area that could use more clarity and that a future TR using the new template would help the Subcommittee to review ancillaries according to the 2016 recommendation.

The Subcommittee asked one question during the Spring 2025 comment period pertaining to essentiality. The comments received indicated its use particularly as a fruit coating and outer chocolate coating.

We did not receive any comments regarding the availability of organic orange shellac.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds orange shellac compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove orange shellac from the National List
Motion by: Kyla Smith
Seconded by: Amanda Felder
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 0