

Sunset 2018 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), §205.605(b), §205.606
April 2016

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2018. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2016 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2016 public meeting. These comments should be provided through www.regulations.gov by April 6, 2016 as explained in the meeting notice published in the Federal Register.

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

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

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

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments Addressing the Availability of Alternatives:

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at §205.606.

For nonorganic agricultural substances on section §205.606, the NOSB 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 would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 6, 2016 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

(Linked below)

[Agar-agar](#)

[Animal enzymes](#)

[Calcium sulfate-mined](#)

[Carrageenan](#)

[Glucono delta-lactone](#)

[Tartaric acid](#)

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

[Cellulose](#)

[Potassium hydroxide](#)

[Silicon dioxide](#)

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

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

(2) [Beta-carotene extract color](#)

Agar-agar

Reference: §205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Agar-agar has been used as a food additive for over 350 years. Current uses in food include: stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. It can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. Useful characteristic of agar-agar include that it can withstand high temperatures, and since it is practically tasteless and doesn't require the addition of cations to form gels, it doesn't interfere with taste profiles. It can be used in foods in combination with other thickening or gelling agents. It is classified as GRAS.

Manufacture:

Agar-agar is derived from red algae. The main species harvested are *Gelidium* and *Gracilaria*, the second of which can be cultivated. After harvesting, the algae are cleaned with water, dried in the sun, pressed into bales and shipped to processors for agar-agar extraction. Prior to extraction the *Gracilaria* species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution) followed by rinsing with water and sometimes a weak acid to neutralize the alkali. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides. This chemical change produces agar-agar with increased gel strength. Without this pretreatment, the gels extracted from *Gracilaria* species would be too weak for most food applications. (TR 2011, 165-176)

After pretreatment, the algae are placed in tanks for the extraction, via hot water pressure, and then filtration. The last step is to remove water from the gel either through a freeze thaw process or by mechanical pressure. The gels are then dried with hot air resulting in a finished product of flakes, strips, or powder.

Based on this manufacturing information, the Handling Subcommittee acknowledges that a reclassification of agar-agar might be needed in the future once the NOP finalizes the Guidance for Material Classification.

International:

Agar-Agar is permitted for use in organic production by CODEX, the Commission of the European Communities, IFOAM, and Canada.

Discussion:

The 2011 TR did not find the substance to be harmful to human health, additionally the report stated that no excessive levels of heavy metals or other contaminants have been reported in agar-agar. In regards to whether the substance may be harmful to the environment or biodiversity, the TR stated there is limited evidence to suggest that the harvesting of agarophytes (algae used to make agar-agar) may be harmful to biodiversity. Additionally, harvesting wild agarophytes may also reduce biodiversity on nearby beaches. The TR concludes through that no studies were found to indicate whether or the not the harvesting of agarophytes in particular is harmful to the biodiversity or nearby beaches or in the

algae beds themselves (TR 2011 296-312).

The NOSB is in the process of reviewing the use of all marine plants currently on the National List, for which a limited technical report will be requested. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

Additional information requested by NOSB:

The 2011 TR provides possible agricultural alternatives to agar-agar in food applications, including: (1) gelling agents, such as pectin (high methoxy), gelatin, unmodified starches, and konjac flour; and (2) thickeners, emulsifiers, and stabilizers, such as vegetable gums (Arabic, locust/carob bean, guar), unmodified starches, tragacanth gum, konjac flour.

1. Have there been any new developments with alternatives to agar-agar?
2. Why is agar-agar used instead of alternatives? What are the unique characteristics that make it essential to organic handling?

Animal enzymes

Reference: §205.605(a) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Technical Report: [2000 TAP](#), [2011 TR](#), [2015 TR](#)

Petition(s): NA

Past NOSB Actions: [11/2000 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

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 (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-142)

Animal enzymes, such as rennet, are used as a coagulant to curdle milk, to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect. For example, the amount of animal-derived rennet used to clot milk is 0.036 percent. (TR 2011 727-728)

Manufacture:

Traditionally the fourth stomach or other organs of goat kids or calves are dried, cleaned, and then sliced into pieces, before being stored in either whey or saltwater. Vinegar or wine can be added to lower the pH. After allowing the solution to sit for a few days, it is filtered repeatedly. A small amount of boric acid is added to the filtrate. In industrial production the stomach is minced and the pH adjusted by adding hydrochloric acid and sodium phosphate. (TR 2011 444-458)

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.

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

Discussion:

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 associate with the ingestion of food containing enzymes commonly used in food processing (FDA, 1995). (TR 2011 752-758).

There are no true alternatives to animal enzymes. Enzymes can only be substituted with another enzyme with the same function. One alternative to animal derived rennet for the production of cheese is genetically engineered chymosin, which is incompatible with organic food handling due to excluded methods.

The 2000 TAP review for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Additional information requested by NOSB

1. Are any animal derived enzymes currently being produced from organic livestock? If yes, on what scale?
2. In the 2011 TR on Animal Enzymes, manufacture of the substance is focused on rennet. Please submit information if the manufacture of other types of animal enzymes differ from rennet.

Calcium sulfate-mined

Reference: §205.605(a)

Technical Report: [1996 TAP](#), [2001 TAP](#)

Petition(s): [2000](#)

Past NOSB Actions: [09/1996 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

- Used as a coagulant in tofu manufacturing. Calcium sulfate is essential to soft and silky tofu types.
- Yeast food and dough conditioner, water conditioner
- Firming agent (in canned foods)
- Gelling ingredient
- Used in baking powder
- Sequestrants, filler, carrier, pH buffer, abrasive agent
- Cosmetics and toothpaste

Manufacture:

Calcium Sulfate can be obtained from natural sources or synthetic sources. The listing restricts calcium sulfate to mined sources and mined gypsum is the primary source. After mining crude gypsum is ground and separated. It is normally sold as pure but may contain impurities of calcium carbonate and natural occurring silica. Calcium sulfate is GRAS.

International: IFOAM – restricted “For soybean products, confectionery and in bakers’ yeast” but not restricted to mined sources. CODEX – restricted to “Cakes & biscuits/soy bean products/bakers yeast. Carrier,” but it is not restricted to mined sources. Japan – restricted to “Limited to be used as coagulating agent or used for the confectionary, the processed beans products or bread yeast,” but it is not restricted to mined sources. Canada – restricted to “as a carrier for cakes and biscuits; for soybean products; and for bakers’ yeast” with the restriction, “Sulfates produced using sulfuric acid are prohibited.” EU - restricted to “use as a coagulation agent and carrier only” but is not restricted to mined sources. Mexico – restricted to “Acidifiers, acidity, anti-caking agent, antifoam, filler and coagulant,” but is not restricted to mined sources.

Ancillary substances: None reported in 2001 TAP

Discussion:

Information from the petition and 2001 TAP review maintain that this material is consistent with OFPA criteria. Unless new information is provided from the public about impacts to the environment or human health this material should be renewed.

Additional information requested by NOSB:

None

Carrageenan

Reference: §205.605(a)

Technical Report: [1995 TAP](#), [2011 TR](#); [2016 Limited Scope TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987 –misspelled as ‘carageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Carrageenan (CAS # 9000-07-1) is a generic term referring to a family of linear polysaccharides (i.e., complex carbohydrate chains) that are extracted from species of red seaweeds (Class *Rhodophyceae*). It is an FDA-approved direct food additive with an average molecular weight of 200-800 kDa, and may be referred to as “undegraded” or “native” carrageenan in the literature. The actual molecular weight of food-grade carrageenan represents a spectrum of molecular weights that are naturally present in live seaweed.

Carrageenan can function as a bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, or thickener. It can promote gel formation and thicken, stabilize and improve palatability and appearance of foods. It is typically used at a rate ranging from 0.03% to 0.75%, and its most common uses are in dairy products, non-dairy “milk” analogs, meats, and drink mixes. It has been used in food processing for more than 600 years.

During the last Sunset Review in 2012, the NOSB discovered that there was a lot of controversy surrounding this ingredient, both among the scientific community and the public. The scientific community disagreed over the research methodology used in studies and meta reviews that were not always consistent with how carrageenan behaves when ingested in food. Several public interest organizations were taking sides with one scientific group's approach over the others because of concerns that carrageenan caused inflammation or worse. The NOSB could not thoroughly investigate these issues within the very short period of time between the sunset announcement and the vote to renew. The members of the 2012 Handling Subcommittee did promise the public to do a more thorough analysis at the time of the next sunset review.

Therefore the Handling Subcommittee commissioned a Limited Scope Technical Report (TR, see link above) to supplement the one that was done in 2011. This report focused on the effects of the substance on human health: Evaluation Question #10. Very specific questions were posed about the research methodology regarding the molecular weights of carrageenan, the relative value of *in vivo* vs. *in vitro* studies, and the newest studies since the last TR was done in 2011.

The TR came back with the following statement, “Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature.” (lines 173 - 174). And this, “ However, since different animal species, different animals within the same species, and different human intestinal cell lines have produced different experimental results, it is reasonable to expect that humans may also experience varying degrees of sensitivity to carrageenan in the diet.” (lines 177 - 180)

Members of the Handling Subcommittee have not decided on whether to propose removing

carrageenan from the National List. We are troubled that the research showing inflammation and glucose intolerance is all from one research team and has not been replicated. We hope that in the next few months before we vote more conclusive research replication or rebuttal will help inform our decision.

It is also worth noting that in the time since the last review the World Health Organization JECFA committee re-evaluated carrageenan for use in infant formula and changed their opinion on restricting its use to have an unrestricted status. (See TR for citation).

This is the first meeting of the two meetings at which carrageenan will be considered under the new sunset review process. All stakeholders can now read the new TR and try your best to mount arguments for one side or the other. It does come down to a core question of philosophy about the organic regulations: if humans have varying degrees of sensitivity to carrageenan in the diet, is that enough reason to prohibit it in all organic foods? Humans are also sensitive to gluten, dairy, legumes, and many other foods; is that a reason to keep them out?

Additional information requested by NOSB

1. After the last review in 2012 we know some companies pledged to remove carrageenan from their products. Has this been successful and what alternatives have been used? Are there any products for which it has not been successful, and why?
2. Are there any stakeholders who rely on this material? If so for what uses and why have alternatives not been successful?
3. Is "sensitivity" to a food ingredient enough of a reason to prohibit a substance in organic products if it is clearly listed as an ingredient on a food label?

Glucono delta-lactone

Reference: §205.605(a) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Technical Report: [2002 TAP](#); [2016 TR](#)

Petition(s): [2002](#)

Past NOSB Actions: [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use: Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly in the production of silken tofu. In tofu production GDL serves as a coagulant. GDL can also be used as a curing agent, leavening agent, pH control agent and sequestrant.

Manufacture: There are a variety of ways a GDL can be produced. The most common form has gluconic acid production is called the Blom process in which gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium hydroxide or calcium carbonate is added to this to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via acid base reactions and fermentation (2016

Technical Review pgs. 10-11). Other processes to make GDL involve oxidation with bromine water (disallowed by the annotation on the National List) and oxidation with purified enzymes.

International: GDL is not listed on the permitted substances lists of Canada, EU, Japan, Codex, or IFOAM.

Ancillary Substances: GDL is >99% pure and has no ancillary substances present. GDL is often sold in formulation with other additives specifically designed for the application – these substances should be reviewed separately as they are not ancillary substances.

Discussion: The original petition and primary use of GDL is for the coagulation of tofu. Several coagulants for tofu exist including magnesium chloride, calcium chloride, calcium sulfate and magnesium sulfate. Acids such as citric or lactic acid can be used as well. Each of these substances produces a different type of tofu texture and flavor, resulting in distinctly different products. Calcium salts produce firm tofu, sulfate salts produce soft tofu, and GDL produces silken tofu. Citrus and Lactic acids produce acidified tofu, which is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

The 2016 Technical Review examined human health and environmental impacts of GDL use and production but found low to no risk. The review did raise the question of classification, given the substance is produced via fermentation and acid-base reactions similar to that of citric acid (also listed on 205.605(a) nonsynthetic). The technical review also raised concerns about the potential for GMO enzymes to be used in the production of GDL via the oxidation with enzymes production method, which is not the most common form of production.

Additional information requested by NOSB

1. Is GDL being used in applications other than tofu production for organic processed foods?
2. If GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salts sufficient to produce all forms of tofu?
3. Should GDL produced from enzymes be prohibited or further restricted due to concerns around GMOs?

Tartaric acid

Reference: §205.605(a) Tartaric acid - made from grape wine.

Technical Report: [2011 TR](#)

Petition(s): [2011 Petition to remove from 205.605\(b\) - made from malic acid](#)

Past NOSB Actions: [NOSB meeting review 11/1995](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Uses:

Tartaric acid is a natural organic acid that is in many plants especially grapes, bananas, and tamarinds. Tartaric acid can be used to create several different salts, including tartar emetic (antimony potassium tartrate), cream of tartar (potassium hydrogen tartrate), and Rochelle salt (potassium sodium tartrate). The primary uses of tartaric acid are associated with its salts.

Tartaric acid and its salts have a very wide variety of uses. These include use as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. It has been used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks.

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to 'rise' without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties. Cream of tartar is used to make cake frosting and candies

International:

The use of tartaric acid (C₄H₆O₆; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredient classified as a food additive in beverages. Use of the synthetic form is allowed only if the nonsynthetic form of tartaric acid is not commercially available. Tartaric acid derived from nonsynthetic sources is also permitted for use as a processing aid in beverages (the Canadian General Standards Board, 2011).

The European Economic Community (EEC) permits the use of tartaric acid as a food additive in organic food if derived from a plant source, which is presumably grapes (EEC 889/2008, 2008).

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, and stabilizer. Tartaric acid from a plant source (i.e. nonsynthetic L(+) tartaric acid) is permitted for use as a food additive in organic food production (although exclusions of the GFSMA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

Additional information requested by NOSB

1. The Handling Subcommittee requests public comment on the use of Tartaric Acid and its essentiality in organic processing.

Cellulose

Reference: §205.605(b) Cellulose - for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Cellulose (CAS # 9004-34-6 alpha cellulose) is available in several different forms with each having varying functional qualities used for multiple purposes in organic handling. There are two specific forms of cellulose currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing. Uses in organic handling include: as a processing aid for filtration of juices; as an anti-caking agent ingredient for use in shredded cheese; and as a processing aid in the form of peelable hot dog and sausage casings. Some of these uses in organic handling have been around since even before the creation of OFPA, with cellulose being allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture:

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth (EMBL, 2015)(TER 2-11-2016). Most commercially available cellulose (powdered) is produced from wood pulp (40-50% cellulose) or other plant sources (such as: corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc.) through a delignification process that results in a chemically changed synthetic end product (Franz and Blaschek 1990; French et al. 1993). The original process for making regenerated cellulose is called the viscose method. It converts cellulose fibers into regenerated fibers and films and with some minor changes is still in use today (this process was invented in the 1890's). The new Technical Evaluation Report (February 11, 2016) mentions several other sources of cellulose such as: from recycled paper and cardboard (US EPA 2015b) and microbially produced cellulose made from the fermentation of sugars with bacteria and microalgae. Cellulose is also currently being looked at in research studies in nanotechnology, according to information provided in the new TR (Hubbe et al. 2008) (Martirosyan and Schneider 2014).

International: Cellulose is permitted by most organic standards outside of the U.S. for at least some uses and applications in organic processing or handling.

- **Canada** – Allowed as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings (CAN/CGSB 2015).
- **European Economic Community** (EEC) Council Regulation EC No. 834/2007 and 889/2008 – Cellulose is authorized for use in the wine sector only for use as an inert filtering aid (EU Commission 2008).
- **IFOAM** –in Appendix 4, Table 1 “List of approved additives and processing/post-harvest handling aids” as a processing and post-harvest handling aid with no annotation (IFOAM 2014).

Discussion:

During the previous Sunset Review cycle there were no sources of either nonsynthetic or organic cellulose identified. During the current cycle we will be asking organic handlers and other stakeholders to help provide answers to that question. There are numerous uses for cellulose in food handling, but

not all uses are allowed in organic food production/handling. The current annotation for cellulose in organic handling under §205.605(b) allows it to be used only as: a filtering aid, as a component of processed meat casings, or as an anti-caking agent. This is a material that was in use by organic handlers in organic food production even prior to the formation of the National Organic Program and the creation of the National List.

The new TR states that food-grade cellulose filters composed of either 100% or food grade 99%+ cellulose without ancillary ingredients are commercially available (ErtolAlsop 2015; Purifiber 2015; International Fiber Corporation 2015). There are other ingredients that sometimes may be added to reduce labor costs or increase the functional efficiency of cellulose for certain processes. While the TR (February 11, 2016) also mentions that these ancillary substances or ingredients may be added for other uses along with cellulose, it does make it very clear that for all of these uses there are well defined sources of commercially available cellulose that do not include these ancillary ingredients (International Fiber Corporation 2015).

The new TR does raise a couple of concerns regarding potential for environmental impact; specifically, depending on the source of the cellulose, there could be some concerns associated with the logging of the trees for wood, and some natural ecosystems have been replaced with fast-growing species of pulp trees (Roberts 2007). Recycling and the use of alternative crops will help to mitigate the impact. Some concerns have also been raised about cellulose waste generated from food processing, but these are a subject of current research to look at conversion of these wastes into useful products. (Das and Singh 2004). Also, recycling and the use of alternative crops will help to mitigate the impact of cellulose manufacturing on biodiversity (Roberts 2007).

The TR also mentions that studies on both animal models and human subjects found cellulose to be non-toxic (LSRO 1973). Although cellulose is not explicitly listed as GRAS in 21 CFR 184, the Select Committee on GRAS Substances concluded that “[t]here is no evidence in the available information on pure and generated cellulose, including micro-crystalline cellulose, that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are at levels that are current, or might reasonably be expected in the future” (SCOGS 2015).

During the October 16, 2001 NOSB Fall meeting the original discussion around listing cellulose for use in organic handling first took place regarding whether or not it should be added to the National List. At that time, it was determined that there were two sources of cellulose approved for use: regenerative casings, and powdered cellulose for use as anti-caking or as a filter aid. Part of the discussion during that time was considering adding the word “powdered” as part of the annotation. It was ultimately decided not to include the more restrictive addition as part of the original annotation for cellulose. During the last Sunset Review cycle at the Spring 2012 NOSB meeting it was discussed and voted on by the board to add the word “powdered” as part of the annotation. When the NOP did the 2013 Sunset Docket they were not able to make the change to the cellulose annotation voted on by the NOSB due to the lack of time needed to add changes, inform the public, and the need to determine/estimate the impact that this more restrictive annotation might have on organic stakeholders currently using this material. So it remains un-clarified at this time if the word “powdered” should be added to the annotation as a means by which to limit the type of cellulose allowed for these particular uses or not. Also, at the Spring 2012 NOSB meeting certifiers and handlers provided information to confirm that the microcrystalline form was not used in organic handling and that, per conversations with the NOP, it was also determined that this form of cellulose was not allowed for use in organic handling.

Additional information requested by NOSB

1. Have there been any new sources for either a nonsynthetic or an organic form of cellulose

identified during this current Sunset Cycle? If so please provide the NOSB with information on this source.

2. Are there any new or potential uses not covered by the current annotation that should be brought to the NOSB's attention? If so please explain.
3. Have there been any possible alternatives to any of the allowed uses for cellulose identified during this current Sunset Cycle, and if so please provide the NOSB with their names and how they compare to the use of cellulose for the specific use.
4. What impact would the inclusion of the word "powdered" as part of the annotation have on your handling process? Should the NOSB consider bringing forth a separate proposal to make this change to the cellulose annotation?
5. Could you help us to identify any ancillary substances that might be used with cellulose in organic handling or processing? The new Technical Evaluation Report mentions several potential ones for both powdered and the inedible form used in regenerative casings. Are any of these currently being used in organic handling and processing?

Potassium hydroxide

Reference: §205.605(b) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): 2001 petition, [2011](#) Amend annotation

Past NOSB Actions: [10/1995 meeting minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: Added to the National list 12/21/2000 ([65 FR 80548](#)); National List amended 11/03/2003 ([68 FR 62215](#)); National List amended 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Uses:

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener and poultry scald agent. It is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as GRAS for humans (21 CFR 184.1631), which are allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. In fruit and vegetable peeling, potassium hydroxide serves to weaken the glycolytic bonds of pectin, which is responsible for skin adhesion. Weakening these bonds allows the peeling of fruit and vegetable skins by water spray or other mechanical methods. According to the TR, Peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution—about 10%—and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to neutralize the pH of the fruit.

International:

- Canada - Canadian General Standards Board Permitted Substances List –Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (CAN/CGSB 2011 Table 6.6).
- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and

Marketing of Organically Produced Foods (GL 32-1999) – Allowed for pH adjustment for sugar processing (FAO/WHO Joint Standards Programme 1999, Table 4).

- European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 – Caustic potash is on Annex VII, “Products for cleaning and disinfection” (EU Commission 2008). However, it does not appear in Annex VIII, “Certain products and substances for use in production of processed organic food, yeast and yeast products.”
- Japan Agricultural Standard (JAS) for Organic Production—“Limited to be used for processing sugar as pH adjustment agent” (Japan MAFF 2000).
- IFOAM – Organics International (IFOAM) – Not found.

History:

In 1995, the NOSB approved the addition of potassium hydroxide to 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read — “prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.” The 2001 TAP review for that expansion noted that: “The stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances.” The 2001 TAP review also noted that the environmental effects which had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step. Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Committee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercially processing methods used for peaches, the NOSB full board favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Additional information requested by NOSB

1. The Handling Subcommittee requests public comment on the use of potassium hydroxide and its essentiality in organic processing.

Silicon dioxide

Reference: §205.605(a) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

Technical Report: [1996 TAP](#), [2010 TR](#)

Petition(s): [2010 petition to remove](#)

Past NOSB Actions: [09/1996 minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: Added to NL 12/21/2000 ([65 FR 80548](#)); National list amended 05/28/2013 (effective 11/03/2013) ([78 FR 31815](#))

Sunset Date: 11/03/2018

Use:

Synthetic amorphous silicon dioxide is used as a food additive for various functions including:

- An anticaking agent in foods
- A stabilizer in beer production, and filtrated out of the beer prior to final processing
- An adsorbent in tableted foods
- A carrier
- A defoaming agent

Manufacture:

Silicon dioxide can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment. According to FDA regulations, silicon dioxide (as a food additive) should be manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

Silicon dioxide can be produced as a nanomaterial, but for use in organics the material would have to be petitioned to be placed on the National List. As stated in NOP Policy Memorandum from March 2015:

As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been: 1) petitioned for use; 2) reviewed and recommended by the NOSB; and 3) added to the National List through notice and comment rulemaking.

Currently there is no silicon dioxide produced with nanotechnology on the National List.

International: Silicon dioxide is permitted in organic handling by Canada, European Union, IFOAM, and Japan. In the EU its use is restricted to an anticaking agent for herbs and spices, of plant origin. In Japan its use is limited to processed foods of plant origin as gel or colloidal solution.

Ancillary substances: None reported in 2010 TR

History:

In 2010 a petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of a commercially produced rice based certified organic alternative to silicon dioxide. In 2011, the NOSB did not pass the petition. New data was presented in the petition claiming that a reformulation of the rice based alternative could now be substituted for silicon dioxide at nearly 1:1 rations, but the Handling Subcommittee felt the data was limited, not published from a third party source, and did not conclusively demonstrate its applicability in all products and processes.

The subcommittee did however wish to acknowledge the availability of a natural alternative and even though they did not vote to remove silicon dioxide in its entirety they did pass (Yes: 11, No: 3) a recommendation to amend the annotation of silicon dioxide to:

§ 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)).” (b) Synthetics allowed—Silicon dioxide—providing sufficient evidence showing nonsynthetic alternatives are not commercially available for a specific product/process is presented.

Resulting in its current listing as:

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available

The subcommittee in their 2010 recommendation also publically noted that additional information and clarification of processors' needs regarding silicon dioxide would be needed for future deliberations by the NOSB.

Discussion:

The 2010 TR did not find the manufacture or use of silicon dioxide to be harmful to people or the environment. The question that the subcommittee has is if silicone dioxide should remain on the list due to 205.600:

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes.

Additional information requested by NOSB

1. Are there instances where due to lack of availability of organic alternatives, you must use silicon dioxide?
2. Are there instances where the organic alternative does not perform the needed function and therefore you must use silicon dioxide? If so, what are those functions? And what has been the undesired result when silicon dioxide was tried?

Colors: Beta-carotene extract

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

(2) Beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7).

Technical Report: [2011 TR](#)

Petition(s): [2007](#), [2009](#)

Past NOSB Actions: [04/2007 recommendation](#), [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 06/27/2007 ([72 FR 35137](#)); National List amended 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Discussion:

Beta-carotene was petitioned by color manufacturers in 2007. No TAP was requested. The NOSB Handling Subcommittee rejected the petition to add this material to 205.606 stating: "the petitioner did not provide credible information regarding the lack of supply of organic raw material, and the ability to process them as organic". (Vote: 4:1)

However, at the March 2007 NOSB meeting the material was approved.

The Interim Final Rule (FR 35141) includes the following: "Though a significant number of comments were received, very few comments submitted were from processors or handlers. Comments from this segment of the industry would be helpful in developing a final rule. A number of comments expressed

concern regarding the information and criteria used for determining the fragility of the organic ingredient supply or organic availability of the proposed 38 nonorganic agricultural ingredients.”

The Interim Final Rule also includes the following: “As a result of the district court's final order and judgment in *Harvey v. Johanns* and requests for an extension of the public comment period on AMS-TM-07-0062, AMS is issuing this interim final rule to: (1) Permit the use of the 38 ingredients during the extended comment and final rulemaking periods to minimize the impact to the organic industry; and (2) extend the comment period (60 days) to receive additional comments regarding the addition of the 38 non-organic agricultural ingredients to § 205.606. Effective Date Effective June 9, 2007, these 38 substances were prohibited for use in processed products labeled as ‘organic.’ Continued loss of the use of these products would disrupt the trade of food products currently being labeled as ‘organic.’ Therefore, the continued use of these products as ingredients in foods labeled as ‘organic’ is necessary to prevent possible significant business disruption for organic producers and handlers. Accordingly, pursuant to 5 U.S.C. 553, it is found, and determined, upon good cause, that it is impracticable, unnecessary, and contrary to the public interest to give further notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this interim final rule until 30 days after publication in the Federal Register.”

In 2009, another manufacturer petitioned to add an amendment to the listing: “...Derived from carrots or algae”. The petitioner stated: “Our research over the past few years shows that at this time the only source of beta-carotene that can be extracted using NOP compliant nonsynthetic methods is algae. The algae derived beta-carotene uses extraction methods of CO₂, ethanol or vegetable oil.”

A Technical Report was requested and received in July 2011.

The TR indicated that a common source of beta carotene color was derived from the micro-algae *Dunaliella salina* and *Dunaliella bardawil*. These species are cultivated in Australia, for example. The TR, lines 327-350, describes the intensive culture system of production in a high salt, nitrate rich medium.

The TR further states: “*Dunaliella* species are commonly observed in salt lakes in all parts of the world from tropical to temperate to polar regions where they often impart an orange-red color to the water. As in commercial cultivation of the production, β-carotene is accumulated as droplets in the algal chloroplast stroma, especially under the environmental conditions in high temperature, high salinity, high irradiance, and nutrient limitation (low nitrogen). Then, β-carotene may be obtained from algal biomass or dried powder by using hot edible oil extraction and supercritical carbon dioxide, see EQ #2. In addition, it is desirable to re-utilize the culture medium remains after harvesting (biomass removal). *Dunaliella* growth medium could be recycled biologically by treating the medium with bacteria that are naturally present in medium because of the high concentration of glycerol, amino acids, and other organic compounds (Ben-Amotz, 1995). In a review article conducted by Dufosse et al. (2005), they concluded that algal forms are the richest source of pigments and can be produced in a renewable manner, since they produce some unique pigments sustainably. The report also stated that the production of β-carotene from *Dunaliella* will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature. (TR 530-545).

The TR supported the petitioner’s research findings. Therefore the Handling Subcommittee voted 4: 0 with 3 absences to approve this amendment, and the NOSB in December 2011 voted 14: 0 to approve the amendment.

The NOSB in 2011 found that the material met all the OFPA Criteria, and in 2013 the Final Rule was published (78 FR 31815).

The NOSB is in the process of reviewing use of all marine plants which are presently on the National List, and will be requesting a limited Technical Report. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

Additional information requested by NOSB

1. Has there been any change in the ability of manufacturers to produce beta-carotene color from carrots using NOP compliant extraction methods?
2. Is this color necessary for organic processors?
3. Which species of algae are used and from where are they harvested?
4. If the typical species used are from the genus *Dunaliella* (as cited in the TR) is harvesting of these species of micro algae from the wild, certified wildcrafted, or cultivated?
5. When used as a color, is this material also a source of Vitamin A?

