

**Sunset 2017 Review
Meeting 2 - Review
Handling Substances §205.605(a)
October 2015**

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Reference: 7 CFR 205.605 *Nonagricultural* (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

§205.605(a) Nonsynthetics allowed:

[Acid, Alginic](#)

[Acid, Citric](#)

[Acid, Lactic](#)

[Attapulgite](#)

[Bentonite](#)

[Calcium carbonate](#)

[Calcium chloride](#)

[Dairy cultures](#)

[Diatomaceous earth](#)

[Enzymes](#)

[Flavors](#)

[Kaolin](#)

[Magnesium sulfate](#)

[Nitrogen](#)

[Oxygen](#)

[Perlite](#)

[Potassium chloride](#)

[Potassium iodide](#)

[Sodium bicarbonate](#)

[Sodium carbonate](#)

[Waxes \(Carnauba\)](#)

[Waxes \(Wood rosin\)](#)

[Yeast](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Acid, Alginic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Alginic acid is derived from wild harvested seaweeds. Increasing demand for alginic acid and alginates has led to some concerns regarding potential for overharvesting of these wild seaweeds.

Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in pure alginic acid. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, it is clear that the free acid form does not appear in nature. (2015 Technical Review – Alginic Acid, Lines 283-286). In the 1995 TAP review for Alginic Acid, the reviewers determined that the material was non-synthetic. However, given the draft Classification of Materials document and the information presented in the 2015 TR, it could be suggested that alginic acid is synthetic.

There has been recent research into production of alginic acid and alginates from a biological fermentation process. However, this process does not currently produce sufficient quantities to be commercially available, (2015 Technical Review – Alginic Acid, Lines 299-300).

FDA limits the use of alginic acid as a stabilizers, emulsifier and thickener in soups and soup mixes.

The Handling Subcommittee had brought forth the following questions for public comment:

1. Please bring forth any information regarding the effect of alginic acid and/or alginates on human digestion.
2. Is alginic acid in use in organic handling and should it have its own National List listing? What are the non-synthetic alternatives in specific handling uses?

Public comment was mixed regarding the relisting of alginic acid. Those in favor of its relisting note the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting, and assert that the properties imparted by alginic acid are essential for some processed food formulations. Those opposed expressed concerns regarding the concentration of heavy metals in the wild harvested seaweed and the fact that alginic acid is used primarily to enhance texture in foods, and is therefore not compatible with OFPA criteria.

The Handling Subcommittee proposes that alginic acid remain on the National List. However, the Handling Subcommittee is bringing forward a separate proposal to change the listing from 205.605(a) to 205.605(b) due to the determination that alginic acid would likely be classified as synthetic under the new draft Classification of Materials document.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of alginic acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Acids – Citric, Lactic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: 1995 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Citric acid is very widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. It is an ingredient in dietary supplements and a nutrient, sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), raising agent and emulsifying salt for many other products. It is also used to improve baking properties of flours, and as a stabilizer.

Lactic acid appears on the National List, 7 CFR Part 205.605(a), without an annotation. Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008).

Common uses include, but are not limited to:

1. In sugar confectionery, it is used in continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and Mesenteric groups of bacteria.
6. It is used in jams, jellies and frozen fruit desserts.
7. In dairy products such as cottage cheese, the addition of lactic acid is preferred to fermentation.
8. Used in imitation dairy products such as cheese and yogurt powder.
9. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.
10. Use of buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
11. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
12. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
13. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.

Approved Legal Uses of the Substance:

Citric acid is listed under 21 CFR Part 184.1033 as Generally Recognized as Safe (GRAS). The listing allows its production from lemon or pineapple juice; through microbial fermentation from *Candida* spp.; or by solvent extraction from *Aspergillus niger* fermentation. It is allowed for use in food with no limitations other than good manufacturing practice. Additionally, sections 21 CFR 173.160 and 173.165 list *Candida guilliermondii* and *Candida lipolytica* as allowed organisms for production of citric acid through microbial fermentation. The regulation requires that the citric acid produced conforms to the specifications of the Food Chemicals Codex (Food Chemicals Codex, 2010).

Section 21 CFR 173.280 covers the solvent extraction purification of citric acid from *Aspergillus niger* fermentation. This process is discussed in detail under Evaluation Question #1 in the section on recovery of citric acid. Current good manufacturing practice (GMP) for solvents results in residues not exceeding 16 parts per million (ppm) n-octyl alcohol and 0.47 ppm synthetic isoparaffinic petroleum hydrocarbons in citric acid. Tridodecyl amine may be present as a residue in citric acid at a level not to exceed 100 parts per billion.

The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inert). The EPA allows citric acid as an active ingredient in pesticide products registered for residential and commercial uses as disinfectants, sanitizers and fungicides (EPA R.E.D. 1992) and it is exempt from tolerances per 40 CFR 180.950. Products containing citric acid in combination with other active ingredients are used to kill odor-causing bacteria, mildew, pathogenic fungi, certain bacteria and some viruses, and to remove dirt, soap scum, rust, lime, and calcium deposits. Citric acid products are used in facilities, and in or on dairy and food processing equipment.

Lactic acid is a “Direct Food Substance Affirmed as Generally Recognized As Safe,” or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061

Discussion: The NOSB in its initial request for public comment did not ask for any specific information from stakeholders.

While there were not specific questions asked of the public, the subcommittee did receive several comments from various stakeholders.

Several commenters in favor of relisting stated:

- One dairy company stated that they use citric acid in the fruit on the bottom of our yogurts to adjust the pH for food safety reasons. While we choose this ingredient for its functional effect, it does also have an impact on the flavor of the product. If we were no longer able to use citric acid, we would have a considerable reformulation challenge to achieve both the technical functionality and the consistent flavor profile that we are aiming for.
- Citric acid is a natural occurring substance but classified as a synthetic due to chemical processing through fermentation. Citric acid has GRAS status by the FDA. Citric acid has many uses in food production. It has a history of safe use in organic foods dating back to 1995. Natural citric may be isolated from organically grown fruit but to our knowledge is not commercially available in the quantities that would be required to service the growing organic sector. Citric acids status as a synthetic should be renewed.
- Our suppliers use citric acid in canned artichoke hearts, water chestnuts, pimentos, tomatoes and orange peel. Citric acid is use to adjust the pH of many of these ingredients as well as maintaining the quality and control of microorganisms. Alternate acids are not more natural and do not give the same flavor profile. We always confirm that the citric acid used by our suppliers is produced by microbial fermentation of carbohydrate substances. It is used for organic fruit processing and spreads as a pH adjuster. The company has been certified for 13 years and products are sold in all 50 states. There are no other alternatives that will work.
- Citric acid is critically essential to our organic processing operation.
- It provides the needed acidity and preservation, including protecting the safety of the food by keep pH below 4.6.
- We use it in many organic products, including baby food, breakfast cereals, frozen desserts, frozen entrees and certified organic personal care products.
- Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with milk. It functions as a flavor agent, preservative and acidity adjuster in foods. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation. Lactic acid is listed as GRAS at 21 CFR 184.1061 and has been shown to be safe for use in foods. We are not aware of any organic alternative to lactic acid. These three acids are important components of organic production and have unique functionality that makes them essential in many organic formulations. As all three lack organic alternatives, are consistent with organic principles and safe for use in food, we strongly urges that they be relisted on the National List at Section 205.605(a).
- We advocate keeping this material on the National List.

- Lactic acid is used in a soy based cheese alternate that we currently use. The lactic acid is present for flavor development and control of microorganisms. Alternates are not more natural and do not have the same flavor profile.
- Utilized in a wide variety of organic products. Shows the same characteristics of citric acid in providing the acidity in a product and helping to preserve the organic product. The acid profile is different than citric acid and is generally well desired in dairy products. Additionally, lactic acid is a naturally occurring element of a number of dairy products.
- One certifier stated that, Lactic Acid is primarily used for carcass wash and many of our meat processors use lactic acid.
- Commenter who opposed the relisting stated: Citric acid should be re-classified as synthetic.

While there are concerns about the relisting of this material, citric acid has been used for many years as a food processing and based on the overwhelming majority of public comments is necessary in the organic industry for proper pH control in many foods.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of Citric Acid.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Acids – Citric and Lactic from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: non given

Vote in Subcommittee

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Attapulgit

Reference: 205.605(a) – as a processing aid in the handling of plant and animal oils.

Technical Report: 2010 TR

Petition(s): 2009 Attapulgit

Past NOSB Actions: 04/2011 NOSB recommendation

Recent Regulatory Background: Added to National List effective 08/03/2012 [[77 FR 45903](#)]

Sunset Date: 08/03/17

Subcommittee Review

The petition (2009) is a comprehensive 158 page document with extensive literature review. Petition

included request for use in animal feed. Attapulgite is one of the so-called Fullers Earths used since biblical times. Modern extraction is by open pit which does have adverse environmental impact, however environmental and mining regulations are in place to remediate or mitigate impacts.

The NOSB recommendation of April 29, 2011 includes the following: “This material was petitioned to the NOSB for use as a processing aid in the production of organic plant and vegetable oils, as a natural substance used to bring oils to a marketable condition through removal of impurities such as undesirable odors, colors, and trace metals, etc. The Handling Committee voted 6 yes, 0 no, and 1 absent for the listing of this material, with the annotation “allowed as a processing aid in the handling of plant and animal oils”, to the National List, thereby recommending that it be listed. The full board voted that attapulgite be classified as non-synthetic and approved listing it with the annotation above at its April 2011 meeting.

This material satisfies the OFPA evaluation criteria.

Public comment strongly supports continued listing of this material.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Attapulgite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Tom Chapman

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Bentonite

Reference: 205.605(a)

Technical Report: 1995 Kaolin Clay and Bentonite

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)),

Sunset Date: 06/27/17

Subcommittee Review

Both bentonite and kaolin are mined by open pit mining and are thus subject to environmental mitigation and monitoring by other agencies.

The subcommittee sought public comment to specifically address the ongoing need for bentonite and

kaolin and received clear indication from a range of stakeholders that it continues to be necessary. There was no public comment in opposition.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Bentonite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Lisa de Lima

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Calcium carbonate

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Subcommittee Review

Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner and to remove acidity in wines.

Public comment indicated broad support for continued listing of this material and there was no opposition to continued listing.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None Given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Tom Chapman

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Calcium chloride

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Specific Use: Used in a wide variety of food processing applications, including as a meat tenderizer and flavor enhancer.

Summary: Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic. However, Dow (the major supplier) and other producers use synthetic chemicals during the purification of the brine.

In the Dow process, which accounts for 75% of the calcium chloride production in the U.S. (Kemp and Keegan, 1985). The starting material is a natural brine solution that is pumped out from underground salt beds. Synthetic materials are used in the purification process, but without changing the chemical structure of the material.

There was very little public comment on this material. One group did urge the NOSB to continue with the listing.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production

Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Dairy cultures

Reference: 205.605(a)

Technical Report: 1995 TAP; [2014 TR for Ancillary Substances](#)

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Use: Dairy cultures are used by organic dairy processors to make yogurt, cheese, cultured sour cream and other fermented milk products.

Manufacture: There are a variety of ways a dairy culture can be produced but generally a dairy or other medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produces different flavor compounds and in turn produced different traditional dairy products.

International: Dairy Cultures and or Microorganisms are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex organic standards.

Ancillary Substances: Ancillary substances are present and will be addressed in a separate review.

There is no current TR however there is a TAP from the original 1995 listing and there was a 2014 TR for microorganisms, a related listing. There is no original petition on file. The 2014 TR for microorganisms should be sufficient for a review of ancillary substances in dairy cultures.

Discussion: The NOSB requested information related to (1) the need of a separate listing given dairy cultures being covered by the broader listing of microorganisms, and (2) on ancillary substances present. Comments were received from trade associations, industry, certifiers and a technical organizations. All comments were generally in favor of continued allowance of dairy cultures. Most industry, while agreeing the dairy cultures were covered under microorganisms still wanted a separate listing for dairy cultures. One commenter wanted to wait till the ancillary substance trial period with microorganisms was complete to make the change. Several certifiers and a technical organization agreed that the listing of dairy cultures was redundant to microorganisms and could be removed. Several ancillary substances were submitted from the public.

While the NOSB Handling Subcommittee notes the separate listing for dairy cultures is redundant with the microorganisms listing, the subcommittee found no issue with continued listing. The substance satisfies OFPA criteria.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Dairy Cultures from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Diatomaceous earth

Reference: 205.605(a) - food filtering aid only

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

NOSB Sunset Review November 2005, Re-listed. NOSB Sunset Review April 2010, re-listed.

Diatomaceous earth is used as a filter aid in production of syrups and other products. Diatomaceous earth is not in the final organic product.

The TAP was a 3 person panel. One reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify “food grade” quality of DE. DE is also used in swimming pool filters which is not a food grade form. All DE is removed during filtering of water, vegetable oils, sugars, syrups, honey, beer etc. DE is fossilized remains of diatoms in marine sediments. As with bentonite, attapulgite and kaolin, human health can be impacted if excessive amounts are breathed into lungs over an extended period of time.

Diatomaceous earth satisfies the OFPA criteria

Public comment indicates a widespread use of Diatomaceous earth as a filter aid.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Diatomaceous earth from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Enzymes

Reference: 205.605(a) - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Technical Report: 1995 TAP; 1996 TAP; 2011 TR; [2014 TR for Ancillary Substances](#)

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset [recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Use: Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients. Commonly used in the production of sweeteners, chocolate syrups, bakery products, alcoholic beverages, precooked cereals, infant foods, fish meal, cheese and dairy products, egg products, fruit juice, soft drinks, vegetable oil and puree, candy, spice and flavor extracts, and liquid coffee, and are used for dough conditioning, chill proofing of beer, flavor development, and meat tenderizing. Enzymes can also be used to help reduce production costs, reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-148)

Manufacture: Microbial rennet describes a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic agriculture.

Bromelain is extracted from the pineapple's fruit, stem, peel and juice. First the fruit is crushed. Bromelain is then further isolated, separated, and purified using chromatography, ultrafiltration, precipitation, freeze drying, and other procedures. (TR 2011 494-496)

Pectinase is produced by the controlled fermentation of nonpathogenic and nontoxicogenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

International: The use of enzymes is permitted in organic processing in Canada, EU, IFOAM and in CODEX.

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

“Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort, 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production,

but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014).”

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

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

Discussion: At the first posting for Enzymes the NOSB asked the public to provide input on a chart of existing ancillary substances and to identify additional ancillary substances that may be used in the formulations of enzymes. The following additional ancillary substances were identified through public comment.

An additional ancillary substance proposal will be reviewed at a later date.

Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.

Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.

Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.

Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.

pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Discussion: A variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

Evaluation question #9 in the 2011 TR does not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

Evaluation question #10 in the 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals (Tucker and Woods, 1995). FDA reports it is not aware of any allergic reactions associated with the ingestion of food containing enzymes commonly used in food processing (FDA, 1995). (TR 2011 752-758).

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Enzymes remain on the National List.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Enzymes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Flavors

Reference: 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Technical Report: 2005 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Use: Natural flavors are derived from natural sources and are compound substances derived from plants, herbs, spices, botanicals and other substances. They are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product.¹ The significant function of flavors must be to impart flavor and not nutritional. The FDA defines Natural Flavors in 21 CFR 101.22 as:

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or

¹<http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in 172.510 of this chapter.

Manufacture: Flavors can be derived via several different methods. Distillates are a clear, flavorful liquid produced from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture. Essential oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing. Essential oil isolate is an isolate of an essential oil. Isolates are a chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass. Oleoresin are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. Single flavor chemicals are single molecules that provide flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A Compounded Flavor is a mixture of ingredients such as extracts, essential oils and natural isolates.² Processed flavors, also known as reaction flavors, are ones which are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins and fat, which must then be heated for a length of time to yield the desired profile.³

Flavoring components as listed here can typically make up 5-100% of the formulation of a flavor. The remaining components can be carriers, preservatives and/or solvents that also act as carriers that can make up 0-95% of a flavor and non-flavor constituents to stabilize or maintain the flavor. Nonsynthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" or containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non flavoring constituents from the named product but still impart the characteristic named flavor.

International: Natural/Nonsynthetic Flavors are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex Standards.

Ancillary Substances: Ancillary substances are present in flavors and are reviewed for compliance

²<http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

³ http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf

against the criteria in the annotation: “must not be produced using synthetic solvents and carrier systems or any artificial preservative.” Flavoring constituents (i.e., ingredients that impart the flavor) are considered proprietary by flavoring companies and are not normally disclosed. No specific ancillary substances were submitted as part of public comment.

Use of organic Flavors since the 2010 Sunset Review: The NOSB completed Sunset Review of Flavors for re-listing and on September 3, 2010 and stated:

The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors...The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was practical to individually list flavors on the National List, so chose to relist the category as a single listing...In order to avoid unnecessary disruption to industry, we are recommending relisting of Flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011 the NOP issued a Policy Memorandum on Use of Natural Flavors

This states in part:

In 1995 the NOSB reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals....The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this organic market will continue to grow and develop...

On November 6th 2014, the NOP received a petition from the Organic Trade Association to change the Flavor annotation to read:

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative

A separate proposal relating to this petition will be considered at the Fall 2015 NOSB meeting.

Discussion: The NOSB requested additional information relating to supply of organic flavors, commercial availability, continued listing, essentiality, standardized compliance document, and Ancillary substances. A large volume of comments were received from Industry, trade associations and ACAs supporting the continued listing of natural flavors. Several ACA’s stated a standardized compliance document for flavors would be helpful. One interest group and one ACA noted that flavors could be certified organic but contain no organic flavoring constituents if the other ingredients (i.e., carriers) were organic and made up over 95% of the formulation. One interest group stated flavors should not be added to the National List if their primary function is flavoring and cited 205.600(b)(4), however 205.600(b)(4) is not germane to the flavor listing as it only applies to processing aids and adjuvants. The HS will address the 2010 NOSB recommendations in the proposal accompanying the November 2014

petition to change the natural flavor annotation.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. The Handling Subcommittee recommends the renewal of flavors on the national list.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Flavors from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

Vote in Subcommittee

Motion by: Tom Chapman

Seconded by: Jean Richardson

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Kaolin

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Bentonite and kaolin are both mined by open pit mining and thus, as with attapulgite, adverse environmental impacts are possible.

The subcommittee sought public comment to specifically address the ongoing need for Bentonite and kaolin and received clear indication from a range of stakeholders that it continues to be necessary.

There was no public comment in opposition

This material satisfies the OFPA criteria.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Kaolin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Magnesium sulfate

Reference: 205.605(a) - nonsynthetic sources only.

Technical Report:1995 TAP (Processing); 2011 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Magnesium sulfate is used as a dietary supplement and to enhance flavor in production of tofu.

Public comment indicated that this material is used by a number of processors, and there was no opposition to continued listing

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None Given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Nitrogen

Reference: 205.605(a) - oil-free grades.

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Nitrogen is colorless, odorless gas. Cryogenic distillation is the most economic and high purity method for separating nitrogen from air. Basically air is compressed, cooled, and then filtered.

It is used to displace oxygen and thereby reduce oxidation of product during processing, storage and packaging. Can be used in the flash freezing of foods. Also functions as a propellant when used under pressure and doesn't have ozone-depleting properties.

There has been no public comment opposed to the relisting of nitrogen. Public comment in support of relisting was submitted by a number of food processors, ingredient suppliers, and associations.

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Nitrogen remain on the National List.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Nitrogen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Oxygen

Reference: 205.605(a) - oil-free grades.

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Oxygen is colorless, odorless gas. Used in the processing of olives and modified atmosphere packaging.

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Oxygen remain on the National List.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Oxygen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Perlite

Reference: 205.605(a) -for use only as a filter aid in food processing.

Technical Report: 1996 TAP

Petition(s): N/A

Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

NOSB Sunset Recommendation November 2005 to re-list. NOSB Sunset Review April 2010 re-listed. No issues raised in public comment.

Perlite is amorphous volcanic glass. It is an excellent filter aid and often substitutes for DE in filtering beer.

The subcommittee received clear indication from a range of stakeholders that perlite continues to be necessary. There was no public comment in opposition

This material satisfies the OFPA criteria.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Perlite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None Given

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Potassium chloride

Reference: (a) Nonsynthetics allowed:

Technical Report: 1995 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Potassium chloride is a common, naturally occurring mineral. According to the Food & Drug Administration, generally recognized as safe (GRAS) affirmed uses of potassium chloride in foods are as: a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. However, potassium chloride is generally used for two main purposes in food products. The first is to provide potassium enrichment to foods. The second is as a salt replacer to reduce the sodium content in foods.

There was very little public comment on this material. One group did urge the NOSB to restrict supplemental vitamins and minerals to only those required by law. Another commenter urges the board to continue with the listing of this material.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production.

Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Potassium iodide

Reference: 205.605(a)

Technical Report: 1995 TAP; 2011 TR; 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Potassium iodide and ethylenediamine dihydroiodide are commonly used as synthetic forms of iodine in trace mineral supplements. Potassium iodide is the most commercially significant iodide compound. It is produced industrially by treating potassium hydroxide with iodine. Iodine is essential in healthy thyroid hormonal function, governing key enzymes involved in metabolic processes.

According to FDA, potassium iodide may be used as food additive and can serve the following functions:

- A nutrient in table salt as a source of iodine
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment.

There was very little public comment on this material. One group urged the NOSB to restrict supplemental vitamins and minerals to those required by law. Another group urged the board to continue the listing for this material.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium iodide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production.

Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Sodium bicarbonate

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

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

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

Sodium bicarbonate is approved for use in the following organic standards: European Union, IFOAM, Canada, Japan, and Codex.

Discussion: The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their previous two Sunset Reviews. There was more information in the original TAP for this material than for sodium carbonate. The original TAP, previous subcommittee reviews, 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 Sunset Reviews. The current Sunset Review and public comments (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling. The original TAP did mention that the primary source material (sodium sesquicarbonate) is from a mined source.

During the 1st public comment period there were several comments in support of its continued listing on the National List. One organic stakeholder survey showed several responses stating that it is a primary component of baking powder and is still used widely in a variety of baked goods. Several organic handlers commented that it is essential as a leavening agent.

The subcommittee would see no reason to delist this material at this time.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sodium bicarbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

Vote in Subcommittee

Motion by: Harold Austin

Seconded by: Tracy Favre

Yes: 0 No: 7 Abstain: 0 Absent: Recuse: 0

Sodium carbonate

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Sodium carbonates are used as raising (leavening) agents. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a stabilizer. It is essential for the characteristic color in the baking of German pretzels and lye rolls. Sodium carbonate is the material used that gives the pretzels and lye rolls their brown crust without burning. It is also used in the making of ramen noodles. It can also be used as a neutralizer for butter, cream, fluid milk, and ice cream. Other uses of sodium carbonate include in the processing of olives prior to canning and in many cocoa products.

Sodium carbonate is produced in North America from natural deposits of trona ore (90% sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then allowed to evaporate to form sodium carbonate monohydrate crystals. This is considered to be the most sustainable form of producing sodium carbonate. Also, in California the two sodium carbonate materials can be produced from similar methods using natural brine (Searles Lake). There are other methods used, but they are considered to be less environmental friendly. This is a sodium salt.

Sodium carbonate is approved for use in the following organic standards: the European Union, Japan, Canada, IFOAM, and Codex.

Discussion: The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their

previous two Sunset Reviews. There was more information originally provided for sodium bicarbonate than for sodium carbonate. The original TAP, previous subcommittee reviews, 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 Sunset Reviews. The current Sunset Review and public comments (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling.

During the 1st public comment period it was mentioned that this is essential for use in organic starches. Also mentioned that when used with alginates it helps to sequester calcium, also help alginates in gelling and is found naturally in the environment. Over-all public comment supported the relisting of this material. There were no comments against relisting.

The subcommittee would see no reason to delist this material at this time.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sodium Carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:
None given

Vote in Subcommittee

Motion by: Harold Austin

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Waxes (Carnauba)

Reference: 205.605(a) Waxes – nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: 1996 TAP; 2014 TR - Carnauba Wax

Petition(s): N/A

Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Carnauba wax is an exudate from the leaves and buds of the palm tree *Copernicia cerifera*, also known as *Copernicia prunifera*, which grows almost exclusively in northeastern Brazil. It is used to coat fruit and vegetables, candies and as a base for chewing gum. It is touch and lustrous with a high melting point.

The main functions of this and other coatings is to retard transpiration and thus prevent water loss and to protect the plant from fungal attacks, thus postponing decay.

During the creation of the National List, Carnauba was included in the review of "Fruit Waxes" under the Crops Committee because it was considered a post-harvest handling substance. It was never classified as either agricultural or non-agricultural at that time. When the rule came out it was on the Handling section of the National List at 205.601(a).

A new Technical Report (TR) was commissioned to determine the classification, provide updated information since the very sketchy 1996 TAP, and to look at ancillary substances. This TR has led the Handling Subcommittee to conclude that this is an agricultural product and should be on 205.606. A separate proposal is being put forward for this purpose.

While there is some organic carnauba wax on the market, there was not a consensus from commenters that there is enough available to meet demand. Public comment indicated that carnauba is commonly used in conjunction with other waxes, other ingredients on the National List, and some possible ancillary substances in formulations of finished products. However raw carnauba is sold without any ancillary substances (2014 TR, Combinations of the Substance).

Public comment was primarily in favor of keeping carnauba and other coatings on the National List and no new information was provided about any of the OFPA criteria. For the specific question posed about re-classification of this to agricultural, no comment was received opposing this suggestion. In regard to the ancillary substance question, no ancillary substances were suggested for the raw carnauba, but concern was raised by public interest groups concerning a substance, morpholine, that may be used in formulated blends. Since there is ample availability of formulations that are fully NOP compliant for their ingredients according to the TR, this issue does not need further action.

One other point brought up frequently in public comment was the desire for labelling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labelled, but this is interpreted in a general way so that the label may only be on a shipping container not visible to consumers or on general signage in a store that does not specify which products are waxed. The Handling Subcommittee recognizes this issue and urges voluntary labelling of produce coatings, but is unable to put forward an additional labelling annotation.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Carnauba Wax from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Waxes (Wood rosin) (sic. Resin)

Reference: (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: 1996 TAP; 2014 TR - Wood Rosin

Petition(s): N/A

Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

This listing is in need of a technical correction because the substance is wood rosin and not wood resin. As the 2014 Technical Report (TR) notes on lines 22-24, "Wood resin is the raw material exuded by coniferous trees before it undergoes distillation and refinement steps as described in this report". Wood Rosin is recognized in 7 CFR §160.12 and known by the CAS number 8050-09-7. The Subcommittee recommends that this Technical Correction be made.

The Technical Report (TR) for this substance provided considerable background on the combinations, uses and functions of Wood Rosin as a coating material. It appeared to satisfy the criteria from the rule as far as effect on human health and the environment.

In regard to the ancillary substance question, no ancillary substances were suggested for wood rosin by itself, but concern was raised by public interest groups concerning the substance morpholine that may be used in formulated blends. Since there is ample availability of formulations of other fruit coatings that are fully NOP compliant for ingredients according to the TR, this issue does not need further action.

One other point brought up frequently in public comment was the desire for labelling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labelled, but this is interpreted in a general way so that the label may only be on a shipping container not visible to consumers or on general signage in a store that does not specify which products are waxed. The Handling Subcommittee recognizes this issue and urges voluntary labelling of produce coatings, but is unable to put forward an additional labelling annotation.

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Waxes, Wood Rosin (sic resin) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:
None given

Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Yeast

Listing: 205.605(a) - When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

Technical Report: 1995 TAP (Smoked Yeast); 1995 TAP (Baker's Yeast); 2014 TR

Petition(s): 2006 Petition; 2010 Petition Supplement; 2010 Petition memo

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 2010 sunset [recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Subcommittee Review

Yeast underwent a significant review that led to a change in the listing in 2010. A new Technical Report (TR) was commissioned in 2014 to review the current status of various yeasts and look at the ancillary substances. Since there are many types of yeast and many uses for them, the NOSB at the first posting sought information about current availability of all forms of yeast.

All commenters recognized that yeast is an important substance on the National List, and no new information was submitted relevant to any of the OFPA criteria. Public comment from yeast users, suppliers, and certifiers indicated that there are some forms of yeast that are not yet available organically. These include torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. One supplier suggested that dry yeast could be removed from the list while others forms stayed.

The following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. One new ancillary substance was suggested for addition to the chart presented with the first posting: starch. One substance on the chart, BHT, was questioned as problematic for exposure. No specific answers were provided for the first posting question #3. "Information is sought on specifically why any of the ancillary substances in yeast do not meet the review criteria in the organic rule."

Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Yeast from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0