

**Sunset 2017 Review
Meeting 2 - Review
Handling Substances §205.606
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 §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

[Casings](#)
[Celery powder](#)
[Chia \(Salvia hispanica L.\)](#)
[Colors \(proposed removals\)](#)
[Colors \(proposed relisting\)](#)
[Dillweed oil](#)
[Fish oil](#)
[Fructooligosaccharides](#)
[Galangal, frozen](#)
[Gelatin](#)
[Gums: Arabic, Carob bean, Guar, Locust bean](#)
[Inulin-oligofructose enriched](#)
[Kelp](#)
[Konjac flour](#)
[Lecithin—de-oiled](#)
[Lemongrass-frozen](#)
[Orange pulp, dried](#)
[Orange Shellac - unbleached](#)
[Pectin \(non-amidated forms only\)](#)
[Peppers \(Chipotle chile\)](#)
[Seaweed, Pacific kombu](#)
[Starches, Cornstarch \(native\), Sweet potato](#)
[Turkish bay leaves](#)
[Wakame seaweed \(Undaria pinnatifida\)](#)
[Whey protein concentrate](#)

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>

Casings

Reference: 205.606(a) casings, from processed intestines

Technical Report: N/A

Petition(s): 2006 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

Recent Regulatory Background: Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Subcommittee Review

Uses: The intestines of beef, lamb and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

Manufacture: Intestines are washed in pure water with no chemicals, and salted in NaCl salt and water. No other ingredients or processing aids are used. Animal intestines used may be from organic or non-organic animals. Slaughterhouses do not separate certified organic and non-organic offal.

Certified organic intestines from certified animals are not available commercially.

History: On 4/21/2007 the NOSB found that “.no processor with the equipment or technology to process slaughter by-products into casings, from processed intestines, has organic certification and /or is unwilling to use their equipment for a batch so small as size as would be needed to fulfill current organic requirements.”

In 2007 there were no public comments specifically opposing the listing of casings from processed intestines.

In 2015 the NOSB requested additional information during first posting of this material:

1. Are there companies manufacturing casings made from certified organic livestock?
2. Are casings from intestines of organic animals commercially available in the US or internationally?
3. What chemicals, other than salt, are used to process animal intestines into casings?

Public Comment: Although more organic animals are being slaughtered than in 2007, no public comment provided any new information as to the manufacturing process or possible availability of certified organic intestines.

Industry strongly supports continued listing and no commenter asked for removal.

Motion to Remove

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

The Subcommittee proposes removal of Casings 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 to remove Casings from 205.606(a)

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

Celery powder

Reference: 205.606(b)

Technical Report: N/A

Petition(s): 2007 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (products must still be labeled “uncured”). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. According to the petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to create the typical cure attributes. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted.

Manufacture: Celery is cleaned, macerated, physically separated (liquid/solid), the liquid is concentrated by evaporation, heated and vacuum dried. There are no other chemicals or preserving agents used in the manufacturing process. Celery powder is typically standardized to specific nitrite content. According to the petitioner, meat preservation via natural nitrites/lactic acid is an ancient technology dating back thousands of years. There are other vegetables and minerals which contain natural nitrates including beets, spinach and sea salt. Although each has its benefits and challenges none are an identical equivalent to natural celery powder in quality, form and function.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Celery powder is not listed in the EU Organic Standards, however, sodium nitrate is allowed for meat products (an alternative to celery powder not currently listed on the National List).

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Public comment was received from industry, certifiers and trade association about its use in processed meat products and its necessity for certain “cured” meat products. One commenter provided details for their search for organic celery powder but noted organic versions so far were unable to meet necessary nitrite standardization profiles for the functional use. The same commenter noted why other alternatives did not function equivalent to celery powder. The original petitioner also notes the need for cured meat products to better utilize

organic meat trim byproduct from organic meat processors. Several comments received were in general opposition to any agricultural items being listed and others commented on the need for OFPA criteria to be applied to the review of conventional agricultural ingredients. Further one comment noted that farmer worker poisonings, pesticide uses, residues and pollinator impacts need to be accessed for conventional agricultural items. It should be noted that under the NOP, products certified to the “made with organic...” claim, and containing 70%+ organic content, may use non-organic agricultural ingredients that are not listed on §205.606 or undergo a review for compliance with OFPA criteria – although such ingredients are still required to comply with § 205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or excluded methods.

The Handling Subcommittee recommends celery powder remain on the National List given the unavailability of a functional organic version or alternatives, low usage level, and its necessity in manufacturing traditional “cured” meat products. This material satisfies the OFPA evaluation criteria.
Motion to Remove

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

The Subcommittee proposes removal of celery powder 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 to remove celery powder from 205.606(b)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

Chia (*Salvia hispanica* L.)

Reference: 205.606(c)(*Salvia hispanica* L.)

Technical Report: N/A

Petition(s): 2007 Petition

Past NOSB Actions: 03/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Chia seeds are consumed directly and added to variety of food products, mostly for their omega 3 fatty acid profile and other nutrient content.

Manufacture: Chia seeds are grown, harvested and mechanically separated and cleaned.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements

(IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Chia seeds are not listed in the EU Organic Standards.

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting Chia noting its wide commercial availability. No specific comments received supported relisting or addressed commercial unavailability of Chia. The Handling Subcommittee recommends Chia (*Salvia hispanica* L.) be removed from the National List.

Motion to Remove

This proposal to remove Chia (*Salvia hispanica* L) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Chia (*Salvia hispanica* L.) 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: Commercially available as organic therefore it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove Chia (*Salvia hispanica* L) from 205.606(c)

Motion by: Tom Chapman

Seconded by: Zea Sonnabend

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

Colors - Black/Purple Carrot Juice color, Blueberry Juice color, Carrot Juice color, Cherry Juice color, Chokeberry/Aronia Juice color, Elderberry Juice color, Grape Juice color, Grape Skin Extract color, Paprika color, Purple Potato juice color, Red radish Extract color, Saffron Extract color, Turmeric Extract color

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

(4) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(5) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

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

(7) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

- (9) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (10) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (11) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (12) Paprika color (CAS #68917-78-2)—dried, and oil extracted
- (14) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (16) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (17) Saffron extract color (pigment CAS #1393-63-1).
- (18) Turmeric extract color (CAS #458-37-7)

Technical Report: 2015 TR - Colors (all)

Petition(s): 2007 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

Recent Regulatory Background: Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Subcommittee Review

Section 205.606 allows for use of non-organic agricultural materials when organic supplies are not commercially available. Colors were added to the National List in 2007 and in 2010 the listing was updated to clarify that they must not be produced using synthetic solvents and carrier systems or artificial preservatives.

Uses: Colors are added to food products to enhance attractiveness of food, assure uniformity in color, add back color lost during processing, protect light susceptible vitamins and preserve flavor (TR 2015, 22-25). Global sales of natural colors were approximately \$600 million in 2011, an increase of almost 29% four years earlier. More recent estimates put the annual growth of the natural colors market at 3–4% annually. The food industry is the largest consumer of natural colors—accounting for 70% of the market share—with the remaining 27% in soft drinks and 3% in alcoholic beverages. The use of natural colors is highest in Europe, where 85% of new products launched between 2009 and 2011 used natural colorants (IFT, 2013). (TR 347-351)

International: Canada permits natural colors; CODEX does not list specific colorants but allows natural sources of colors; EU Organic Standards allow some natural colors and provides for petition for ingredients meeting specific criteria; Japanese Agricultural Standard (JAS) does not discuss colors per se; International Forum of Organic Agricultural Movements (IFOAM) states “...substances should “not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the

replacement of nutrients is required by law.” The individual colors are not listed in the IFOAM Norms (IFOAM, 2014). (TR 408-411). FDA states that GRAS does not apply to colors (TR 613-622)

Manufacture, Human Health: Natural colors appear to meet the criteria in OFPA related to manufacture and human health, in fact some of the colors are beneficial to human health (TR 681-682, Table 8).

Alternatives: For all of the listed colorants, organically grown (as opposed to conventionally-grown) vegetables and fruits can be used as an alternative source for the colorant. Manufacturers of the non-organically grown colorants claimed in their 2007 National List petition that the supply of organic fruits and vegetables was insufficient to allow for colorant uses. It is unknown whether organic fruit and vegetable production has become sufficient since 2007. However if sufficient stocks of organically grown fruits and vegetables used for colorants are now available or become available in the future, then the organically grown fruits and vegetables can be used as alternatives for colors derived from non-organic agricultural products. (TR 82-826). Given the expansion in the production of certified organic fruits and vegetables it would appear that most if not all colors should be available commercially in organic form.

Public Comment: Some public comment states that use of non-organically produced products allowed as ingredients in or on processed products labeled as “organic” fail to meet OFPA criteria not only because organic alternatives are available, but also because they are not compatible with a system of sustainable agriculture.

Other public comment indicates that most of the colors are now available in organic form with the possible exception of the following 4 colors: Beet Juice extract color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage extract color. One certifier stated that 73 of its clients use organic colors (122 actual colors used).

Based on its present understanding that, except for the above four (4) colors that may not presently be commercially available in organic form, the Handling Subcommittee recommends removing from the National List the following 13 colors: Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color.

Motion to Remove

This proposal to remove : Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of : Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color 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: Material is available in organic form.

Vote in Subcommittee

Motion to remove the thirteen (13) colors as listed above from 205.606

Motion by: Jean Richardson

Seconded by: Lisa de Lima

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

Colors - Beet juice extract color, Black Currant juice color, Pumpkin Juice color, Red Cabbage Extract color

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

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

(3) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

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

(15) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: 2015 TR - Colors (all)

Petition(s): 2007 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Section 205.606 allows for use of non-organic agricultural materials when organic supplies are not commercially available. Colors were added to the National List in 2007 and in 2010 the listing was updated to clarify that they must not be produced using synthetic solvents and carrier systems or artificial preservatives.

Uses: Colors are added to food products to enhance attractiveness of food, assure uniformity in color, add back color lost during processing, protect light susceptible vitamins and preserve flavor (TR 2015, 22-25). Global sales of natural colors were approximately \$600 million in 2011, an increase of almost 29% four years earlier. More recent estimates put the annual growth of the natural colors market at 3–4% annually. The food industry is the largest consumer of natural colors—accounting for 70% of the market share—with the remaining 27% in soft drinks and 3% in alcoholic beverages. The use of natural colors is highest in Europe, where 85% of new products launched between 2009 and 2011 used natural colorants (IFT, 2013). (TR 347-351)

International: Canada permits natural colors; CODEX does not list specific colorants but allows natural sources of colors; EU Organic Standards allow some natural colors and provides for petition for ingredients meeting specific criteria; Japanese Agricultural Standards (JAS) does not discuss colors per

se; IFOAM states “...substances should “not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law.” The individual colors are not listed in the IFOAM Norms (IFOAM, 2014). (TR 408-411). FDA states that GRAS does not apply to colors (TR 613-622)

Manufacture, Human Health: Natural colors appear to meet the criteria in OFPA related to manufacture and human health, in fact some of the colors are beneficial to human health (TR 681-682, Table 8).

Alternatives: For all of the listed colorants, organically grown (as opposed to non-organically grown) vegetables and fruits can be used as an alternative source for the colorant. Manufacturers of the non-organically grown colorants claimed in their 2007 National List petition that the supply of organic fruits and vegetables was insufficient to allow for colorant uses. It is unknown whether organic fruit and vegetable production has become sufficient since 2007. However if sufficient stocks of organically grown fruits and vegetables used for colorants are now available or become available in the future, then the organically-grown fruits and vegetables can be used as alternatives for colors derived from conventional agricultural products (TR 82-826). Given the expansion in the production of certified organic fruits and vegetables it would appear that most if not all colors should be available commercially in organic form.

Public Comment: Some public comment state that use of non-organically produced products allowed as ingredients in or on processed products labeled as “organic” fail to meet OFPA criteria not only because organic alternatives are available, but also because they are not compatible with a system of sustainable agriculture. Other public comment indicates that most of the colors are now available in organic form with the possible exception of the following 4 colors: Beet Juice extract color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage extract color. Based on its present understanding that the above four (4) colors are not presently commercially available in organic form the Handling Subcommittee recommends leaving these four materials on the National List

Motion to Remove

This proposal to remove Beet Juice Extract Color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage Extract color will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Beet Juice Extract Color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage Extract color 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 to remove the four (4) colors as listed above from 205.606

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

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

Dillweed oil

Reference: 205.606(e) Dillweed oil (CAS # 8006-75-5)

Technical Report: none

Petition(s): 2006 Petition

Past NOSB Actions: 2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Dillweed oil is used in the manufacture of dill pickles and used in place of dillweed to provide the traditional and characteristic flavor of dill pickles.

Manufacture: Dillweed oil is produced from harvested dillweed that is steam distilled to remove the oil. The resulting condensate is purified and standardized.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. It is possible dillweed oil could be used in the EU under the Annex IX allowance for fats and oils not from cocoa, coconut, olive, sunflower, palm, rape (canola), safflower, sesame or soya (soy).

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of dillweed oil. It appears the dillweed oil also meets the definition of flavors, non-synthetic. Searches of publically available organic sourcing pages by the NOSB in the February of 2015 resulted in sources of both organic dillweed and organic dillweed oil. The Handling Subcommittee recommends dillweed oil be removed from the National List.

Motion to Remove

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

The Subcommittee proposes removal of dillweed oil 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: Commercially available as organic therefore it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove dillweed oil from 205.606(e)

Motion by: Tom Chapman

Seconded by: Harold Austin

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

Fish oil

Reference: 205.606(f) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606

Technical Report: [2015 TR](#)

Petition(s): 2007 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Section 205.606 allows for use of non-organically produced ingredients to be used in processed products labeled “organic” when the ingredient is not commercially available in organic form.

The NOP does not presently have production standards for aquaculture, therefore organic fish cannot be commercially available.

Uses: Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids—primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis (Chang et al., 2009; Lee et al., 2014). Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat products, cookies, crackers, snack foods, condiments, sauces, and soup mixes (Rizliya and Mendis, 25 2014). (Technical Report 2015 lines 19-25).

In addition to aquaculture—estimated to use about 81% of the fish oil produced worldwide—fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture.

History: Fish Oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report or TAP. The NOSB 2007 Recommendation indicated that the OFPA criteria were met in all categories, but provided no scientific rationale or citations to support such findings. However, the NOSB Final Recommendation May 9, 2007 stated ...”pursuant to the judgment in *Harvey v. Johanns*, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed on § 205.606. These criteria were finalized in the NOSB “Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606” of October 19, 2006. “That recommendation allows for pro-active listing on § 205.606 of materials which may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather or trade-related issues.

Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a § 205.606-listed material may be used, on a case by case

basis. ...” “.... After discussion, the Board decided to add an annotation to the recommendation to list Fish Oil to the National List. The annotation is “stabilized using only allowed ingredients on the National List.” The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market.”...

“The Handling Committee (2007) noted that agricultural substances are only required to be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

6517(c)(1)(a)

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

The NOSB (2007) further noted that “There were no public comments specifically opposing the listing of Fish Oil on §205.606....” In its Five Year Review in April 2010 the NOSB received no public comment and fish oil remained on the List.

In February 2015 the NOSB posed the following questions in the first posting of this material under the new Sunset procedure:

1. What are the primary geographic sources of fish oil and primary fish species harvested for the purpose of oil extraction?
2. Are there conservation and environmental issues surrounding harvest of wild caught fish for fish oil?
3. What is the manufacturing and purification process?
4. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB’s for example? How is purity assessed?
5. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
6. What is the most current research on plant-derived alternatives such as flax and chia and how comparable are they to the Omega 3 in fish and algal oils?

In addition, in preparing for the 2017 Sunset Review the NOSB requested a full Technical Report which was received in March 2015 after the posting of the initial Sunset review.

The 2015 TR provides a valuable in-depth analysis and provides up to date research and citations allowing the subcommittee to re-evaluate the fish oil comprehensively against the OFPA criteria.

Sources: Fish oil is derived from a wide range of wild caught fish species including, tuna, mackerel, sardines, anchovy, halibut, (TR lines 69-79). NOTE: The TR also lists fish oil from whales and seal under fish, although these are mammals. (TR lines 75-76). Fish oil is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil (TR lines 283-284). Farmed fish are not a source of fish oil, they are often fed fish oil supplements to boost their own levels of omega 3 fatty acids (TR 332-333). Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States

(Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports. Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). (TR 90-110)

Manufacturing: Fish oil remains intact through the purification process and is not chemically modified (TR 338). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002) (TR 307-320). There are also other purification methods, which are discussed in the TR.

Human Health: Fish oil is a naturally sourced product which appears to provide a multitude of health benefits (as listed above under "Uses"). It is one of the best sources of Omega 3 EPA and DHA fatty acids. Fish oil such as cod liver oil which has been given to children in many areas of the world for generations to promote healthy brain development and prevent inflammation. Fish oils are added to many foods and taken as dietary food supplements to promote heart health and reduce risk of atherosclerosis.

However, the health benefits from consumption of fish oil is currently a debated topic in the scientific community (TR 471) and some sources suggest that there are health risks from fish consumption that may outweigh the benefit of omega 3 fatty acids from fish oil (TR 489-494).

Fish bioaccumulate many contaminants (TR 503-507). A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for EPA 407 and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012). PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (\pm 415.8) ppb (Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012). Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009). The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively

(GOED, 2012). There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. (TR 404-426).

Note: The TR addresses the February 2015 NOSB Questions 1, 2, 3 and 6 listed above under History, and partially answers Question 4, but it is not clear if the Voluntary Standard for contaminant limits is still in effect (Question 5).

Conservation issues: There is a very high demand for fish oil. 81% of fish oil goes to Aquaculture. Demands on fisheries may overburden the current supply of fish (TR 441-450). Fish oil used is from wild caught and not farmed fish. Overfishing may also lead to species extinctions and a decrease in biodiversity. There are more than 100 confirmed cases of extinctions in marine fish population's worldwide (Jenkins et al., 2009). Exploitation of fisheries is the largest contributor to marine extinctions, higher than habitat loss, climate change, invasive species, pollution, and disease (Dulvy et al., 2003) (TR 462-465). While some countries have highly regulated fisheries to prevent overfishing, many do not. According to the Food and Agriculture Organization's (FAO) State of the World's Fisheries and Aquaculture, most of the pelagic fish stocks, globally, are considered either fully fished or overfished. Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department (2014). The State of the World Fisheries and Aquaculture. pp. 39. While many different species are used for fishmeal and fish oil, small pelagics are most commonly used due to their high oil content. Peruvian anchoveta, Japanese anchovy, and Atlantic herring are the most common pelagic species harvested for fishmeal and fish oil, with primary stocks in the Southeast Pacific, Northwest Pacific, and Northeast and Northwest Atlantic, respectively. In 2010, all of these were either fully exploited or depleted. (Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department. (2010) The State of the World Fisheries and Aquaculture. pp. 35. Available at: <http://www.fao.org/docrep/013/i1820e/i1820e.pdf>)

In the Mediterranean, sardine and anchovy stocks have been assessed as fully fished (FAO 2014, p 40). According to FAO, fisheries that target species of a specific trophic level, such as those that target pelagics for fishmeal and fish oil production, remove "one ecosystem component without considering cascading effects on the dependent species...Concerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems." (FAO 2014, p 136). Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds, serving as an important link in the transfer of energy from plankton to species higher in the marine food web, some of which are endangered (FAO 2014, p 137), such as humpback whales.

Plant derived alternatives: Flaxseeds are a good source of both omega-3 (linolenic) and omega-6 (linoleic) fatty acids, with both oil types combined comprising about 40 percent of the flax seed mass. The oil content will vary depending on where and how the flaxseeds were grown, but omega-3 fatty acids can make up 30–60 percent of the total oil content, while omega-6 fatty acids make up 10–20 percent of the oil content (Teneva et al., 2014). Chia seed oil and perilla seed oil are additional sources of LC-PUFA, and their oil content distribution is very similar to that of flaxseed oil (Ciftci et al., 2012). Chia, perilla, and flax seed oils all contain ALA in relatively high amounts ranging from approximately 58 to 61 percent of the total oil (Ciftci et al., 2012). Humans can convert dietary ALA to EPA and DHA, but

synthesis from ALA is inefficient in the body. Several species of seaweed and algae can provide some fatty acids, but not with the same profile of fatty acids as fish. (TR 539-576)

International: Fish oil is not listed as allowed for organic processing in Canada, Japan, EU, or under IFOAM and is not listed in CODEX (TR 245-275). However, it should be noted that CODEX, IFOAM and JAS do not have discreet lists for non-organic agricultural substances. The EU does have a positive list and it does not list fish oil, but the EU Organic Standards also allow for organic certification of aquaculture. Thus the international status of fish oil in organics is not entirely clear.

Public Comment: Public comment is divided on the subject of fish oil use. There is a high consumer demand and industry strongly supports continued listing, especially as there are no organic sources. Industry comments (April 2015) include the following: "Used in Gummy Confections, Gummy Nutritional Supplements, Panned Jelly Beans... Fish Oil is used in our products as a natural source of DHA. An organic form is not available.... No alternative management practices that would eliminate the need for the specific substance. This ingredient is essential to our organic products."

Other Industry comments: "Fish oil provides nutritional benefits which our consumers are seeking"; "Peru fisheries are well regulated"; "specification sheets indicate levels of PCB's, arsenic, cadmium and lead are tested 3 times a year to meet very strict guidelines; plant sources of omega 3 are not as complete as found in fish oil".

On the other hand conservation groups are concerned about impact on world fisheries, and NGO's are concerned about the cumulative risk impact of fish oil on human health recommend removing fish oil as it fails to meet OFPA criteria relating to human health, environmental conservation and compatibility with a sustainable system of agriculture.

Answers to Questions 3, 4, and 5 above relating to voluntary standards and controlled fisheries and contamination limits were very limited in scope or detail and further clarification of those issues would be very helpful.

Motion to Remove

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

The Subcommittee proposes removal of fish oil 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: 6517(c)(1)(a): effect of the substance on human health, environmental conservation, its compatibility with a system of sustainable agriculture and alternative availability of a wholly natural substitute.

Vote in Subcommittee

Motion to remove fish oil from 205.606(f)

Motion by: Jean Richardson

Seconded by: Lisa de Lima

Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Fructooligosaccharides

Reference: 205.606(h) Fructooligosaccharides (CAS # 308066-66-2)

Technical Report: 2006 TAP; 2015 TR

Petition(s): 2006 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Fructooligosaccharides (FOS) is on the National List as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic.” FOS is a non-digestible carbohydrate that is used as a soluble prebiotic fiber, sweetening agent, flavor enhancer, bulking agent and humectant. It is used in many foods including yogurts, infant foods, medical food, baked goods, candies, soups beverages and other dairy products. FOS is mostly indigestible by human digestive enzymes.

Manufacture: There are two common commercial methods to produce FOS: Inulin and Sucrose.

Inulin derived. Inulin, a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchockes), agave and other plants. Chicory inulin is extracted from the source material via water extraction – the resulting inulin undergoes a partial enzymatic hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger*. The hydrolysis breaks long chain inulin into the shorter chain FOS.

Sucrose derived. Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas*. The *A. japonicus* cells must be immobilized for production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicus* culture suspended in calcium alginate, an immobilizer. *A. japonicus* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfers fructose molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicus* is generally inefficient, and higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzymatic reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid (a strong acid) or sodium hydroxide (a strong base); potassium phosphate is also used for pH control. The FOS produced can then be further purified through filtration or further fermentation.

Ancillary Substances: According to the 2014 TR: “There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation.”

International: FOS is not specifically listed in the Codex, EU or Japanese organic standards however non-organic agricultural products are not listed in these standards. FOS is not specifically listed on the Canadian organic standards.

Discussion: The NOSB requested information from the public related to (1) ancillary Substances, (2) commercial demand, (3) availability of organic sources, (4) alternatives and (5) function need. No comments were received from public on ancillary substances, availability of organic sources or alternatives. An organic ingredient broker and one manufacture of the substance asked for the continued listing and noted its usage in baked products. Upon reviewing draft guidance NOP 5033 on Agricultural/Non-Agricultural Classification and the information contained in the Technical Review the handling committee continues to believe the Agricultural classification is correct. No alternatives or organic versions were identified.

Motion to Remove

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

The Subcommittee proposes removal of Fructooligosaccharides 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: 6517(c)(1)(a)(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products.

Vote in Subcommittee

Motion to remove Fructooligosaccharides from 205.606(h)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

Yes: 1 No: 4 Abstain: 2 Absent: 0 Recuse: 0

Galangal, frozen

Reference: 205.606(i) Galangal, frozen

Technical Report: none

Petition(s): 2006 Petition

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Galangal is a rhizome in the ginger family and is used in various Asian cuisines.

Manufacture: Galangal, frozen is harvest, cleaned and frozen. Other forms of Galangal are fresh, dried and powdered.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards list “lesser galanga.”

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of galangal, frozen. Searches of publically available organic sourcing pages by the NOSB in February of 2015 resulted in sources of both organic galangal in Southeast Asia and a producer of galangal, frozen in Hawaii. The Handling Subcommittee recommends galangal, frozen be removed from the National List.

Motion to Remove

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

The Subcommittee proposes removal of galangal, frozen 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: Commercially available as organic therefore it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove galangal, frozen from 205.606(i)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

Gelatin

Reference: 205.606(j) Gelatin (CAS # 9000-70-8)

Technical Report: 2002 TAP

Petition(s): 2001 Petition; 2007 Petition

Past NOSB Actions: 05/2002 NOSB recommendation for addition to the National List; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Gelatin on the National List can be derived from cows, swine, or fish. Gelatin is used in a wide range of products as a clarification or fining agent in teas and wine, as a stabilizer and thickener, and in capsules. It may either be an ingredient or a processing aid.

While there is starting to be organic gelatin available from cows, there definitely is not from fish. One trade association and several certifiers indicated that while some products use organic gelatin, there is not enough supply for all uses. Fish gelatin is widely preferred for uses in kosher foods and is never available as organic. Some individuals expressed concerns over the use of animal gelatin from conventionally raised animals and the level of contamination that might be present from conventional

practices. However, no specific new evidence was presented that such gelatin had been identified as harmful in organic food.

One commenter indicated that gelatin is formulated with sodium hexametaphosphate for cross linking. An ancillary substance proposal for this is accompanying this review.

Motion to Remove

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

The Subcommittee proposes removal of gelatin 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 Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove gelatin from 205.606(j)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

Gums: (Arabic, Guar, Locust bean , and Carob bean)

Reference: 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

Technical Report: 1995 TAP

Petition(s): N/A

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

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

Sunset Date: 6/27/2017

Subcommittee Review

The listing for gums has four different names that refer to three different source products (locust bean and carob bean are two common names for the same plant species). They are used as binders and thickening agents in a very large variety of foods. The Handling Subcommittee recognized that the 1995 TAP review was really old and incomplete as far as the extraction process for these gums, and a new TR was requested but was not done because it was not among the highest priority substances for new reviews.

Public comments generally were favorable to the continued use of these gums, especially as they are alternatives to some of the other gums from seaweed or microorganisms. Written comments and testimony from product formulators and users identified how each type of gum has its unique situations where use is necessary, and many times the gums are used in combination to produce the desired effect. Guar gum, for instance, can hydrate rapidly at low temperatures, while locust bean gum can retard ice crystal formation.

Some commenters mentioned that locust and guar gum are available from organic suppliers. Others indicated that this supply is inconsistent and one mentioned that guar gum had had some contamination issues in the past and so was not reliably available in suitable organic form.

No commenters provided any ancillary substances used in gum formulations.

Motion to Remove

This proposal to remove Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) 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: Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) from 205.606(k)

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

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

Inulin-oligofructose enriched

Reference: 205.606(l) Inulin-oligofructose enriched (CAS # 9005-80-5)

Technical Report: 2015 TR

Petition(s): 2007 Petition

Past NOSB Actions: 04/2007 recommendation; [2010 NOSB sunset recommendation](#)

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Inulin-oligofructose enriched (IOE) is on the National List as a nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.” IOE is a non-digestible carbohydrate that is used to increase calcium bioavailability and absorption, as a soluble dietary fiber, as a non-caloric sweetener, and for functional effects on the texture/consistency of food. It is used in many foods including yogurts, baked goods, candies, jams and other dairy products.

Manufacture: IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin however it is the common commercial method to produce the oligofructose from inulin when used in IOE production. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), agave and

other plants. Chicory inulin is the most commercially available inulin, however organic inulin is generally derived from agave (Mexico) and Jerusalem artichokes (China). Chicory inulin is produced by shredded chicory roots, which are treated with hot water, juiced, and filtered to remove the raw inulin. The raw inulin is purified by treatment with calcium hydroxide, carbonated, and filtered and spray-dried. The resulting inulin polymers range in chain length from 2–60 units. The shortest polymers range from 2–10 fructose units and are called oligofructose. The longer polymers range from 10–60 units. If insufficient amounts of oligofructose are present, polymers range from 10–60 units are treated with inulinase enzyme from *Aspergillus niger* to create more oligofructose and is mixed back in with the original inulin.

Ancillary substances: The 2015 TR found no ancillary substances but noted that IOE could contain up to 20% glucose, fructose, and sucrose left over from the chicory source material or enzymatic conversion. Further the TR noted processing aids are removed in favor of a pure IOE product. The amounts of these remaining substances may vary, but the general approach in producing IOE is to purify the IOE solution and thereby limit the amount of processing aids that remain. The TR for fructooligosaccharides (FOS) noted the follow residuals: glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol. There are no ancillary substances to list for IOE.

International: IOE is not specifically listed in the Codex, EU or Japanese organic standards however non-organic agricultural products are not listed in these standards. IOE is not specifically listed on the Canadian organic standards.

Discussion: The NOSB requested information from the public related to (1) ancillary substances, (2) current use of IOE, (3) commercial availability of organic inulin and if conventional FOS could be used with organic inulin in place of conventional IOE, (4) other alternatives. No public comment was received on ancillary substances. Public comment was received from one organic handler on the usage of IOE in fruit fillings. One certifier noted they had seen clients switching to organic inulin. No comments were received about the unavailability of inulin or the short comings in the available organic supply. No comments were received about the availability of alternatives. Other public comment questioned the classification of IOE as agricultural. Upon reviewing draft guidance NOP 5033 on Agricultural/Non-Agricultural Classification and the information contained in the Technical Review the handling committee continues to believe the Agricultural classification is correct. Given the availability of organic inulin, the separate listing of FOS, information from certifiers of operations switching to organic inulin, and the absence of information on continued commercial unavailability of the organic inulin, the Handling Subcommittee recommends this item can be removed from the National List at this time.

Motion to Remove

This proposal to remove Inulin-oligofructose enriched will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Inulin-oligofructose enriched 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: 6517(c)(1)(a): unavailability of a whole natural substitute product

Vote in Subcommittee

Motion to remove Inulin-oligofructose enriched from 205.606(l)

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

Kelp

Reference: 205.606(m) Kelp—for use only as a thickener and dietary supplement.

Technical Report: [1995 TAP](#)

Petition(s): N/A

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

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

Sunset Date: 6/27/2017

Subcommittee Review

Kelp is a term used for seaweeds belonging to the brown algae (Phaeophyceae) class in the order Laminariales. There are about 30 genera and many species. Kelp is dark green or brown in color and has a salty, characteristic taste. Through the 19th century, the word "kelp" was closely associated with seaweeds that could be burned to obtain soda ash (primarily sodium carbonate). The seaweeds used included species from both the orders Laminariales and Fucales. The word "kelp" was also used directly to refer to these processed ashes. The material is harvested, dried and then ground or chopped for use in food. Giant kelp can be harvested fairly easily because of its surface canopy and growth habit of staying in deeper water.

Used for centuries in traditional Japanese food, kelp provides a unique flavor profile and can be used as a thickening agent or as a base for broth. Kelp can also be used as a source of iodine within maximum daily iodine intake limits. (TAP Review, March 5, 1995)

While the term "kelp" generally refers to seaweeds belonging to the brown algae in the order Laminariales, by tradition some forms of kelp have more specific names, for instance, wakame or kombu. Most kombu is from the species *Saccharina japonica* (*Laminaria japonica*). However, some edible kelps in the family Laminariaceae are not always called kombu, such as arame, kurome (*Ecklonia kurome*) or *Macrocystis pyrifera*.

The name "wakame" was derived from the Japanese name wakame. Starting in the 1960s, the word "wakame" started to be used widely in the United States, and the product (imported in dried form from Japan) became widely available at natural food stores and Asian-American grocery stores.

There was very limited public comment regarding this material. One commenter did suggest removing the annotation that limits kelp's use as a thickener and dietary supplement. A second commenter objected to the continued listing of kelp, citing that all non-organic agricultural ingredients should be eliminated from the National List. Another raised possible issues of some contamination and harvesting. There is organic kelp available, but not in large enough commercial supply to meet demand.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the sunset review to make changes to the listings on the National List.

Motion to Remove

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

The Subcommittee proposes removal of Kelp 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 to remove Kelp from 205.606

Motion by: Tracy Favre

Seconded by: Harold Austin

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

Konjac flour

Reference: 205.606(n) Konjac flour (CAS # 37220-17-0).

Technical Report: None

Petition(s): [2001 Petition](#)

Past NOSB Actions: 05/2002 NOSB minutes (determined to be agricultural); 10/2010 NOSB sunset recommendation

Recent Regulatory Background: 2007 Interim Rule ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Subcommittee Review

Konjac flour is derived from tubers of the elephant yam, *Amorphophallus konjac*. It is also called glucomannan. It has been used in traditional foods in Asia such as Shirataki noodles and konjac curd. It is considered a binder, gelling agent, thickener and stabilizer. What makes konjac flour unique is that it can absorb up to 50 times its weight in water. It is now widely used in weight loss supplements because it promotes a sense of fullness and pushes more calories out through the colon instead of letting them be absorbed. It is one of the few fibers that are tolerated by diabetics and it helps lower serum cholesterol and blood glucose.

No public comment was received with new information on the OFPA criteria regarding konjac flour, and no sources of organic konjac flour were identified in public comment. One trade association indicated that it was still important, particularly for use with meat products like sausages and in fruit gels. Other starches and gums do not produce the unique combination of functions that konjac flour has.

An internet search for organic konjac turned up several websites that offered organic konjac noodles (such as <http://www.konjacfoods.com/>) and organic konjac powder (such as <http://www.alibaba.com/showroom/organic-konjac.html>). All sources apparently originate from China. It is difficult for this Subcommittee to assess the availability from these sources, as well as whether they are suitable in form and function for the needs of organic processors.

Motion to Remove

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

The Subcommittee proposes removal of Konjac Flour 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: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove Konjac flour from §205.606

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Lecithin -de-oiled

Reference: 205.606(o) Lecithin—de-oiled.

Technical Report: [1995 TAP](#); [2009 TR](#)

Petition(s): [Lecithin, bleached \(remove 2008\)](#)

Past NOSB Actions: 04/1995 minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606)

Recent Regulatory Background: Annotation change effective 03/15/2012 ([77 FR 8089](#))

Sunset Date: 03/15/17

Subcommittee Review

Lecithin is a very widely used ingredient in food, as an emulsifier, dispersing agent, and to reduce the hydration properties of powders in water and milk products. Lecithin occurs naturally in several foods, such as egg yolks and soybeans. Historically lecithin has been produced commercially from soybeans, but there are now alternative sources available from sunflowers, canola and other crops.

In 2009, the NOSB corrected the listing for lecithin on the National list, by removing it (lecithin—bleached) from § 205.605(b) and adding it to § 205.606 in the de-oiled form only. This also corrected the terminology for the types of lecithin by removing the terms "bleached" and "unbleached" from the listing. The fluid form of lecithin is now widely available from organic soybeans. The 2009 NOSB recommendation to amend the listing stated that de-oiled lecithin was the only form appropriate for certain types of uses and it was not yet available organically.

For this sunset review the Subcommittee heard testimony from one supplier that organic, de-oiled soy lecithin has been available since 2013. They also stated that the resistance to using fluid lecithin is mostly a matter of convenience for users rather than necessity.

Multiple companies who use lecithin, however, stated that there was consistency of supply issues with the organic de-oiled lecithin, and that they were reluctant to rely on just one supplier of this important ingredient. It was also noted that it had a unique functionality that is not achieved in either liquid lecithin or other powdered lecithin, in that the hydrophilic/lipophilic balance is much higher so that it disperses in oil-in-water solutions.

Furthermore, there was no public comment that sunflower or other lecithins were available as organic de-oiled, and the supplier of the organic soy said they did not have organic de-oiled sunflower or other source lecithins. These sources are important for formulators to try to avoid soy in their products.

The Subcommittee believes that progress is being made towards having all types of lecithin available in organic form but believes the market has not reached that point at this time for lecithin from all source ingredients. Therefore the de-oiled lecithin is recommended for renewal on § 205.606.

Motion to Remove

This proposal to remove Lecithin – de-oiled will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lecithin – de-oiled 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: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove Lecithin - de-oiled from §205.606

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

Lemongrass

Reference: 205.606(p) Lemongrass—frozen.

Technical Report: N/A

Petition(s): [2006 Petition](#)

Past NOSB Actions: 04/2007 recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Cymbopogon or lemongrass is part of the grass family (Poaceae) and its leaves are used in various Asian cuisines.

Manufacture: Frozen lemongrass is harvested, cleaned and frozen. Other forms of lemongrass are fresh, dried, cut and powdered. According to the petitioner, lemongrass is commercially grown in South and Central America and Asia.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list lemongrass.

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Comments were received from a cross-section of the organic community in support of delisting frozen lemongrass noting it is commercially available. No specific comments received supported relisting or addressed commercial unavailability of frozen lemongrass. The Handling Subcommittee recommends lemongrass-frozen be removed from the National List.

Motion to Remove

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

The Subcommittee proposes removal of Lemongrass—frozen 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: Commercially available as organic, therefore, it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove Lemongrass—frozen. from 205.606(p)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

Orange pulp, dried

Reference: 205.606(q) Orange pulp, dried.

Technical Report: N/A

Petition(s): [2008 Petition](#)

Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National [List](#)

Recent Regulatory Background: Added to NL effective 03/15/2012 ([77 FR 8089](#))

Sunset Date: 03/15/17

Subcommittee Review

Use: According to the petitioner, dried orange pulp is a fiber with about 33.3% soluble fiber and 34.9% insoluble fiber. It is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use, but is self-limiting after that point due to loss of desirable eating qualities.

Manufacture: Dried orange pulp is a byproduct of the orange juice industry and is manufactured from the washed orange peel, core and rag (membrane) remaining after juicing. The pulp is then mechanically dewatered, stabilized with heat, dried and mill ground to a powder. The only processing aid used is water and no chemicals are used to process the product. The petitioner notes, due to food safety and economics, dried orange pulp manufacture must be co-located with orange juice processing facilities.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list dried orange pulp.

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments received supported relisting or addressed commercial unavailability of dried orange pulp. While the NOSB could not find organic dried orange pulp during a search of publically available sourcing resources in February 2015, there were several listed organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp. The Handling Subcommittee recommends dried orange pulp be removed from the National List.

Motion to Remove

This proposal to remove Orange pulp, dried will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Orange pulp, dried 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: its compatibility with a system of sustainable agriculture and availability of a wholly natural substitute.

Vote in Subcommittee

Motion to remove Orange pulp, dried, from 205.606(q)

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

Orange shellac

Reference: 205.606(r) Orange shellac-unbleached (CAS # 9000-59-3).

Technical Report: [2002 TAP](#); [2014 TR](#)

Petition(s): N/A

Past NOSB Actions: 10/1999 NOSB minutes and vote; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Orange shellac is the purified product of the natural resin lac which is the hardened secretion of the insect *Kerria lacca*, the lac insect. It is used as a coating for fruit and vegetables as well as a confectionary glaze.

A new Technical Report (TR) was commissioned for this review to provide updated information and to look at ancillary substances. Shellac is usually used in combination with other coatings such as carnauba or wood rosin.

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. In regard to the ancillary substance question, no ancillary substances were suggested for the raw ingredient, but ancillaries may be used once it is formulated with other coating agents. Since there are fully compliant organic formulations on the market, this does not need further action.

One other point brought up frequently in public comment was the desire for labeling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public comments mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labeled, 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 labeling of produce coatings, but is unable to put forward an additional labeling annotation.

Motion to Remove

This proposal to remove Orange shellac – unbleached (CAS # 9000-59-3) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Orange shellac – unbleached (CAS # 9000-59-3) 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 to remove Orange Shellac from 205.606(r)

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

Pectin

Reference: 205.606(s) Pectin (non-amidated forms only).

Technical Report: [1995 TAP](#); [2009 TR](#); [2010 supplemental TR](#); [2015 TR](#) (limited scope)

Petition(s): [2005 Petition – low methoxy pectins](#)

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

Recent Regulatory Background: Sunset Review effective 06/27/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Subcommittee Review

Pectin is extracted from citrus and pome fruits but so far there is no organic source of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. The excess sugar has the potential for more negative human health effects than pectin.

Pectin was widely supported in public comment from its users. No negative comments were received with substantive information on why pectin would not meet the OFPA criteria.

Ancillary substances used in pectin include sugar and dextrose for standardizing products, and trisodium citrate (or other salt buffers described in the 2015 TR). A separate ancillary substance proposal is accompanying this substance.

Motion to Remove

This proposal to remove Pectin (non-amidated forms only) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Pectin (non-amidated forms only) 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: OFPA criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove Pectin (non-amidated forms only) from §205.606(s)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

Peppers (Chipotle chile)

Reference: 205.606(t) Peppers (Chipotle chile)

Technical Report: N/A

Petition(s): [2006/2007 Petition](#)

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Chipotle chiles are added to a variety of food products as a flavoring to give products a distinct hot (spicy) and smoky chili flavor common in Latin foods.

Manufacture: Chipotle chiles and smoked dried-jalapeños. Harvested chiles are sorted, smoked-dried and then are used whole, crushed or powdered.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Chipotle peppers are not listed in the EU Organic Standards.

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting chipotle chiles noting commercial availability. No specific comments received supported relisting or addressed commercial

unavailability of chipotle chiles. The Handling Subcommittee recommends peppers (Chipotle chile) be removed from the National List.

Motion to Remove

This proposal to remove Peppers (Chipotle chile) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Peppers (Chipotle chile) 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: Commercially available as organic, therefore, it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove Peppers (Chipotle chile) from §205.606(t)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

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

Seaweed, Pacific kombu

Reference: 205.606(u) Seaweed, Pacific kombu

Technical Report: N/A

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

Past NOSB Actions: 05/2008 NOSB recommendation

Recent Regulatory Background: Added to NL effective 03/15/12 ([77 FR 8089](#))

Sunset Date: 03/15/17

Subcommittee Review

Kombu is an edible kelp belonging to the family Laminariaceae. It is dark green or brown in color and has a salty, characteristic taste. Most *kombu* is from the species *Saccharina japonica* (*Laminaria japonica*), and is extensively cultivated on ropes in the seas of Japan and Korea. With the development of cultivation technology, over 90% of Japanese *kombu* is cultivated, mostly in Hokkaidō, but also as far south as the Seto Inland Sea. The material is harvested, and typically dried and then ground or chopped for use in food. Used for centuries in traditional Japanese food, kombu provides a unique flavor profile and can be used as a thickening agent or as a base for broth.

The 2008 NOSB recommendation stated that there are certified organic seaweeds but they do not impart the same characteristics as kombu. Although there are a number of specific varietal identifications of “kombu,” the common term Pacific kombu was determined to be adequate and appropriate for identification. That petitioner was unable to locate a source of certified organic kombu. The separate inquiries of Board members supported this finding. It was felt that it might be possible in the future that kombu could be certified organic under the “Wild Harvest” portion of the Rule (§ 205.207). The Board concluded that the material satisfied the criteria of all four categories required for a material to be listed on § 205.606.

There was very limited public comment regarding this material. One commenter did object to the continued listing of kombu, citing that all non-organic agricultural ingredients should be eliminated from the National List.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the sunset review to make changes to their listings on the National List.

Motion to Remove

This proposal to remove Seaweed, Pacific kombu will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Seaweed, Pacific kombu 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 to remove Seaweed, Pacific kombu from §205.606(u)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

Starches; cornstarch, sweet potato

Reference: 205.606(v) Starches.

(1) Cornstarch (native).

(2) Sweet potato starch - for bean thread production only.

Technical Report: [1995 TAP - Cornstarch](#)

Petition(s): N/A – Cornstarch; [2007 Petition - Sweet Potato Starch](#)

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset review Sweet potato starch; 10/2010 sunset recommendation on cornstarch

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

Sunset Date: 6/27/2017

Subcommittee Review

Starches are used in many foods as thickeners, formulation aids, bulking agents and moisture adsorption agents. Cornstarch is made from special strains of corn that are high in amylose and amylopectin. Sweet potato starch is specifically used as a formulation aid for bean thread production.

There is an organic cornstarch on the market, but it is not suitable for all uses. Cornstarches are described by the relative content of two glucose polymers: amylopectin and amylose. Special strains of corn are grown to achieve the right ratio of the polymers and these special varieties are all identity preserved to maintain their amylose ratio and so are never genetically engineered. A supplying company

and a trade association indicated that there is not a supply of organic moulding cornstarch, or the type with very high amylose content, or special strains with freeze-thaw properties.

No public comments were received with new information about any of the other OFPA criteria other than a concern over GMOs in cornstarch. GMO cornstarch would not be allowed in organic food in any case, but is unlikely to occur as discussed above.

Motion to Remove

This proposal to remove Starches; cornstarch, sweet potato will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Starches: cornstarch, sweet potato 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: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion to remove Cornstarch (native), and Sweet Potato Starch from §205.606(v)

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

Turkish bay leaves

Reference: 205.606(x) Turkish bay leaves.

Technical Report: N/A

Petition(s): [2006 Petition](#)

Past NOSB Actions: 04/2007 recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Turkish bay leaves are an herb that has been used traditionally to flavor food.

Manufacture: Turkish bay leaves (*Laurus nobilis*) are widely cultivated in the Mediterranean and Asia. Leaves are harvested, sorted and then sold as fresh or dried.

International: There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list Turkish bay leaves.

Ancillary Substances: No ancillary substances were provided.

Discussion: The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. One commenter, the original

petitioner, noted that they have identified a source of Turkish bay leaves but believe the supply is too fragile to have the listing removed at this time. Searches of publically available organic sourcing pages by the NOSB in June of 2015 resulted in 85 NOP organic certificate holders of bay leaves with 12 specifying *Laurus nobilis*. Additionally 3 spice companies were contacted and all had sources of Turkish bay leaves from Turkey, India or both. One commenter noted that plantings, pesticide uses and residues, and pollinator impacts need to be assessed for conventional agricultural items. It should be noted that under the NOP, products certified to the “made with organic...” claim, and containing 70%+ organic content, may use non-organic agricultural ingredients that are not listed on §205.606 or undergo a review for compliance with OFPA criteria – although such ingredients are still required to comply with § 205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or excluded methods. Additionally, the commenter provided no data specifically on pesticide usage and residues on Turkish bay leaves and just cited EPA tolerance levels for pesticides on herbs subgroup 19A. The Handling Subcommittee recommends Turkish bay leaves be removed from the National List.

Motion to Remove

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

The Subcommittee proposes removal of Turkish bay leaves 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: Commercially available as organic therefore it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove Turkish bay leaves from 205.606(x)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

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

Wakame seaweed

Reference: 205.606(y) Wakame seaweed (*Undaria pinnatifida*).

Technical Report: N/A

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

Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Wakame is an edible seaweed, most often served in soups and salads. Native to cold temperate coastal areas of Japan, Korea, and China, in recent decades it has become established in New Zealand, the United States, France, Great Britain, Spain, Italy, Argentina, and Australia. It was nominated one of the 100 worst invasive species in the world. It has been grown for centuries in Japan and Korea, where it is still primarily consumed. The name "wakame" was derived from the Japanese name *wakame*. In the

1960s, the word "wakame" started to be used widely in the United States, and the product (imported in dried form from Japan) became widely available at natural food stores and Asian-American grocery stores.

The material was petitioned in 2007, where the petition stated that organic wakame (*Undaria pinnatifida*) was not available. While other organic seaweeds were, they did not provide the same flavor profile and could not be used in the instant soup for which wakame was being petitioned as an ingredient.

In 2010, the NOSB reaffirmed a recommendation for the continued listing of wakame along with additional § 205.606 materials: 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. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list these materials. As § 205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products.

There was very limited public comment regarding this material. One commenter did object to the continued listing of wakame, citing that all non-organic agricultural ingredients should be eliminated from the National List.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the Sunset review to make changes to their listings on the National List.

Motion to Remove

This proposal to remove Wakame seaweed (*Undaria pinnatifida*) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Wakame seaweed (*Undaria pinnatifida*) 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 to remove Wakame seaweed from 205.606(y)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

Whey protein concentrate

Reference: 205.606(z) Whey protein concentrate.

Technical Report: [2015 TR](#)

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

Past NOSB Actions: 05/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

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

Sunset Date: 6/27/2017

Subcommittee Review

Use: Whey protein concentrate is used in dairy products, protein bars, and infant formulas. Whey protein concentrate is used as a source of protein, as a fat replacer, and as a texturizer.

Manufacture: Whey protein concentrate is a soluble fraction of bovine milk composed of protein, minerals and lactose and is a byproduct of cheese manufacturing. The primary method of production mixes milk with rennet to coagulate the casein to make cheese curds, the resulting liquid is whey. Another method of production is via microbiological fermentation or direct addition of lactic acid that acts to reduce the pH and coagulate the casein. The whey undergoes an ultra-filtration process to remove a large portion of the lactose and minerals. Low temperature processing ensures retention of both nutritional and functional properties. Whey protein concentrate is evaporated then spray-dried and sold as a dry ingredient. The whey protein concentrate may also be bleached with hydrogen peroxide or benzoyl peroxide if it was the product of colored cheddar cheese. Whey protein concentrate can be concentrated to different protein levels (i.e., 35%) but max out around 80%. Concentrations higher than 90% are considered whey protein isolate.

International: Whey protein concentrate is not specifically listed in the Codex, Canadian, or Japanese organic standards. "Whey powder 'herasuola'" is listed on the EU Organic Standards.

Ancillary Substances: Soy lecithin added as an "instantizing" ancillary substance was identified.

Discussion: The NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, (5) use in the industry. One public comment was received from a certifier on the use of soy lecithin as an ancillary substance. No information was provided on commercial demand, alternatives or its use in the industry. One trade association commented on its essentiality and lack of supply but provided no detailed information on why the supply identified by the NOSB was insufficient. One certifier noted they have clients producing and selling whey protein concentrate. The Subcommittee asked the original petitioner to comment to which they noted they have had a secure supply of organic whey protein concentrate for several years. Given the availability of organic whey protein concentrate and the absence of information on continued commercial unavailability from industry the Handling Subcommittee recommends this item be removed from the National List at this time.

Motion to Remove

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

The Subcommittee proposes removal of Whey protein concentrate 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: Commercially available as organic therefore it is inconsistent with organic farming and handling.

Vote in Subcommittee

Motion to remove Whey Protein Concentrate (WPC) from 205.606

Motion by: Tom Chapman

Seconded by: Jean Richardson

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