National Organic Standards Board Meeting
Virtual
October 28 - 30, 2020

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee

Request for Discussion and Recommendations:
Human Capital Strategy for Organic Inspectors and Reviewers
August 11, 2020

On July 31, 2020, National Organic Program (NOP) Deputy Administrator Dr. Jennifer Tucker shared a memo and work agenda item with the Board, requesting that the Board facilitate a public discussion related to Human Capital Strategy for Organic Inspectors and Reviewers. Dr. Tucker presented a document discussing different elements of human capital management, focusing specifically on organic inspectors and reviewers. As the document notes, the topic of inspector and reviewer qualifications and training has been of interest to the NOP and the organic community for several years.

This work agenda item and related paper seek to build on this ongoing discussion, summarizing a broader set of human capital dimensions that are needed to develop, support, and retain a robust and well-supported pipeline of certification professionals over time. The goal is to initiate a broader discussion on these topics across the organic community. The paper presents several key areas of human capital and poses questions to support an inclusive discussion.

The Compliance, Accreditation & Certification Subcommittee (CACS) welcomes this discussion, is eager to receive feedback, and invites the community to start the conversation by submitting comments during the Fall 2020 open docket and webinar comment sessions. Time will be set aside during the Fall 2020 meeting for Board discussion and consideration of comments received. We look forward to continued discussion across future meetings as a means to further strengthen the capacity of the certification and broader organic community.

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Paper Based Crop Planting Aids
July 21, 2020

Summary of Petition and Petition Addendum for Paper (Plant Pots and Containers)

The NOSB received a petition in August 2018 for the addition of paper planting pots to the National List: **§205.601(o) production aids- Plant pot or growing container-hemp or other paper, without glossy or colored inks.**

This material has not been petitioned for inclusion on the National List in the past. However, paper chain pots have been historically allowed for the past 12 years by some organic certification agencies, under the allowance for "Newspaper or Other Recycled Paper as a mulch or compost feedstock".

In February 2018, the NOP notified all certifiers that paper chain pots are not allowed in organic systems. However, because some certifiers had previously approved their use, NOP allowed a phase-out period until the end of the 2018 crop season. The NOP's decision on this material was based primarily on the presence of an unapproved synthetic adhesive in the product and the use of virgin paper. Further, the current allowance for paper on the National List does not extend to the use associated with paper pots. At the October 2018 and April 2019 NOSB meetings, there were numerous oral and written public comments requesting a longer time period allowing use of these paper pots while the NOSB reviewed the petition. The NOSB also formally requested this extension in November 2018. The NOP agreed to allow the use of paper pots in organic agriculture in late Fall 2018, with no time restriction, in order to give the NOSB time to go through the review process of this material.

Paper pots are used by small scale farming operations to efficiently transplant using a non-motorized machine transplanting system. More information on this transplanting method can be found on these websites: http://paper-pot.com/ and http://www.smallfarmworks.com/. This equipment, along with the paper pots, is imported from a manufacturer in Japan. According to the petition, the Nitten paper pot chain system uses paper, produced from a non-bleached Kraft pulp, and adhesives. Non-paper synthetic fibers have been used in small quantities (15%) in the paper pots, but these fibers are proposed to be replaced by a natural hemp fiber. The petitioner and public comment at the Spring and Fall 2018 NOSB meetings stated this system is unique and essential for smaller scale growers. The only alternative would be the much slower and more costly hand planting of individual plants. The system is used for closely spaced crops such as onions, beets, baby salad, etc. The petition states that, similar to newspaper, these pots decompose in the soil readily. At the time of this proposal, the first trial replacing the synthetic fibers with hemp fibers was not successful, and a second trial was in process.

In addition to the paper pots indicated in the petition, there are numerous other paper pot systems, both to be used to transplant single plants as well as in chains. In addition to paper, these other paper pot systems have various percentages of non-paper synthetic fibers, which may or may not be biobased. Paper pots can also include other ingredients, such as cow manure, synthetic antimicrobials, fungicides and fertilizers. Public comment from another manufacturer based in Denmark, Ellepot (https://www.ellepot.com/), provided further information on non-chain paper pots for a variety of uses from fast maturing annuals to long term woody perennial crops. The percentage of cellulose based synthetic fibers in their paper pots can be 20-100%. Synthetic adhesives are currently the only synthetic material used in the Ellepots other than the paper itself.

The petition states that, in addition to information on paper, the TR on newspaper addresses the presence of adhesives and synthetic fibers in recycled newspaper as well. The three adhesives in the Nitten paper chain pots are vinyl-acetate resin (water soluble and stated to be leached from the pots before transplanting), ethylene-vinyl-acetate resin, and acrylic acid ester copolymer.

It should be noted that paper itself is a synthetic fiber due to the manufacturing process. However, for the purposes of this discussion, a distinction is made between synthetic paper fibers and synthetic fibers that are not strictly paper. These non-paper synthetic fibers can be biobased and made from cellulose or they can be non-biobased and made from a number of other materials such as petroleum-based plastics. In general, many of the biobased, cellulose derived synthetic fibers used in paper pots are expected to biodegrade whereas the same might not be true of other petroleum-based fibers. Thus, it is important to distinguish not only between synthetic paper fibers and other non-paper synthetic fibers but also between whether these non-paper fibers are biodegradable (as referenced to some recognized standard) or might persist in the soil.

The Crops Subcommittee has viewed paper pots, used as a crop production aid, as another use of paper beyond compost feedstocks and mulch, which are allowed under the NOP regulation. However, in order to do due diligence, the Crops Subcommittee requested a [Technical Review (TR)] to help identify the adhesives and synthetic fibers used in paper pots and identify if there are any that would not be present in the already allowed paper used in compost and mulch. Pots, compost, and mulch all degrade into the soil, and the Subcommittee believes if the fibers and adhesives are allowed in the other listings for paper, then their use in pots should be allowed as well.

The Technical Review clarified that the adhesives and non-paper synthetic fibers found in a variety of paper pots are also found in newspaper and recycled paper that are allowed for compost feedstock and mulch. Other possible adhesives and synthetic fibers for paper pots that were not mentioned in the petition are described in the TR.

Summary of Public Comment:

Many users of the paper pot chain system provided written and verbal comment to the NOSB at the Fall 2018 through Spring 2020 public meetings. They spoke in favor of its use due to its efficiency in transplanting at a small-scale level. Some certifiers spoke in favor of this material and noted that if the paper was torn off the pot before transplanting, it would then be allowed as a mulch or as a compost feedstock under our current regulation. Certifiers who had not allowed the use of these paper pots still supported the extended allowance for use while the NOSB performed its review.

There is more than one supplier of paper pots beyond the supplier noted in the petition. Approval of this material will open the door for other manufacturers to produce these pots once there is clarity on what would be allowed under the organic regulations. Paper pots can be made with all-natural fibers or with a mixture of synthetic and natural fibers. The pots with higher non-paper, synthetic fiber contents are more typically used in the nursery trade where perennial plants may be in the pots for 9-12 months before transplanting into the field. Natural fiber pots can, at times, be sufficient for use in transplanting annual vegetable and flower plants, depending on the time frame from planting into the pot to planting in the field and if the pots need extra strength for a “chain of pots” planting system. All of the paper pots contain some type of synthetic adhesive, but these same adhesives are also found on recycled paper which is already allowed in organic agriculture.

Numerous commenters mentioned that all uses of paper as a production aid should be included when the NOSB does its review for paper pots. Cloches or hot caps, seed tape, and cutworm prevention collars are other examples of production aids made from paper and typical paper adhesives.

There were also a number of comments about whether the listing for paper pots should be expanded to include additional distinct uses of paper as a production aid. Many commenters favored a listing that extended beyond only paper pots to include, but not be limited to, items such as seed tape, and other materials with direct soil contact. However, commenters also wanted to make sure that there was a differentiation between paper materials being used that are later incorporated into the soil versus paper materials that are intended to be removed after use. The Crops Subcommittee has narrowed the use from a "production aid" to a "planting aid" to limit the use of this paper to that period of the crop production, and to those aids that would be incorporated into the soil.

Specific Uses of the Substance:

These paper pots are either single or in chains to allow for "mechanical" transplanting, either with a hand driven machine or with a tractor implement. The paper pots decompose into the soil, and lessen transplant shock since the roots are not exposed to the air before transplanting like plants being removed from plastic pots. The use of paper pots can contribute to less use of plastic in the produce industry. Growers can also use soil blocks, which are compressed soil without any container, to grow transplants.

Other paper crop production aids include: cloches (a temporary covering used to protect newly transplanted plants), seed tape (where individual seed is spaced correctly on a paper tape which lessens the need for thinning), and collars to prevent cutworm damage to plants at the soil line. There could be other uses of paper currently used as crop production aids or there may be other uses developed over time. The composition of the paper allowed in paper pots and other planting aids, as well as the adhesives approved, would meet the manufacturer needs of these other paper planting aids.

Approved Legal Uses of the Substance:

Newspaper and recycled paper are allowed under the organic regulations in these two references:

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspapers or other recycled paper, without glossy or colored inks.
Reference: 205.601(c) - As compost feedstocks - Newspapers or other recycled paper, without glossy or colored inks.

There have been three technical reports (TRs) for Newspaper, in 1995, 2006 and 2017, which can be found here: https://www.ams.usda.gov/rules-regulations/organic/national-list/n.

NOP guidance 5034-1 "Materials for Organic Crop Production" from December 2016 excludes virgin paper from the "newspaper or other recycled paper" allowance for mulch or compost feed stocks. The guidance states: *"Includes newspaper and other recycled paper such as cardboard, without glossy or colored inks. Does not include paper that is not recycled (i.e., virgin paper)."*

The July 2019 Technical Review of Paper Pots and Containers, detailing the specific possible synthetic and natural fibers as well as synthetic adhesives found in paper pots currently commercially available, provided more clarity for the NOSB.

Manufacture:
Paper can be made from various plant sources including wood, trees, straw, hemp, bamboo, reeds, kenaf, sisal, jute, sugarcane bagasse, sunflower stalks as well as recycled sources of pulp. Cellulose sources are typically mechanically ground and then chemically "cooked" using an alkali or sulfite process. Newspaper and recycled papers can also have a variety of inks, although colored ink and glossy paper are not allowed as compost feedstocks or mulch under the organic rule. The paper used as a planting aid could include the typical adhesives found in newspaper and recycled paper.

Subcommittee Discussion:
The Crops Subcommittee has reviewed the petition, technical reviews, and public comments and have developed a listing and annotation that we believe meets the needs of producers while addressing environmental concerns that might be associated with some types of paper. When discussing the possible allowance for paper used as a planting aid, the subcommittee also considered the fact that currently there is an allowance for "newspaper or other recycled paper" as weed control or as compost feed stocks and there are very few differences between the currently allowed paper and the paper as a planting aid under review, with the exception of paper pots that have a very high percentage of non-cellulose synthetic fibers. Requiring 60% cellulose fiber prevents the planting aids from being completely made of biobased, non-degradable plastics and yet allows current products on the market. It is hoped that this percentage can increase over time. Requiring 80% biobased content prevents the use of planting aids made primarily from petroleum sources and also allows the products currently on the market. Again, it is hoped that this percentage can be increased over time and that future Boards will be able to modify this annotation to reflect manufacturing technological advances that incorporate more natural materials and additional cellulose and biobased content. Small changes have been made to the annotation to reflect concerns from stakeholders. There is concern that the annotation specifically notes that allowed paper planting aids are not limited to those listed and that the materials will be incorporated into the soil (without reference of intent to biodegrade). Finally, as pointed out in public comment, the wording that allows the use of newspaper "without colored or glossy inks" was intended to prevent use of glossy paper and colored inks and the wording for paper planting aids is changed to prevent the use of glossy paper or colored inks.

Category 1: Classification

1. **For CROP use: Is the substance _____ Non-synthetic or __x__ Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

   Due to the paper pulping production process and use of synthetic adhesives, this material is considered to be synthetic.

2. **For CROPS: Reference to appropriate OFPA category:**
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

This material is considered a crop planting aid and is not a pesticide. Although some paper pots available on the market might have prohibited pesticides (insecticides, antimicrobials, fungicides etc.) embedded in the fiber, these would not be allowed in organic production. In order to be explicit, the annotation states that any added nutrients or pesticides must conform to the National List or be allowed under OFPA.

Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

   Most of the paper used as a crop planting aid is functionally identical to newspaper and recycled paper. The current listing of newspaper and recycled paper has been found to have no detrimental interactions with other materials in organic agriculture.

2. **What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]**

   No toxicity or negative mode of action has been found in the breakdown of paper (cellulose) in the environment. No colored inks or glossy paper would be allowed for paper as a crop planting aid, similar to paper as it is currently annotated as a compost feedstock and/or mulch. The 2019 TR found many of the adhesives and synthetic fibers biodegraded with no negative impacts. There were some that were not as environmentally neutral as others, but all were also present in newspaper. The percentage of adhesives in the paper pots is very small. There could be an issue with paper used as a planting aid, containing large percentages of synthetic fibers that would not biodegrade readily.

3. **Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

   There could be contaminants released into the environment during the manufacture of paper, and environmental degradation caused by harvest of cellulose, but no more than newspaper or recycled paper, which historically have been approved for use in organic agriculture. A difference between this paper and the previously approved newspaper is that we are not restricting it to the use of only recycled paper products. The annotation will allow virgin stocks of cellulose to be used in the paper used as a planting aid in organic agriculture. There are negative environmental impacts from harvesting trees to make paper such as road building, soil erosion, degraded water quality, and loss of habitat, but there are forestry best management practices that can mitigate some of these negative effects. The synthetic fibers that could be used in paper are manufactured in a wide range of production systems. These were not specifically addressed in the TR.

4. **Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

Paper, depending on the percentage of cellulose and type of synthetic fibers/materials used, is biodegradable and has no negative effects on human health. The 2019 TR did not find any evidence of harmful effects to human health.

5. **Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]**

   Paper, depending on the percentage of cellulose and type of synthetic fibers/materials used, is not harmful to the environment. The 2019 TR did not find any evidence of harmful effects to environmental health.

6. **Are there any adverse impacts on biodiversity? (§205.200)**

   Paper planting aids with high percentages of synthetic fibers that do not biodegrade readily could leave residues that would be harmful to terrestrial, avian and aquatic wildlife if consumed. Use of synthetic pesticides embedded in the pots could also have adverse impacts on biodiversity, but only organically allowable pesticides or nutrients would be allowed in the paper used as a planting aid.

Category 3: Alternatives/Compatibility

1. **Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

   There are biodegradable pots made from composted cow manure (https://cowpots.com/) but these have never been petitioned for use in organic agriculture. We do not know if they could be approved or not. The manufacturer states the pots contain post-consumer newsprint and are 100% biodegradable. In addition, they state they are not approved for Certified Organic operations as of January 2020. It is unclear if there are adhesives or synthetic fibers as well and what they are.

   There are also tools to help growers roll up newspaper into a pot. The paper chain pots offer greater efficiency for small scale transplanting, although mechanical or hand transplanting operations can be used in both small- and large-scale operations with other types of pots or soil blocks.

2. **In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

   The Crops Subcommittee has developed the definition and annotation described in the motion below to both meet the OFPA criteria and to provide a practical and achievable material for manufacturers to produce and for organic farmers to use. The material is a planting aid and the intent is to limit the use of this material to activities around planting of seeds or plants.

   The annotation of no less than 60% cellulose-based fiber content meets the needs of current manufacturers with the possibility that hemp or other natural cellulose fibers, capable of providing the strength needed to meet this annotation, could be used in the future. The 80% biobased requirement ensures that materials beyond the cellulose base are derived from biological sources. Both the 60% cellulosed based fiber content and 80% biobased content requirements could be made more stringent by future Boards through an annotation change. As the technology of these planting aids advances it's possible manufacturers will be able to use more natural and biobased materials to strengthen the planting aids. Continuing the prohibition on glossy paper and colored inks prevents the incorporation into organic soil of the worst contaminants. It is understood that there would be a small percentage of adhesives and coatings and the Technical Reviews on paper and paper pots described how these are already allowed in paper as mulch or compost feedstocks.

The allowance for virgin paper allows for special papers to be developed that meet the specific crop planting needs for a variety of uses, and the amount of paper produced from virgin sources for these planting aids would be very small compared to the amount of paper manufactured for all uses. Added fungicides, antimicrobials, insecticides or other synthetic items not typically found in paper would not be allowed under the current annotation unless they were on the National List for that purpose or otherwise compliant with the OFPA. Genetically modified materials are prohibited under the organic regulation and would not be allowed as ingredients in paper-based crop planting aids. With the recommended annotation, paper-based crop planting aids are compatible with a sustainable system of agriculture.

The Crops Subcommittee did not include a biodegradability standard in this proposal due to the time and cost needed for testing to that standard. The Subcommittee would like to see continued innovation to move to 100% biobased as well as an increase in the natural fiber content of these planting aids. Additionally, the Subcommittee wants to make sure that these materials are promptly and economically available to growers of all sizes. The Subcommittee would like to encourage testing and trials of increased natural and/or biobased contents and believe that manufacturers would be less likely to provide small innovations of these new products to organic farmers if this testing were required.

Classification Motion:

Motion to classify "paper-based crop planting aid" as a synthetic substance.
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add to 205.2 Terms Defined:

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil. Contains no less than 80% biobased content as verified by a qualified third party assessment (e.g. laboratory test using ASTM D6866 or composition review by qualified personnel).

Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 6 No: 1 Abstain: 0 Absent: 1 Recuse: 0

Add to 205.601 (o) Production Aids:
Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without glossy paper or colored inks. Added pesticides or nutrients must comply with §205.105, 205.203, and 205.206.

Motion by: Steve Ela
Seconded by: Rick Greenwood
Yes: 6 No: 1 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jesse Buie, Crop Subcommittee Chair, to transmit to NOP July 28, 2020

National Organic Standards Board
Crops Subcommittee Proposal
Wild, Native Fish for Fertilizer Production
July 21, 2020

Summary:
The use of fish in crop fertility products has a long history in organic agriculture. Over the past five years, the board has heard from stakeholders about potential negative environmental impacts of harvesting some marine materials for organic production. The purpose of this proposal is to limit the impact of harvesting wild, native fish for fertilizer and to ensure that liquid fish fertilizer products used in organic production are not harmful to the environment.

Background:
As part of the most recent sunset review of Liquid Fish Products (LFPs) under Section 205.601(j)(8) of the organic regulations, the Crops Subcommittee posed questions to stakeholders asking about the number of products using wild fish harvested solely for fertilizer versus products utilizing fish waste or byproducts. The board learned that the majority of LFPs use fish byproducts (offal), and some use whole fish harvested to control invasive species. At its Spring 2018 meeting, the board received testimony that some manufacturers are using wild, native fish harvested exclusively for fertilizer. Consequently, the Crops Subcommittee requested the development of a **Technical Report (TR) on Fish-Based Fertilizers** to investigate this further. At its spring 2020 meeting, the board put forward a Discussion Document on the topic soliciting stakeholder feedback.

Relevant Areas of OFPA and the Regulations:
OFPA Section 6517 [National List] (c) [Guidelines for Exemptions or Prohibitions] (1)(a)(i) and (2)(a)(i) which allows for the prohibition of synthetic or nonsynthetic substances, respectively, that would be "harmful to ... the environment."

OFPA Section 6518 [National Organic Standards Board] (m) [Evaluation] which directs the Board to consider—(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."

§205.601 Synthetic substances allowed for use in organic crop production
In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided that, use of such substances does not contribute to contamination of crops, soil, or water...
(j) As plant or soil amendments.
(8) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

NOSB Policy and Procedures Manual, Principles of Organic Agriculture Organic agriculture, adopted 2001, 1.1 states: Organic agriculture…is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity.

Discussion:
In its TR request, the Subcommittee asked the following questions:

1. During the Spring 2018 public meeting, the Crops Subcommittee asked if there are manufacturers using exclusively wild-caught, native fish to manufacture liquid fish fertilizers and learned that there are. Public testimony suggested that other non-synthetic fish-based fertilizers, such as fishmeal, may also be derived from wild fish harvested solely for fertilizer production. Is any new information available about the impact of fish fertilizer manufacturing on the sustainability and health of wild, native fish stocks harvested solely for fertilizer production?
2. To what extent does the harvesting of wild, native fish exclusively for use as a fertilizer harm the environment?
3. Do different methods, locations, and/or frequencies of harvest pose different levels of risk for wild, native stocks?
4. Are there any species of wild, native fish for which there are no negative environmental impacts of harvest?
5. Are there any fish fertilizer products derived from farmed fish, and if so, are there any negative environmental impacts?
6. Are there any fish fertilizer products derived from wild, non-native fish populations, and if so, are there any negative or positive environmental impacts?
7. Please describe the environmental impact of using wild, native fish harvested exclusively for fertilizer versus using byproducts or invasive species.
8. Please provide universally agreed upon definitions of "wild, native fish", "wild-harvested", and "invasive species".
9. Please provide examples of non-regulatory/practice-based approaches (e.g. training, guidance) that should be considered.

The findings of the TR were different from previous public comments. Specifically, the TR states that "based on available data, wild, native fish are not harvested solely for fertilizer production (see Table 1, in 268 Specific Uses of the Substance) (OMRI, 2019a). Rather, fish waste or otherwise unusable material is generally used as the starting material for fish-based fertilizers." (TR Lines 267-69). This statement is explained below (TR Lines 93-109):

> Of the 124 fish-based fertilizers listed by OMRI, 76 percent contained at least some wild fish, 15 percent contained at least some farmed fish, and 27 percent contained fish where it was not possible to tell if a source was farmed or wild (OMRI, 2019a). Products in some cases used various combinations of wild, farmed, and unknown fish. Twelve percent of products contained at least some fish meal, 45 percent contained at least some fish hydrolysate, and 43 percent contained at least some fish solubles. One product contained both meal and solubles and was counted in both groups.
>
> It is worth noting that in Table 1, fish harvested for meal, oil, and solubles were not considered to be harvested solely for fertilizer production. The majority of fish-based fertilizers derived from the wet reduction process contain solubles—a material that is sometimes considered a byproduct of the process. A few products contain meal, but they do not also include fish oil; therefore, only a portion of the saleable fish biomass is utilized specifically for fertilizer and one cannot say that the fish were harvested exclusively for fertilizer use. An analogous example would be beef cows raised for steaks, ground meat, renderings and leather; those animals were not raised exclusively for any single one of those materials. Furthermore, only 2 percent of products contained fish meal that was derived from fish harvested specifically for wet

> reduction. The remaining 10 percent of products containing fish meal are derived from fish waste that undergoes further processing.

Table 1 in the TR states that of OMRI listed products, 43.5% are derived from market fish waste for human consumption (hereafter referred to as "waste"), 3.2% from bycatch and mortality, 31.5% from meal, oil, and solubles, 12.9% from market fish waste and bycatch/mortalities, 8.9% from market fish waste, meal, oil, and solubles, and 0% from fish sources specifically and exclusively for fertilizer.

The TR is extensive and answers the questions posed by the CS. While the amount of fish harvested globally for fertilizer is not available due to limited data, the TR addresses the generally negative impacts of commercial fishing on many wild, native stocks. The TR states:

> Production of fish-based fertilizers could, to a small degree, drive demand for fish harvested for meal, oil, and solubles production. Fish-based fertilizers are unlikely to create demand for fish waste that drives fish harvesting rates for human consumption. The extent that harvesting wild, native fish for use as a fertilizer harms the environment is small compared to the primary uses of fish because of the difference in scale (Lines 319-23).

The TR goes on to explain that:

> While none of the fish species known to be harvested for fish reduction purposes and which are incorporated into fish-based fertilizer products are threatened or endangered species (see Table 2), their population dynamics are not understood in many cases. It is also difficult to ascertain the effect of removing biomass, even from a sustainable fishery, considering that these species may be a food source for other species. Meal and oil fish can be critical to the function of entire ecosystems; for example, Pacific thread herring (Opisthonema libertate) and Pacific anchoveta (Cetengraulis mysticetus) are critical links in the Gulf of California, transferring energy through the food web and controlling the organization of these ecosystems (Hernandez-Padilla et al., 2017). (TR Lines 342-49)
>
> Regardless of the intended use, harvesting wild, native fish can contribute to biodiversity loss, habitat destruction, and loss of ecosystem services. (TR lines 327-28)

The TR discusses some species used for meal/oil that have experienced documented large-scale population declines, though not always exclusively as a result of over-fishing. It addresses the effects of large-scale harvesting on fisheries and the broader ecosystems, yet it notes the relationship to fish used in fertilizer is scale-dependent. Harvest methods, location and timing, and gear are discussed. The use and impacts of farmed fish for fertilizers is also explained. Moreover, fertilizers made from waste of fish harvested for human consumption include species with well documented declines and collapses (TR lines 386-94).

During the spring 2020 meeting, the Board solicited public comment on the following questions:

1. Given the results of the TR indicating that there are no species of wild, native fish harvested exclusively for use in LFPs, please provide feedback on any next steps the subcommittee should take on this issue.

2. The TR outlines the wet reduction process for fish meal, oil, and solubles and states that solubles are a byproduct of meal (solid phase) and oil (liquid phase) production. Because of the multiple products derived, it did not consider fertilizers using them to be from fish harvested exclusively for fertilizer. Please comment.
3. Please provide any additional information you may have to help answer the TR questions, particularly:
    - During the Spring 2018 public meeting, the Crops Subcommittee asked if there are manufacturers using exclusively wild-caught, native fish to manufacture liquid fish fertilizers and learned that there are. Public testimony suggested that other non-synthetic fish-based fertilizers, such as fishmeal, may also be derived from wild fish harvested solely for fertilizer production. Is any new information available about the impact of fish fertilizer manufacturing on the sustainability and health of wild, native fish stocks harvested solely for fertilizer production?
    - Do different methods, locations, and/or frequencies of harvest pose different levels of risk for wild, native stocks?
    - Please provide examples of non-regulatory/practice-based approaches (e.g. training, guidance) that should be considered.

A number of public commenters advised that since the TR indicates that no fish are harvested exclusively for fertilizer, the board should not continue work on this topic. Others stated that the discrepancy between the spring 2018 public comments and the TR results should be clarified. The subcommittee confirmed with the TR authors that they conducted additional research and analysis that revealed the multi-use purpose of fish harvested for wet reduction, namely for meal, oil, and solubles, information unavailable for the spring 2018 public comments.

Commenters noted that organics should not degrade one ecosystem—in this case, the marine environment—to promote the health of another—agriculture. As one certifier stated, some producers think liquid fish products are already the result of waste only. Others expressed support for the precautionary principle. Several noted that even if fish are not harvested exclusively for fertilizer, having an outlet for meal and solubles provides some economic incentive to harvesting fish for meal for livestock feed and oil.

It was suggested that the environmental impact should be considered in balance with all evaluation criteria. It was recommended that the NOP issue an instruction to Material Review Organizations to collect data on 1) the types of fish used, 2) the percentage that is waste, by-catch and mortalities, and meal, oil, and/or solubles, and 3) farmed, wild, or invasive.

Fish-based fertilizers are widely used by organic farmers. The board heard from several producers of fish-based fertilizers stating that they share the board's concern that fish should not be harvested exclusively for fertilizer and that they use waste material (heads, racks, skin, and viscera) left over from fish and shellfish processed for human food products. They explained that previously, these materials were dumped back into the ocean. Several harvesters noted that the waste they use comes from fish harvested in the U.S. Exclusive Economic Zone. They expressed concern over a lack of government oversight in some other regions.

One commenter shared his experience as an organic inspector for a fish-based fertilizer:

> Several years ago, I undertook an inspection of a liquid fish production facility for OMRI, part of the mandatory inspection of facilities producing high nitrogen liquid fertilizer products that is now mandated under NOP. The inspection took place in a region that I know has been heavily, negatively impacted by years of unregulated or poorly regulated commercial fishing, namely Mexico's Sea of Cortez. While I previously assumed that most if not all fish fertilizer products were generated from bycatch or processing waste from canneries, while performing the inspection I was deeply shocked, surprised and saddened to learn that the operation was harvesting fish stocks solely for the purpose of producing fish emulsion and fish meal.

The commenter further states:

> I believe the TR actually does a disservice by attempting to separate fish stocks that are harvested for fishmeal from those that are harvested for fish solubles. Either way, we are talking about mining the oceans for agricultural nutrients, whether they are fish solubles or fish meal used as fertilizer or feed, at a time when there are not enough resources left to support healthy marine ecosystems, not to mention the many poor people who depend on these fisheries to survive.

A number of commenters expressed support for allowing fish-based fertilizers from human consumption waste only.

Proposal:
In its initial discussions, the Subcommittee considered how any negative environmental impacts associated with harvesting wild, native fish for fertilizer might be addressed in the regulations. There is no intention to exclude the use of farmed fish or invasive species that are harvested to protect native ecosystems, though the TR explains that there are currently few such products on the market (TR lines 662-87). The Subcommittee explored the merits of an annotation to Section 205.601(j)(8) prohibiting the use of wild, native fish harvested solely for the manufacture of those materials, as well as listing wild, native fish harvested solely for fertilizer at Section 205.602. While the Subcommittee initially proposed that a prohibition on 205.602 alone would suffice, public comment suggested that an annotation should also be listed at 205.601(j)(8). The Subcommittee consulted with the Organic Materials Review Institute (OMRI) and found that the overwhelming majority of fish fertilizer products they list are synthetic. In discussion with the National Organic Program and review of OFPA section 6517(c), it was determined that the best course of action would be a single listing at 205.601(j)(8). The proposed definitions were crafted based on language in the TR. The definition of bycatch, in particular, is a fusion of federal definitions and wording from the TR.

As noted above, the TR Table 1 lists the source of fish for OMRI listed products, and a total of 60% are from a combination of waste and/or bycatch/mortalities. Of the remaining products, 31.5% are from meal, oil, and solubles from the wet reduction process, and 9% are a combination of waste and meal, oil, and solubles. It is important to note that meal, oil, and/or solubles can be derived from fish waste. The TR explains that "some meal, oil, and solubles are produced from fish originally harvested for other purposes" (TR pg. 3, footnote 3). In other words, "waste from fish harvested for other purposes is sometimes diverted into fish meal production" (TR pg. 3, footnote 3). Additionally, "the majority of fish meal used in fish-based fertilizers is produced from fish waste, but a minor amount (2 percent) is produced from fish caught specifically for reduction purposes (fish meal and fish oil, with fish solubles as a byproduct or coproduct)" (TR lines 337-39). The TR goes on to explain that "fish solubles used in fish-based fertilizers on the other hand most often come from fish harvested specifically for meal and oil production" (TR lines 339-40). Finally, "while 55 percent of fish-based fertilizers currently approved by OMRI contain fish meal or solubles, the remaining 45 percent contain hydrolysates, most of which are produced from fish scraps of wild fish, harvested for human consumption" (TR lines 384-86). It is unclear from the TR how many of the OMRI-listed products in Table 1 derived only from meal, oil and solubles (31.5% of the total) are sourced from fish harvested exclusively for wet reduction (see footnote below for a breakdown of products by source).

The question before the subcommittee is whether fertilizer products containing fish harvested exclusively for the wet reduction process should be used. The wet reduction process harvests fish for meal, oil, and solubles. After harvest, the fish are cooked and pressed. The solids and liquids are separated. The solids become fish "meal". The liquids can be further separated into "oil" and "solubles". Solubles are then evaporated and concentrated.

> Fish-based fertilizers occur in liquid and dry forms. Dry forms are typically composed of the same materials as liquid products, though some dry products contain fish meal, which is not typically found in liquid formulations. Ingredients are usually in one of the following forms: solubles, hydrolysates, or meals. (TR lines 42-45)

The Subcommittee agrees with public commenters that fertilizer derived from fish harvested for the wet reduction process, while not harvested exclusively for fertilizer, is not in keeping with organic principles as both the meal and solubles are used in dry and liquid fertilizers. The Subcommittee also recognizes the importance of fish-based fertilizers for organic producers. Consequently, this proposal recommends an annotation that does not prohibit fish fertilizers but instead requires that they be derived from waste from human use or bycatch/mortalities. The majority of OMRI-listed fish-based fertilizers already meet these criteria.

Public comment questioned how such an annotation could be verified. Because this annotation relates to easily identified ingredients—fish hydrolysates, meal, and/or solubles —an affidavit from producers attesting that the fish ingredients in their products are sourced from waste, bycatch/mortalities, and/or invasive species would be sufficient. Either the product does or does not contain fish products sourced from waste, bycatch, and/or invasive species.

The Subcommittee contacted the TR authors to ascertain the number of fertilizer products containing fish meal, oil, and/or solubles from fish harvested exclusively for the production of meal, oil, and solubles versus fertilizers containing meal, oil, and/or solubles derived from fish waste and/or bycatch. The majority of LFPs are derived from waste and/or bycatch/mortalities[1].

[1] The following data is from a combination of dry products (27) and liquid products (97), for a total of 124 products altogether.

For meal-based products, 11 of the 15 were derived from waste, and 4 were derived from fish harvested for meal/oil/solubles.

As organic production increases, the use of LFPs will rise. This proposal prevents the use and expansion of LFPs from fish harvested exclusively for meal, oil, and solubles, regardless of their portion of market demand relative to other uses for those products.

The TR notes that "In general, commercial fishing has been detrimental to the sustainability and health of many wild, native fish stocks" (lines 290-91). While not specific to those species harvested for meal, oil, and solubles, the TR provides an overview of global fisheries:

> Globally, collapses in large predatory fish now occur in all large marine ecosystems, primarily due to mismanagement and overfishing (Worm et al., 2007; Costello, Gaines, & Lynham, 2008). Except for the Northwest and Northeast Pacific regions, harvests in temperate areas have declined for several years (FAO, 2018), indicating reduced populations of fish biomass, generally. Models have indicated that by 2050, overfishing and habitat degradation will have depleted not only the oceanic shelves, but also deep slopes, canyons, seamounts, and deep ocean ridges of "bottom fish" such as orange roughy, Chilean seabass, and hagfish (Pauly et al., 2003; Worm et al., 2006). In 2015, the FAO considered 33.1% of fish stocks to be harvested at biologically unsustainable levels (2018). (TR lines 299-306)

Specific to fish harvested for meal, oil, and soluble production, the TR provides the following details:

> Of the primary meal/oil fish that are likely to be used in fish-based fertilizers, three species have documented large-scale population declines (collapses) within the last 50 years or so (Table 2). In some cases, localized populations have undergone severe declines, but these declines are not always captured within FAO fact sheets and International Union for Conservation of Nature (IUCN) data. For example, the FAO's fact sheet for Indian oil sardine (*Sardinella longiceps*) does not capture collapses and declines shown by Kripa, et al. (2018). Pacific anchoveta experienced collapse in 1947 around the Gulf of Nicoya (Bayliff, 1969), but this is both outside of the data range, and possibly too localized to show up in FAO fact sheets and IUCN data. These declines are not always due exclusively to overfishing, but also due to climate, ocean currents, and

For solubles-based products, 4 of the 54 were derived from waste, 2 were derived from waste and from bycatch/mortalities, 36 were derived from fish harvested for meal/oil solubles, and 11 were derived from waste and from fish harvested for meal/oil solubles.

None of the hydrolysates-based products (56) were derived from fish harvested for meal/oil/solubles.

Therefore, 40 of the 124 are derived from fish harvested for meal/oil solubles, and 11 were derived from waste and from fish harvested for meal/oil solubles for a total of 51 of 124 products. Note that this proposal only deals with liquid fertilizers. Of the liquid products, 48 would meet the proposed annotation because they are hydrolysates-based (are all which are derived from market waste). Of the 48 solubles-based liquid fertilizers, 4 are derived from waste, 2 are from waste and bycatch/mortalities, 11 are from a combination of waste and from fish harvested for meal/oil solubles, and 31 are from fish harvested for meal/oil solubles. The 1 meal-based liquid fertilizer is derived from waste from market fish.

Finally, it is important to emphasize that this information cannot be assumed to be without error, though every attempt was made to assess the products as accurately as possible. The subcommittee thanks the TR authors for the additional detail they provided.

> food web changes—though the exact mechanisms are not always well understood (Chavez, Bertrand, Guevara-Carrasco, Soler, & Csirke, 2008; Bayliff, 1969; Punt, et al., 2016).
>
> Perhaps the most important fish with regard to meal, oil, and solubles production is the Peruvian anchoveta (*Engraulis ringens*). Up to one third of the raw material for fishmeal comes from this fish (FAO, 2007), which is used for animal feed (both terrestrial and aquatic) and fertilizer (Pauly, et al., 2003). According to the FAO, Peruvian anchoveta have been exploited more than any other fish in world history (FAO, 2019a). In 2017, fishers were only able to capture 46 percent of the allotted quota (1.49 MMT), due to a population composed largely of juvenile fish (Fraser, 2018). According to the IUCN, the Peruvian anchoveta population trend is unknown, and this fish has undergone population collapse in the past due to overfishing and climatic conditions (IUCN, 2019; FAO, 2019a).
>
> Likewise, Pacific sardines (*Sardinops caeruleus*) also experienced a population collapse in 1967 (FAO, 2019h). In 2015, the harvest was just 7 percent of what it was in 2009. The most recent decline in Pacific sardines has been attributed to unfavorable environmental conditions (Punt et al., 2016) and intense fishing pressure (Williams, 2014). The population decline of the Pacific sardine has affected populations of brown pelicans, marbled murrelets, Brandt's cormorants, and sea lions, which rely on the sardines as a food source (Williams, 2014; Spratt, 2016). NOAA, however, does not consider the Pacific sardine overfished as of 2017 (NOAA, 2019c). (TR lines 355-81)

Although fish harvested for human consumption has ecological impacts as well, the parts used in fertilizer are considered waste products that would not otherwise have a use. Since the majority of OMRI-listed fertilizers containing fish are sourced from a combination of fish waste and/or bycatch, ample alternatives exist to LFPs that are derived from fish harvested for meal, oil, and solubles. For the spring 2020 meeting, the board received a letter signed by "three companies … compris[ing] the majority of the domestically manufactured Fish Protein Hydrolysate used in organic farming in the U.S.", and they wrote to explain that "all the fish we use to make Fish Protein Hydrolysate comes from the byproduct of fish processing for human consumption". Furthermore, in its 2016 recommendation to allow squid in fertilizers, the board voted to limit the listing to squid byproducts. The limitation to byproducts reflected the board's desire to ensure that squid are not harvested for fertilizer and that materials used in organic production contain only waste products left over after processing for human consumption.

Conclusion:
Harvesting wild native fish for use in meal, oil, and solubles is not essential for organic farming as alternative products using fish waste, bycatch, or even invasive species exist. As stated in public comment, the majority of fish fertilizers used by U.S. farmers comes from fish byproducts. Organic farmers often assume these products come from byproducts, and several large producers have expressed their support for the Board's work on this topic. To avoid contributing to population declines of fish and the associated species within the ecosystems dependent on them, LFPs made from fish harvested for meal, oil, and solubles are not compatible with a system of sustainable agriculture.

Vote in Subcommittee

Motion to amend Section 205.601(j)(8) as follows:
(8) Liquid fish products—sourced only from fish waste, bycatch, or invasive species–can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

Motion by: Emily Oakley
Seconded by: Dave Mortenson
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion to add the following definitions to Section 205.2 Terms defined:
Fish waste. Waste or byproduct left over after market fish are processed for human consumption.
Bycatch. Incidental or discarded catch that have no economic value, fish that must be discarded because of management regulations, or fish that are killed by fishing gear (mortality).
Motion by: Emily Oakley
Seconded by: Steve Ela
Yes: 8 No: 0 Abstain:0 Absent: 0 Recuse: 0

Approved by Jesse Buie, Subcommittee Chair to transmit to NOSB, July 21, 2020

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sodium Carbonate Lignin
August 4, 2020

Summary of Petition:

Sodium carbonate lignin has been petitioned for use in organic crop production through addition to the National List at 205.601(j)(4) of "lignins" as a dust suppressant. Lignin sulfonate, another type of lignin, is currently listed at 205.601(j)(4) for use as a chelating agent and dust suppressant. The petitioned material results from a paper pulping process that uses sodium carbonate and sodium hydroxide to extract lignin. Lignins found in plant cell walls are amorphous, complex biopolymers. Lignins make up 20-30 percent of plant cell walls, 30 percent of the total mass in softwood, 20-25 percent of the total mass in hardwoods and a smaller percentage of the total mass of herbaceous species. Commercial lignins are obtained as byproducts of the bioethanol and paper pulping industries.

Sodium carbonate lignin has a variety of potential uses. Lignins are used for binding and are added in fertilizer formulations to improve granule formation by binding extrusion granules. They also prevent fertilizer caking during storage. Lignins are also used for dust suppression. They are useful as binders in fertilizer and feed formulation because improving the quality of the pelletizing or granulation of these materials is a well-known measure for dust suppression. Adding binders such as lignin increases fertilizer granule strength, thereby reducing the formation of dust . Lignins have also been sprayed on roads for dust control.

Lignins are used to chelate micronutrients in fertilizer formulations to form more stable, yet still soluble, complexes that improve plant micronutrient availability.

Summary of Review:

At this time there has not been any public comments on sodium carbonate lignin, but lignin sulfonate has been reviewed and public comments on this product have been positive for relisting during sunset review. A survey of regulations for organic production from a number of countries and international organizations indicates that the use of sodium carbonate lignin is not generally permitted while lignin sulfonate is approved by many of the international organizations.

Category 1: Classification

1. For CROP use: Is the substance **Non-synthetic** or X **Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

   The petition describes the process used to manufacture sodium carbonate lignin both as soda ash pulping and soda pulping. Wood chips are subjected to a solution of either sodium carbonate or a combination of sodium carbonate and sodium hydroxide and coked in steam under pressure for 15 minutes. The cooked wood chips are then mechanically pressed to separate the spent cooking liquor which is then evaporated to a dry powder. Lignin is a natural product that is chemically altered to become synthetic.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   The petitioner is requesting that sodium carbonated lignin to 7 CFR 205.601(j)(4) as a synthetic substance allowed for use in organic crop production as a plant and soil amendment for dust suppression in addition to lignin sulfonate.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   Soil stabilization with sulfur-free lignin has been studied and application of the lignin was found to slightly decrease soil pH, but was still comparable to the pH of natural soil. Different types of lignin phenols can be inhibitory to some fungal species, but they may also stimulate microbial activity depending on the amount of lignin applied. The use of the petitioned substance for dust control has the potential to increase soil aggregate size and water retention, which some researchers suggest may be ecologically beneficial.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   Environmental studies over the last 30 years have shown lignin sulfonates to be nontoxic at concentrations above those used (TR 621). Lignins have been shown to be an important precursor in the formation of humic substances (TR 601) and they can increase soil organic carbon and total nitrogen. Lignins are toxic in wastewater streams from the paper pulping process and can be toxic to aquatic organisms. Using lignin sulfonates in organic farming could benefit the environment by removing them from the paper manufacturing process waste stream.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

   There are four pulping processes that make up the majority of production methods. As one study reported, the soda process has the lowest potential environmental impact as measured by a waste reduction algorithm developed by the EPA's National Risk Management Research Laboratory. None of the literature reviewed by the 2020 Technical Review suggested that the use of lignins as petitioned would result in environmental contamination of organic systems.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

   In the Technical Review performed in 2020 a review of environmental studies of the last 30 years found that lignin sulfonates are nontoxic at the concentration used. In fact, it was stated that worker safety is improved with the use of lignins as dust suppressants in preventing dust inhalation when workers dispense fertilizers, and also obviates the need for wearing respirators. The U.S. EPA issued an exemption from the requirement of a tolerance for lignin sulfonates when they are used as inert ingredients pre- and post-harvest in agricultural product and the same would be expected for lignin carbonates.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   The use of the petitioned substance is for dust control in the context of a plant or soil amendment and as such, is applied to the soil at relatively low rates. As the Technical Report stated, this consideration with the potential effects of lignin to increase soil aggregate size and water retention and enhance microbial activity, suggest that its use as petitioned is likely to be benign and may even be ecologically beneficial.

6. Are there any adverse impacts on biodiversity? (§205.200)

   At the rates this substance is applied, no adverse impacts on biodiversity are expected.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

   OMRI has 11 products listed in the category of "Dust Suppressants" and another 29 in the category of "Lignin Sulfonates." Many of these products contain wax emulsions or combinations of oil and wax emulsions. Also vegetable oils, magnesium or calcium chloride solutions, glycerin and natural fatty acids are also used. Their effectiveness over time may decrease as oils volatilize or become adsorbed in fertilizer particles and waxes and oils have limited binding capacity. Other nonsynthetic fibrous materials have been suggested and include wood flour, peat moss, compost, manure, cotton, straw and clay. Dust suppression for roads can also include management practices such as maintaining vegetative cover in non-traffic areas, mulching, application of stone or gravel to disturbed roads and air current barriers such as trees. In reviewing the petition, the Crop Subcommittee feels that there is no need to add another synthetic lignin product for dust suppression since numerous lignin alternatives already are available for use.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   Yes, sodium carbonate lignin, when used in fertilizer as a dust suppressant, allows finer particles to be produced. These smaller particles allow faster breakdown and with moisture, more immediate nutrients are available to plant life. Additionally, removing lignins from the paper pulping industry and repurposing them to organic farming use prevents a source of lignin contamination in discharge in wastewater. However, given that there are viable alternatives already on the National List, the Crops Subcommittee feels that there is no need to add another synthetic lignin product for dust suppression.

Classification Motion:

Motion to classify sodium carbonate lignin as synthetic
Motion by: Rick Greenwood
Seconded by: Dave Mortensen
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add sodium carbonate lignin at 205.601 (j)(4)
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Approved by Jesse Buie, Crop Subcommittee Chair, to transmit to NOP August 4, 2020

Sunset 2022
Meeting 2 - Review
Crops Substances §205.601, §205.602
October 2020

Introduction

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

Request for Comments

Written public comments will be accepted through October 1, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 2 - Review
Crops Substances §205.601, §205.602
October 2020

Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.

Soap-based algicide/demossers
Ammonium carbonate
Soaps, insecticidal
Vitamin D3
Aquatic plant extracts
Lignin sulfonate
Sodium silicate
EPA List 4 - Inerts of Minimal Concern

205.602 Prohibited nonsynthetic substances
Arsenic
Strychnine

Soap based algicide/demossers

Reference: 205.601(a)(7) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
Technical Report(s): 1996 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: Actions: 09/1996 NOSB recommendation; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
As an approved algicide/demossers, synthetic soap salts are permitted for the control of algae and mosses in and around production areas, including walkways, greenhouse surfaces and irrigation systems.
Manufacture:
A variety of preparatory methods are employed depending on the desired soap salt composition for a particular herbicide/algicide formulation. Potassium salts of fatty acids are produced through a process known as saponification, whereby aqueous potassium hydroxide is added to fatty acids found in animal fats and plants oils. Sources of potassium soap salts are prepared through hydrolysis of triglycerides using water under high pressure and temperature. A carbonate or hydroxide salt of an alkali metal (potassium or sodium) traps the free fatty acid into a soap salt. Commonly used fats (triglycerides) include coconut oil, sunflower oil, palm oil, tallow, and olive oil. Soaps are mixtures of fatty acid salts having a variety of carbon chain lengths and generally do not consist exclusively of one soap salt compound.

International acceptance:
The Canadian General Standards Board, the European Union, Codex Alimentarius Commission, the Japanese Ministry of Agriculture, Forestry and Fisheries, and the International Federation of Organic Agriculture Movements (IFOAM) all allow soap-based compounds for the purposes listed for this product.

Environmental issues and human health:
Soap salts essentially behave as the carboxylate anions of fatty acids when released into the environment. In general, potassium and ammonium salts of fatty acids decompose rapidly and do not accumulate or persist in the environment. Biodegradation is expected to be an important fate process and field tests show half-lives at less than one day for these salts. US EPA has waived all generic mammalian toxicity data requirements for potassium and ammonium soap salts due to the lack of effects at high doses in the available toxicity literature. Potassium salts of fatty acids are generally recognized as safe (GRAS) by the FDA. Also, studies have shown that soap salts are practically non-toxic to honeybees.

The Crops Subcommittee voted to delist soap-based algicide/demossers in 2015 because it was thought that they were no longer used in organic crop production and it was not necessary to keep them on the National List. However, public comments indicated that these materials were still being used by some producers. Based on public comment they were not removed. Public comments in 2020 were supportive of continued listing of these products and indicated that they are still being used in organic farming.

Subcommittee Vote:
Motion to remove soap based algicide/demossers from §205.601(a)(7) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Ammonium carbonate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate —for use as bait in insect traps only, no direct contact with crop or soil.
Technical Report: 1995 TAP (Ammonium bicarbonate)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Used as bait in insect traps, not intended for direct contact with the crop or soil. Ammonium carbonate is used in small quantities as an attractant in traps. In some cases, ammonium carbonate is used alone and in others, as a mixture with yeast to enhance its chemical attraction to insects. It is marketed for the control of a range of fly types problematic in livestock as well as fruit and nut production. The main alternatives are manure management and enhancement of predators and parasitoids, but its use to trap adult flies complements the use of other methods that control egg-laying and immature stages. While ammonium carbonate is used as a fly bait, we were able to find little published literature on the effects of the bait on other insect species. Natural alternatives include natural attractants. Other alternative materials include other ammonia-releasing chemicals. Practices that would make its use unnecessary include a good organic environment and enhancement of predators and parasitoids.

Manufacture:
Ammonium carbonate is produced by combining carbon dioxide and aqueous ammonia. Ammonia is volatile and toxic and a known irritant to eyes and nose. It is incompatible with strong acids, nitrates, nickel, copper. However, the current annotation makes interaction unlikely. At room and field temperatures, ammonium bicarbonate will spontaneously decompose into ammonium bicarbonate and ammonia which further decomposes to carbon dioxide, water and another molecule of ammonia.

International Acceptance:
Canadian General Standards Board Permitted Substances List - permitted as an attractant in insect traps.
Codex Alimentarius Commission - not listed
European Economic Community (EEC) Council Regulations - not listed
International Federation of Organic Agriculture Movements (IFOAM) - not listed
Japan Agricultural Standard for Organic Production - not listed

Environmental Issues:
The intended use in crop production is as a bait that would not come in contact with plants or soil. A small amount of ammonium carbonate is used alone or in a mixture with yeast. The ambient temperature during

use would result in ammonium carbonate volatilizing, releasing ammonia and carbon dioxide as gases. Given the small amount of ammonium carbonate used, the impact of its volatilization would be small. We were unable to find reports of non-target effects on other insect species. Such information would aid in our review of this material.

Discussion:
During the April 2015 public comment period, most respondents supported relisting including a number of respondents who voiced strong opposition to other insect pest management chemicals up for relisting. The past two sunset reviews of ammonium carbonate resulted in limited stakeholder input attesting to the efficacy and need of the material. During the period leading up to the April 2020 NOSB meeting information was sought on the following questions: 1) to what extent is ammonium carbonate used as a bait for trapping and thereby managing fly and other insect pest populations? 2) How effective is the practice for managing flies? and 3) to what extent is the population behavior of beneficial insects altered by the ammonium carbonate bait? From the considerable public comment received on ammonium carbonate, it is clear it is being used by organic farmers, particularly those with poultry and livestock herds and by fruit and nut growers where cherry fruit fly and spotted wing drosophila are issues. Several stakeholders indicated the use of ammonium carbonate as an attractant in insect baits aided the management of fly and other pest insect populations. There were no calls for delisting the compound given its widespread use in organic poultry and livestock production systems. While data on non-target effects on beneficial insects is lacking, there is little data to support challenging the benign effects of this compound when used as a bait for pest insect management in organic production systems. It is clear that the use of baited insect traps is consistent with an integrated approach that would also include controlling flies through manure management and enhancement of predator and parasitoid populations.

Subcommittee Vote:
Motion to remove ammonium carbonate from §205.601 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Dave Mortensen
Seconded by: Emily Oakley
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).
Technical Report: 1994 TAP; 2020 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Insecticidal soaps are used for control of soft bodied insects and hard bodied insects in the larval stage on organic crops.

Manufacture:
A reaction of an alkali such as sodium or potassium hydroxide on natural fatty acids (from both animal and

plant sources) is used to prepare insecticidal soaps. The fats, such as laurate, myristate, oleate, and ricinoleate are further processed to create a blend of selected fatty-acid chain lengths. The cation for soap molecules is determined by the base used in its production. Potassium soaps are derived from the treatment of fatty acids with potassium hydroxide while ammonium soaps are produced by saponification with ammonium hydroxide.

International acceptance:
European Economic Community (EEC) lists potassium soaps as an insecticide with applications "from traditional us in organic farming." Japan Agricultural Standard (JAS) lists soaps as agents for cleaning or disinfecting livestock and the Canadian General Standards Board Permitted Substances List includes ammonium soaps as a permitted substance. IFOAM lists potassium soaps as an equipment cleanser and equipment disinfectant.

Environmental issues and human health:
The toxicological profile of the substances differs based on the environment in which it is located. Insecticidal soaps are widely regarded as having low toxicity to terrestrial organisms, like mammals and avian animals. Insecticidal soaps are rapidly biodegradable in the environment and the half-life is estimated to be less than one day. Microbial organisms rapidly degrade fatty acids in soils. Potassium salts are highly toxic to aquatic invertebrates and slightly toxic to both cold water and warm water fish species. Due to this potential toxicity to aquatic environments, insecticidal soap product labels stipulate that the products are not intended for application to aquatic systems including ponds and streams. EPA has given these insecticides the lowest Toxicity Category IV (indicating the lowest level of toxicity). Potassium salts of fatty acids used on food and feed crops have been exempted from the requirement of a tolerance (or maximum residue limit) for all raw agricultural commodities since 1982. They are also generally recognized as safe (GRAS) by the FDA. Recent studies (2018) have shown insecticidal soaps to be non-toxic to desirable insects such as lady bugs and the coccinellid beetle. A recent technical review (2020) reports that "there is little to suggest that insecticidal soaps pose a threat to the environment when used as approved." In fact, the report goes on to state that because of the low toxicity, even if it is used improperly, environmental impact would be minimal.

Alternatives:
Alternatives include cultural pest control methods or oils, botanicals, or biological controls (depending on species). A variety of essential oils have been used as well as pyrethrum, however, horticultural oils and pyrethrum are easily degraded under common conditions like UV-radiation. Moreover, differences in the mode of action and in their targets (hard-bodied vs. soft-bodied) of essential oils and pyrethrum make one a poor substitute for the other.

In the previous Sunset review in 2015 there was overwhelming support for the continued listing of this material. Public comments stated that this material remains a necessary tool in organic crop production and in fact has increased in use due to the growth of organic production. Public comment stated that these oils are allowed for use world-wide by most organic certifying bodies. The 2020 public comments for this product again showed overwhelming support for the continued listing of insecticidal soaps and that they were also in wide use.

Subcommittee Vote:
Motion to remove insecticidal soaps from §205.601(E)(8) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Rick Greenwood
Seconded by: Dave Mortensen
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Vitamin D3

Reference: 205.601(g) - as rodenticides.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Vitamin D3 (cholecalciferol) is used to fortify food and aids in the growth and maintenance of bones, typically found in milk and cereals. Forms of vitamin D are also found in margarine and infant formula. In this listing, vitamin D3 is used as a synthetic rodenticide both in gel and pellet baits. Vitamin D3 kills gophers, mice, rats and other rodents by causing an excessive, highly elevated level of calcium which results in hypercalcemia and mineralization of major organs (including kidney failure) leading to death.

Manufacture:
The 2011 TR states: The commercial manufacture of vitamin D3 utilizes cholesterol obtained by organic solvent extraction of animal skins (pig, sheep, or cow) and extensive purification (Norman, 2000). Typically, cholesterol is extracted from the lanolin of sheep wool and converted to 7-dehyrdocholesterol after a process of chemical synthesis that involves eighteen steps (Norman, 2000). The crystalline 7-dehyrdocholesterol is then dissolved in an organic solvent and irradiated with UV light. This process causes a photochemical transformation of 7-dehyrdocholesterol into cholecalciferol that is similar to the natural process that occurs in the skin of humans. It is then purified and crystallized further before being formulated for use (Norman, 185 2000). Details of the manufacturing process are subject to several patents (Norman, 2000) and are not publicly available.

Since the formulations contain .075% of cholecalciferol, with the remainder "inerts," it is unknown what the other ingredients are, although much of it will be attractive food stuffs to the rodents.

International Acceptance:
The Canadian General Standards Board Permitted Substances List has this annotation on vitamin D3 (cholecalciferol) "if used outdoors and inside greenhouses for rodent control when methods described in 5.6.1 of CAN/CGSB-32.310 have failed. Prohibited inside on-farm food processing and food storage facilities."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999), has an allowance for rodenticides with this caveat "Products for pest control in livestock buildings and installations. Need recognized by certification body or authority". The European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 states rodenticides are only to be used in traps. The Japan Agricultural Standard (JAS) for Organic Production and the International Federation of Organic Agriculture Movements (IFOAM) do not list this product, nor have any specific requirements for rodenticides.

Environmental Issues:
According to the TR, vitamin D3 is not expected to mobilize in soil and its bioconcentration in aquatic life is expected to be very low. Because of its insolubility in water, its use is unlikely to cause contamination to ground or surface waters. Since its use is restricted by the Environmental Protection Agency to bait

stations, the risk of accidental poisonings of non-target species has been addressed. Vitamin D3 is of low toxicity in birds, unlike the more widely used anti-coagulant rodent baits not approved for organic production.

Subcommittee Review:
A range of stakeholders provided public comment on vitamin D3 as a rodenticide at the April 2020 NOSB public meeting, and with almost no exception, the community has expressed its support for the material's continued listing for permitted use in organic production. Most of the comments addressed the issue of non-target species toxicity.

Since birds of prey can be of great use in controlling rodents on the farm, the use of vitamin D3 is preferred due to its very low risk to bird populations. Birds have a much lower body weight and the consumption of just one or two rodents who had consumed an anticoagulant bait could be detrimental to the bird's health or cause death. Using a rodenticide that does not harm the predator population is an ecosystem friendly approach to controlling rodent populations. While non-target mammals could consume rodents that are ill from consuming vitamin D3, it would take many of these rodents to cause harm up the food chain. There are system-based methods that can be used to control rodent populations, such as improving structures to prevent their entry, as well as keeping food/water and harborage to a minimum. However, there are times when the use of a toxic bait is necessary to lessen the rodent population so that other system-based approaches can then take over.

Vitamin D3 as a rodenticide continues to be reported in wide use by many organic stakeholders, particularly in situations where environmental factors and built structures create conditions conducive to rodent infestations. There has been some critique of its efficacy, but nearly no grower or certifier expressed opposition to its continued listing as an essential substance for the organic toolkit. Most stakeholders report anecdotal findings that vitamin D3 has low toxicity to birds and to other non-target species, particularly as compared to other rodenticides. Notably, one non-profit stakeholder organization has suggested via public comment that vitamin D3 can lead to painful death in rodents and could be replaced with other substances. Given the widespread support from stakeholders for keeping this material available to organic growers, the Crops Subcommittee recommends relisting of this material.

Subcommittee Vote:
Motion to remove vitamin D3 from §205.601 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Aquatic plant extracts

Reference: 205.601 (j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount is limited to that amount necessary for extraction.
Technical Report: 2006 TR; 2016 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 [(82 FR 14420)](#)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Plant extracts are composed of chemicals naturally found in aquatic plants (TR 2006 line 19), namely marine plants (also called seaweed). Aquatic plant extracts are used as foliar fertilizers or as soil conditioners. They also are used in combinations as a foliar/soil feed or transplant solution and seed treatment. The material is absorbed into the plant and acts as a growth promoter (TR 2006 lines 63-6). Aquatic plants contain proteins, lipids, sugars, amino acids, nutrients, vitamins, plant hormones, and other biochemicals (TR 2006 lines 26-7). Aquatic plants contain a wide range of naturally occurring plant nutrients and trace minerals essential to plant growth, health, and productivity (TR 2006 lines 41-42). Cytokinins, a class of plant hormones present in aquatic plant extracts, have been reported to have beneficial effects on crops, including increase in number or size of fruits or seed heads, synchronization of flowering within a field, and delayed decay of mature plants (TR 2006 lines 46-8).

Manufacture:
Seaweeds are classified into three broad groups based on pigmentation: brown, red, and green; respectively, *Phaeophyceae*, *Rhodophyceae* and *Chlorophyceae* (TR 2016 lines 103-4), and all three classes are used in aquatic plant extracts. Seaweeds are also called macro-algae, distinguishing them from micro-algae (*Cyanophyceae*) which are microscopic in size and often unicellular (TR 2016 lines 108-110). Seaweeds used in aquatic plant extracts are macro-algae.

Seaweed extract is produced from fresh, live plants which are processed into a soluble powder or liquid and may be stabilized with synthetic acids and fortified with other ingredients. An alkali extraction process is used to “digest” the plants and derive both micronutrients and naturally occurring plant hormones. This process also transforms the plants into a soluble, easily transported form. The majority of manufacturers use potassium hydroxide as the primary reagent in the alkali extraction process. Other alkali reagents used by some manufacturers include sodium hydroxide, calcium hydroxide, and sodium carbonate (TR 2006 lines 181-189).

International Acceptance:
Canadian General Standards Board Permitted Substances List permits use of aquatic plants products not containing synthetic preservatives, such as formaldehyde, and extracted with potassium hydroxide or sodium hydroxide.
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) lists seaweed and seaweed products as a soil conditioner.
European Economic Community (EEC) Council Regulation, 2092/91 allows aquatic plant extracts for organic crop production following “Annex IIB – Seaweed and seaweed products”.
Japan Agricultural Standard (JAS) for Organic Production allows the use of dried algae as fertilizer for terrestrial plants.
International Federation of Organic Agriculture Movements (IFOAM) lists seaweed as a soil input in appendix 2.

Environmental Issues:
Aquatic plant extracts are biodegradable and are likely to have a low impact on crops (TR 2006 lines 242-3). They are not expected to cause toxicity to plants, soil organisms, or higher animals (TR 2006 lines 151-2). There are no known human health hazards (TR 2006 line 320). The potential for over-harvesting of

kelp/seaweed fields for production of aquatic plant extracts was identified as a possible environmental concern in the 1995 TAP review, but it offered no additional information.

The 2016 TR and 2016, 2017, and subsequent public comments raised concerns about the potential for negative environmental impact on marine ecosystems from seaweed harvesting. Some examples noted in the 2016 TR were specific to species used in organic crop fertility inputs and aquatic plant extracts. For example, in mechanical harvesting in Iceland, as with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (TR 2016 lines 892-6). In Nova Scotia, commercial yields of rockweed are maintained. There still isn't sufficient information or analysis from industry or third-party research proving that their harvest rate is not detrimental to the habitat value that rockweed provides to associated plants and animals. Estimated recovery times based on percentages removed vary between publications (TR 2016 lines 597-600). Additionally:

> There is one species of red algae and two species of brown algae growing along the coasts of the United States that have gained attention as ecologically threatened in recent years. They are respectively, Irish moss (*Chondrus crispus*), rockweed (*Ascophyllum nodosum*), and giant kelp (*Macrocystis pyrifera*). These plants are economically important and drive several seaweed industries including cosmetic products, nutraceuticals, fertilizers and hydrocolloids. Fertilizer applications are similar to farmyard manure, but may also include extracts and foliar applications (Chojnacka, 2012).
> Kelp and rockweed, are foundational species forming large expansive marine habitats supporting a diverse range of wildlife, including other algal species, marine animals and many species of protozoans and bacteria (Seeley and Schlesinger, 2012). Without a good accounting of all of the species present it is hard to predict the effects of harvesting rockweed and kelp on each ecological niche. Thus, it has been important to recognize that sustainable seaweed production perceived as reproducible harvest capacity, may not guarantee the sustained subsistence of each resident species. Although not part of any agricultural waste stream, extracts from wild-harvested kelp and rockweed are allowed for use in organic production as soil amendments (§205.601(j)(1)). [TR 2016 lines 522-535].

Even within the 2016 TR, differences of opinion about the environmental impacts of harvesting were noted within the scientific community. For example:

> One study addressing the major components of the resident fish community in the rocky intertidal zone after rockweed harvest found no evidence linking rockweed harvest to changes in the ichthyoplankton component or the juvenile and adult fish of that community (van Guelpen and Pohle, 2014). In a summarized review of selected work, a researcher at the University of Maine also concluded that the effect of 17% rockweed harvest on some species including seabirds was negligible (Beal, 2015). [TR lines 326-31]

The TR goes on to explain that:

> Notwithstanding, rockweed has an important role as habitat, as food and as a nutrient source supporting a community of organisms that inhabit its "forests." Any cutting of rockweed can produce an effect on the supported eco-communities. Furthermore, many aspects of this ecosystem have not been elucidated, encouraging more precaution as the brown algae "forestry" industry grows into the future (Seeley and Schlesinger, 2012). [TR lines 356-60]

Subcommittee Review:

As part of the Spring 2020 public meeting, the Crops Subcommittee asked what species of seaweed are used in aquatic plant extracts but received very few comments on this topic. The Board asked if nonsynthetic alternatives to this material provide the same functionality. Several harvesters stated that nonsynthetic forms require more seaweed biomass to achieve the same benefit. One commenter noted that natural extracts are available and expressed concern over environmental impacts of harvesting. A broad range of stakeholders affirmed their support for this material, noting that growers have long experience with aquatic plant extract as part of organic fertility management plans. Certifiers reported a very high number of farmers who list this material in their Organic System Plans, and the Board heard directly from growers who rely on this material. One suggested that the board continue to allow this material while simultaneously exploring the environmental impact.

The Subcommittee was divided on this topic. Two members expressed a desire to gather more information, particularly with regard to the related work agenda item of marine macroalgae in plant fertility products in the Materials Subcommittee, before making a final determination on their position on this material. One member was concerned about the environmental impact of harvests.

Subcommittee Vote:
Motion to remove aquatic plant extracts from §205.601 (j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Emily Oakley
Seconded by: Wood Turner
Yes: 1 No: 3 Abstain: 2 Absent: 2 Recuse: 0

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.
Technical Report: 1995 TAP; 2011 TR
Petition(s): 2014 Petition to remove as floating agent
Past NOSB Actions: 10/1995 NOSB Minutes and vote; 04/2006 Sunset Rec; 04/2011 NOSB Rec to amend, 04/2011 NOSB Sunset Rec; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Lignin sulfonate is currently included on the National List as a synthetic substance allowed for use in organic production. It is used in a plant or soil amendment as a dust suppressant or chelating agent.

Manufacture:
Lignin sulfonates are produced from the process of sulfite chemical pulping. Sulfite pulping involves cooking softwood chips under pressure in sulfur dioxide-containing cooking liquors. When the cooking process is complete, sulfonated lignin is collected as a liquid by-product in the spent liquor, while the pulp is used for paper production. Lignin sulfonates may also be obtained from the Kraft pulping process and is similar to sulfite pulping, but involves treating the wood at high temperatures and pressure in a water solution containing sodium sulfide and sodium hydroxide.

International acceptance:
The Canadian General Standards Board allows the use of lignin sulfonate as a dust suppressant, formulant ingredient and chelating agent. IFOAM includes calcium lignosulfonate on its "Indicative List of Substances

for Organic Production and Processing." As of 2009, calcium lignosulfonate is allowed by CODEX Alimentarius Commission as a food additive. Lignin sulfonate is not specifically discussed by the European Economic Community Council regulations.

Environmental issues and human health:
Sodium lignosulfonate is relatively low in toxicity based on results of tests in laboratory animals. However, high doses have been found to cause adverse health effects in laboratory animals. Rats that were given drinking water containing purified sodium lignosulfonate at a 10 g/100 ml concentration for 16 weeks had skin lesions, decreased weight gain and increased white cell counts. No evidence of genotoxicity was found in microbial assays and in a test for chromosomal aberration in Chinese hamster cells. Lignin sulfonates are soluble in water, so it is possible for dissolved lignosulfonates to enter waterways through direct contamination or soil runoff. Also, as they break down in water they consume dissolved oxygen in water due to their high BOD, which affect aquatic organisms through decreased available oxygen. In a previous TAP Report (1995) the issue of potential dioxin contamination was addressed as a potential contaminant from the process of pulping paper. Dioxin is created during the bleaching process of paper production and the lignosulfonates are removed from the pulp before the bleaching process making it unlikely they would be generated.

Lignin sulfonates break down by physical or microbiological processes but may persist in soil for up to one year. Breakdown of lignin sulfonate occurs in part because it is used as a carbon source by a variety of wood-decaying organisms. It is postulated that large amounts of lignin sulfonate applied to soils could stimulate soil microbial activity.

The EPA issued an exemption from the requirement of tolerance for lignin sulfonates when they are used as inert ingredients pre- and post-harvest in agricultural production. The exemption is based on the conclusion that there is a reasonable certainty the no harm will result to the general public, infants and children from aggregate exposures to lignosulfonates.

Magnesium chloride and calcium chloride from non-synthetic sources are allowed for use as a dust suppressant under certain circumstances and magnesium chloride from synthetic sources is allowed for use in organic agriculture for dust suppression only if it is derived from seawater. Non-synthetic amino acids and non-synthetic citric acid are allowed for use as chelating agents.

Physical manipulation of landscape can also be used for dust suppression - water sprays and gravel and no-till farming practices can also be used.

Summary:
At the last Sunset review in 2015, public comment was in support of relisting lignin sulfonate as a chelating agent and a dust suppressant. Lignin sulfonate is in wide use by the trade and is considered to be necessary for both dust suppression and as the chelating agent for many micronutrient formulations. No significant new issues were raised by the public at that time. At the 2020 public comment period again there were no comments for delisting this product and many comments stating that it was still in use. Lignin sulfonate is still being used extensively. One certifying agency reported that it is listed on over

Subcommittee Vote:
Motion to remove lignin sulfonate at 205.601(j) As plant or soil amendments. (4) Lignin sulfonate chelating agent, dust suppressant of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Rick Greenwood
Seconded by: Emily Oakley
Yes: 0   No: 7 Abstain: 0   Absent: 1   Recuse: 0

Sodium silicate

Reference: 205.601 (l) As floating agents in postharvest handling. Sodium silicate—for tree fruit and fiber processing.
Technical Report: 1996 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290 Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Sodium silicate, also known as "water glass", has had a range of uses that include fiber processing, fire prevention, adhesives, egg preservation, and as an anti-corrosion agent (2011 TR). For organic production, it may be used to modify water density in the water tanks that remove fruit from picking bins at the start of the packing process. This is especially important for pear packing lines since pears are denser than water and will sink to the bottom of the water tank. Adding sodium silicate to the water increases the density of the water thus causing the pears to float and making them easier to remove from the dump tank and onto the packing line.
The 2011 TR notes that there are a number of uses of sodium silicate for fiber processing, but it did not specifically identify organic uses in fiber processing. For fiber processing in general, sodium silicate may be used as a peroxide buffer for processing cotton and jute. It also has uses as a bleaching agent, detergent for fiber cleaning, degumming of jute fibers and in combination with various other bleaching and processing compounds.

Manufacture:
Solid glass is usually produced in a rotary kiln or tank furnace by fusing quartz sand with potash or soda at temperatures ranging from 1,100 to 1,330 degrees C. Sodium silicate, which makes up the majority of soluble silicates produced, is converted from solid glass to a liquid solution at 100 degrees C. The concentrations of sodium silicate in water can be varied according to particular processing needs (2011 TR).

The 2011 TR notes that the production processes for lump glass and sodium silicate require high temperatures and sometimes high pressures to change silicon dioxide and soda or potash to soluble silicates. These processes do not occur in nature and thus this material was deemed to be synthetic.

International Acceptance:
Sodium silicate is allowed for organic use by several international organizations (from the 2011 TR):

Canadian General Standards Board – allows for its use for tree fruit and fiber processing
Codex Alimentarius Commission – permits its use for the production of organic foods
IFOAM – it is included in the silicates group and allowed under substances of mineral origin in the crop protectants and growth regulators with no additional conditions for use
European Economic Community (EEC) Council Regulations – not listed for use
Japan Agricultural Standard for Organic Production – permits it for manufacturing, packaging, storage, processing, other processes in the case that ordinary- …means are not effective enough; it is restricted for the purpose of pest control on plants.

Environmental Issues:
As noted in the 2011 TR, sodium silicates are quickly diluted and depolymerize in the environment. These

processes yield molecular forms that are indistinguishable from natural dissolved silica in naturally occurring water. Other testing has shown these silicates to be generally non-toxic, except for contact exposure to very high concentrations of the material which can cause dermatitis, or, if ingested, vomiting and diarrhea. Additionally, the 2011 TR concluded that, based on its normal use patterns, sodium silicate is unlikely to contaminate soil or adversely affect soil organisms. Sodium silicate has been characterized as Generally-Recognized as Safe (GRAS) by the Food and Drug Administration. The U.S. Environmental Protection Agency has determined it is exempt from the requirement of a tolerance when used as an inert ingredient in pre- and post-harvest products (2011 TR).

While normal uses of sodium silicate are unlikely to cause environmental damage, large scale spills of sodium silicate could have some environmental effects, either by altering the pH of the spill area or affecting the balance of nitrogen and phosphorous in the spill area (2011 TR).

Subcommittee Review:
There were few public comments received for this material during the spring 2020 comment period. One commenter noted that this material is not compatible with a system of organic agriculture and should be delisted. Other commenters noted that this material is used primarily by small pear packers to float the pears out of their water dump tanks and onto their packing lines. Larger pear packers utilize mechanical means to accomplish this, but for smaller packers, this equipment is expensive and could prevent them from operating. No comments were received as to the use of this material for fiber processing.

Given that sodium silicate still provides a benefit to the organic industry, does not contribute to environmental degradation during normal usage, is Generally-Recognized as Safe (GRAS) by the Food and Drug Administration, and the U.S. Environmental Protection Agency has determined it is exempt from the requirement of tolerance when used as an inert ingredient in pre- and post- harvest products (2011 TR) the Crops Subcommittee recommends that this material remain on the National List.

Subcommittee Vote:
Motion to remove sodium silicate from §205.601 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Wood Turner
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

EPA List 4 Inerts of Minimal Concern

Reference: 205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 – Inerts of Minimal Concern.
Technical Report: 2015 Limited Scope TR: Nonylphenol ethoxylates (NPEs)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2010 recommendation, 10/2010 NOSB sunset recommendation; 10/ 2012 NOSB recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:

“Inert” ingredients in pesticide formulations, also described as “adjuvants,” are added to enhance functionality and efficacy. Any of the pesticides approved for organic use may contain “inert” ingredients. For example, surfactants may improve the solubility and half-life of active pesticide ingredients. As described in Shistar (2017), “The relatively few registered pesticides allowed in organic production are contained in product formulations with so-called “inert” ingredients that are not disclosed on the product label. The “inerts” make up the powder, liquid, granule, or spreader/sticking agents in pesticide formulations. The “inerts” are typically included in products with natural or synthetic active pesticide ingredients recommended by the National Organic Standards Board (NOSB) and listed by the National Organic Program (NOP) on the National List of Allowed and Prohibited Substances.”

Manufacture:

Since this listing covers many different materials, the manufacture of these substances cannot be specifically stated.

International Acceptance:

Since this listing covers many different materials, a specific listing of international acceptance cannot be provided.

Environmental Issues:

As noted below, some of the materials listed on EPA List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of materials listed as to environmental issues is not possible without Technical Reviews of each material.

Discussion:

“Inerts” are not necessarily biologically or chemically inert. They may be relatively benign or may be documented as harmful to the environment or human health. Without a way to individually evaluate each substance listed on EPA List 4 or to evaluate substances as a group, it is difficult to discern the acceptability of each substance for use in organic agriculture.

Presently, the National List, under §205.601(m), references the EPA List 4 – Inerts of Minimal Concern, as acceptable in organically approved pesticide formulations. List 4, however, is outdated and no longer maintained by EPA. The list of “inerts” that is referenced for review of products for organic certification was last updated in August 2004 (EPA website https://www.epa.gov/pesticide-registration/epas-national-organic-program-guidance) and may include materials that some stakeholders believe are inappropriate for organic agriculture. For example, nonylphenol ethoxylates (NPEs) are included on List 4. These materials are endocrine disruptors, may adversely impact fauna and flora, and have been identified by the California Department of Toxic Substances Safer Consumer Products program as a likely high priority chemical that should be formally phased out (https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf, https://dtsc.ca.gov/scp/proposed-priority-product-nonylphenol-ethoxylates-npes-in-laundry-detergents/). If evaluated on an individual basis, NPEs would likely not meet OFPA criteria for acceptability.

Over the last decade, the NOSB and NOP have struggled with how to evaluate the EPA List 4 – Inerts of Minimal Concern during sunset review. OFPA has specific criteria for inerts which states: “*(ii) … contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern”* (§6517 C.1.B.ii). Due to EPA changes in its categorization of inerts and discontinued support for List 4, the NOSB (starting in 2010) has adopted a series of recommendations to revise this sunset listing.

Initially it was thought that there should not be a grouping of these materials, but that each individual substance should be evaluated and, if appropriate, added to the National List. However, this process was cumbersome, slow, and difficult to implement. It was also likely to cause uncertainty in the marketplace if materials already used in organic products were not recommended for listing and if a known timeline was not available to manufactures. At each sunset review the Board has balked at the blanket renewal of List 4 inerts but has not had a viable alternative to relisting. During the most recent sunset review in 2015, the Crops Subcommittee and full Board moved forward a proposed solution to review inerts that were formerly on EPA List 4 by collaborating with the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The specific language of the NOSB recommendation is linked here and pasted below:
https://www.ams.usda.gov/sites/default/files/media/CS%20LS%20EPA%20List%204InertsAnnotation_final%20rec.pdf.

Statement of the Recommendation:

The purpose for the annotation change is to remove reference in the regulation to the EPA List 4 which is no longer in use and which the EPA requested be removed in 2010. In order to thoroughly evaluate inerts for compatibility with organic materials, the NOSB has decided to work with the EPA Safer Choice Program and in order to move forward with a formal relationship, an annotation change to recognize this collaboration is needed. The recommendation acknowledges the current nomenclature in use by the EPA regarding FIFRA 25(b) and 40 CFR 180.1122, while laying a framework for some inerts to be reviewed individually.

> 205.601(m) and 205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
>
> (i) Substances permitted for use as inerts in minimal risk products exempt from pesticide registration under FIFRA section 25(b).1,
>
> (ii) Substances included on the EPA's Safer Chemical Ingredient List.
>
> (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
>
> [Reserved] (for any other inerts individually petitioned and reviewed)]

The NOSB approved the recommendation above by a 10 to 4 vote. The NOSB then renewed the existing inerts listing under §205.601(m) with the expectation that a working relationship would be established between the NOP and EPA, with NOSB engagement, to develop a working list of acceptable inert materials for organically approved pesticide formulations. Acceptable inerts would be approved on a class basis, with room for individual material reviews and listing on the National List. To date, the NOP has made no changes to the regulations.

The current situation, where NOP policies are tied to long outdated US EPA guidance, is broken. Numerous environmental and consumer groups have submitted comments raising concerns about the slow progress on resolving this problem. Private companies and advisors also assert that the lack of a transparent and consistent approach for reviewing and approving “inerts” stifles development of organically approved plant protection tools. This undermines organic production and the larger agricultural economy. The issues identified in 2015 remain nearly the same during this sunset review.

There are specific recommendations by the NOSB *and* a recommendation by the U.S. EPA to remove references to List 4 on the National List that must be acted upon. Several factors are in place for the NOSB, NOP, and EPA to work together to solve these problems now. The EPA Safer Choice Program is well established and offers a strong partner to identify acceptable inert materials. The Crops Subcommittee strongly requests that the NOP act on the 2015 recommendation. The concerns of product developers, stakeholders, and the NOSB must be addressed. This would encourage innovation of new products, lessen concerns of stakeholders over environmental and health concerns, and make future reviews of inert materials much easier.

Figure 1. Timeline of NOSB Actions on “Inerts” (from Shistar, 2017[1]).

1992	First NOSB appointed.
1995	NOSB says it will review “inerts” after the National List is published in the Federal Register and passes the resolution, “Inerts on the EPA List 4 are considered generally recognized as safe and will be accepted for organic production, <u>unless</u> an NOSB evaluation finds a specific List 4 inert to be unacceptable. Inerts proposed for organic production on EPA’s List 2 which are potentially toxic and List 3 which are unknown will be compiled by the NOSB and forwarded to the EPA as materials for fast-track review and possible reclassification. List 1 inerts are prohibited by the OFPA.”
1997	First proposed rule would have allowed all but List 1 “inerts.”
1999	NOSB recommends allowing List 4 and prohibiting all others, with the exception of particular List 3 “inerts” approved on a case-by-case basis.
2000	Following the NOSB recommendation, the final rule allowed “inerts” on Lists 4A and 4B.
2002	NOSB votes to allow the use of List 3 “inerts” in passive pheromone dispensers and to temporarily allow List 3 “inerts” while under review.
2004	NOSB and the public objected to a directive by the NOP that allowed the use of pesticides containing undisclosed “inerts,” including those on Lists 2 and 3.
2006	EPA tells USDA that it had completed the review mandated by FQPA and would no longer be maintaining the “inerts” lists on which the NOP regulations depended.
2007	NOSB relists List 3 “inerts,” limiting the renewal to those identified as List 3 by October 9, 2007 and says, “Future petitions to add, remove or renew an inert ingredient to the National List will need to reference a specific inert ingredient.”
2008	NOSB discussion document on “inerts” options.
2009	Another NOSB discussion document on “inerts.”

[1] Shistar, T. “Inert” Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017

2010	Spring: NOSB establishes the baseline position, “The NOSB needs to review all inert ingredient components used in current NOP compliant pesticide formulations for consideration for inclusion on the National List.” The 2010 recommendation also recommended six steps to accomplish the changes in regulation. Inerts Working Group (IWG) is established. Fall: NOSB votes to re-list List 4, with a minority opinion stressing the importance of moving ahead with NOSB review. The summary of the recommendation stated that the relisting was “pending review by the program of inerts individually and as a class of materials.”
2011	IWG, through the Crops Subcommittee, submits a discussion document that presents some initial considerations and some proposals.
2012	Spring: NOSB recommends an expiration date of October 21, 2017 for List 3 “inerts” in passive pheromone dispensers, to coincide with the sunset date for List 4 “inerts.” The NOP refused to codify the recommendation. Fall: NOSB follows up on the IWG’s 2011 discussion document by unanimously recommending a changed annotation and a plan of action. NOSB proposes to review of “inerts” by classes.
2013	In its response to the fall 2012 NOSB meeting, the NOP said it intends to conduct a public notification and comment process, including notification to the public of “inert” ingredients known to be used in organic production and NOSB’s review plan, and a request for public comments regarding any other “inert” ingredients currently used in organic production that are not identified in the list provided by the NOP. It said that changes to the National List would be considered after NOSB completion of “inerts” review. Spring: NOP reiterates its intentions as stated in its response to the fall 2012 meeting and said that a Federal Register notice to this effect was in review.
2014	Spring: NOP update describes meetings with EPA Design for the Environment (DfE) program and suggests the possibility of cooperating with DfE on “inerts.” Fall: NOP reports that since the spring meeting: Office of General Counsel (OGC) reviewed the concept of collaborating with EPA; NOP provided more background to DfE; and NOP has been planning for interagency meetings. NOP sees next steps: (1) NOP and EPA meet further to develop plans for collaboration; (2) NOP consults with NOSB on options; and (3) public notice will be given via Federal Register.
2015	Spring: NOP provides a TR for one category of List 4 inerts –nonylphenol ethoxylates (NPEs). NOP and DfE (now Safer Choice) presentations. NOP outlined “next steps”: (1) NOSB reviews Safer Choice to consider referring to it for “inerts” review, (2) NOSB reviews current List 4 reference as part of 2017 sunset review, (3) NOSB and IWG may draft alternate language proposal to replace current references to List 4 and List 3-for fall 2015 meeting, (4) NOSB reviews EPA Safer Choice Criteria, and compares to OFPA criteria. Fall: NOSB passes an annotation to the List 4 listing on the National List that allows: substances permitted for use in minimal risk products, (ii) substances included on the EPA’s Safer Chemical Ingredients List, (iii) “inert” ingredients that are exempt from the requirement of a tolerance for use only in passive pheromone dispensers, (i) and (iv) other inerts individually petitioned and reviewed.

2016	Spring: Crops Subcommittee presents a discussion document on a proposal to prohibit use of NPEs. Fall: Saying that the listing will be superseded by the annotation change approved at the Fall 2015 meeting, the NOSB votes to relist List 3 "inerts." No further action on NPEs.

[1] Shistar, T. "Inert" Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017

Subcommittee Review:
Public comment during the April 2020 meeting was emphatically supportive of removing the reference to EPA List 4 on the National List and immediate implementation of prior NOSB recommendations outlined above. Stakeholders largely agreed that the current system is broken, unacceptable, and a threat to organic integrity. A key example noted by several commenters was the presence of NPEs on List 4 despite known concerns about their safety and the fact that they are banned by other organic governing bodies, including the European Union. Additionally, several organic pesticide producers confirmed that uncertainty resulting from reference to an outdated list of inert ingredients (List 4) stifles production of new materials which could benefit organic production. A typical comment from stakeholders in April 2020 is we "…***strongly support[s] and requests that the NOP act on***…" prior NOSB recommendations to end the reliance on EPA List 4. Commenters provided detailed roadmaps for the programmatic and administrative steps needed to implement existing NOSB recommendations and build necessary relationships between the NOSB, NOP, and the EPA Safer Choice Program. Concerns were raised by some trade organizations that abrupt removal of List 4 inerts would cause upheaval in the organic pesticide market and potentially limit the availability of some materials, especially if new formulations required efficacy and other testing. However, it is likely that many chemicals on the outdated EPA List 4 would be migrated to a new list of acceptable materials so that many existing organic pesticide formulations would be unchanged, and no new testing would be required. Materials that are not migrated to a new list for safety or other reasons would not be compatible with organic agriculture, strengthening organic integrity. For example, in public comments, OMRI reports that "Of the 365 distinct inert ingredients that are used in OMRI Listed products as of March 10, 2020, 153 appear on the EPA Safer Chemicals Ingredient List (SCIL) or the 25b Minimum Risk Inerts List.", indicating that many materials on EPA List 4 would already qualify for an EPA inert SCIL for organic pesticide formulations.

According to the NOP, "EPA has informed USDA that the "Inerts List" system may no longer be effective or available for the NOP to reference in the Regulations. Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations. NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations" (https://www.ams.usda.gov/sites/default/files/media/5008.pdf). Given these acknowledgements, the Crops Subcommittee recommends removing EPA List 4 at 205.601(m) from the National list and initiating steps to implement prior NOSB recommendations to develop a Safer Chemical Ingredient List for inerts in an orderly manner.

Subcommittee Vote:
Motion to remove EPA List 4 - inerts of minimal concern from §205.601 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): 7 U.S.C. 6518(m)(1) – (7)
Motion by: Asa Bradman
Seconded by: Wood Turner
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Arsenic

Reference: 205.602(b)
Technical Report: none
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Arsenic and its compounds, especially trioxide, are used in the production of pesticide treated wood products, herbicides, and insecticides. These applications are declining due to the toxicity of arsenic and its compounds.

Arsenic is sometimes alloyed with lead to form a harder, more durable metal. Some areas of use include car batteries and bullets. Until recently, arsenic was commonly used in glassmaking. However, due to pressure from the EPA and environmentalists, most glass manufacturers have slowed down or stopped using arsenic.

Manufacture:
Arsenic is a naturally occurring element in the environment that can enter the food supply through soil, water, or air. Arsenic levels in the environment are generally low but can vary depending on the natural geological makeup of local areas.

International Acceptance:
In 2017 CODEX adopted a code of practice for the prevention and reduction of arsenic contamination in rice. The Codex provides national or relevant food control authorities, producers, manufacturers and other relevant bodies with guidance to prevent and reduce arsenic contamination in rice as source directed measures and agricultural measures. The Codex also includes guidance on monitoring and risk communication.

Health Canada continues to monitor the concentrations of various chemicals, including arsenic, in foods through its ongoing Total Diet Study surveys and also conducts targeted surveys of arsenic in specific foods. Additionally, the Canadian Food Inspection Agency carries out monitoring and surveillance work for arsenic in foods, including those commonly consumed by infants and children. Health Canada will also continue to evaluate the potential human health risks associated with dietary arsenic exposure.

Environmental Issues:
Contamination from mining, fracking, coal-fired power plants, arsenic-treated lumber, and arsenic-containing pesticides also contribute to increased levels of arsenic in certain locations. As a naturally occurring element, it is not possible to remove arsenic entirely from the environment or food supply. The FDA, therefore, seeks to limit consumer exposure to arsenic to the greatest extent feasible.

The FDA tests arsenic levels in foods as part of a comprehensive approach to monitoring toxic elements and nutrients. The agency prioritizes monitoring inorganic arsenic levels in foods more likely to be eaten by infants and toddlers. These foods are a greater potential source of dietary inorganic arsenic exposure for infants and young children than for adults, because:

- they are commonly consumed by infants and young children;

- infants and children's dietary patterns are often less varied than those of adults, and
- infants and children consume more food relative to their body weight than do adults.

The FDA tests for toxic elements through:
- the Total Diet Study;
- the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program; and
- sampling assignments.
- sampling assignments may be conducted in response to reports of elevated arsenic levels in certain foods or to focus on a specific food, food additive, or specific food group (such as foods commonly eaten by infants and toddlers).

The Crops Subcommittee determined that arsenic still does not meet the OFPA criteria and sees no reason to recommend removing it from its prohibited status on the National List. Additionally, there were few public comments, and none were in support of removing arsenic from the prohibited list.

Subcommittee Vote:
Motion to remove arsenic from §205.602 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 0   No: 6 Abstain: 0   Absent: 2   Recuse: 0

Strychnine

Reference: 205.602(i)
Technical Report: none
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It was widely used in poison (toxic) baits to kill rodents and other mammals. Exposure to strychnine can be fatal. It is colorless, odorless and has a bitter taste.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts very rapidly, producing muscular hyperactivity, which can quickly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for oral and ocular effects; inhalation toxicity is also presumed to be high.

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

Manufacture:
The primary natural source of strychnine is the plant *Strychnos nux-vomica*. This plant is found in southern Asia (India, Sri Lanka, and East Indies) and Australia.

International Acceptance:
Under the authority of the Pest Control Products Act and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing strychnine for control of ground squirrels do not meet current standards for environmental protection and, are therefore, proposed to be cancelled.

Canada is a member of the Organization for Economic Co-operation and Development (OECD), which provides a forum in which governments work together to share experiences and seek solutions to common problems. Strychnine is currently registered for certain uses in other OECD member countries, including the United States and Australia, although registered uses do not include control of ground squirrels. As of 18 April 2018, no decisions by an OECD member country to prohibit all uses of strychnine for health or environmental reasons have been identified.

Environmental Issues:
According to the EPA, acute toxicity to birds is assumed to be very high. Subacute dietary data indicate that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds who may be subject to repeated or continuous exposure from spills.

Mammalian studies indicate that strychnine is very highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occur within one hour. Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicate that strychnine is moderately toxic to aquatic invertebrates.

The Crops Subcommittee determined that strychnine still does not meet the OFPA criteria and sees no reason to recommend removing it from its prohibited status on the National List. Additionally, there were few public comments, and none were in support of removing strychnine from the prohibited list.

Subcommittee Vote:
Motion to remove strychnine from §205.602 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jesse Buie
Seconded by: Rick Greenwood
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Ammonia Extract
August 4, 2020

Summary of Petition:
The NOSB Crops Subcommittee has determined the petition by TRUE Organic Products, Inc., submitted April 14, 2020 to be sufficient and has requested a third-party technical review to aid the Subcommittee's deliberations. The petitioner seeks to prohibit nonsynthetic ammonia extracts for use in organic crop production. Specifically, the petition claims that both synthetic and naturally derived forms of ammonia can be synthesized or derived and applied to soils in order to meet the nitrogen demand of plants. Since nonsynthetic sources of ammonia is not currently permitted by Certifiers and Material Review Organizations (but also not explicitly prohibited) in organic production and because such use of ammonia is caustic, lowers soil pH, is known to decrease soil biotic activity, and bypasses other soil based sources of nitrogen, the petitioner seeks to list ammonia extract on §205.602 of the National List as a prohibited nonsynthetic substance.

Questions:
The Crops Subcommittee seeks input from the technical review process and from stakeholders to answer the following questions:

1. Is it difficult to distinguish between ammonia derived from natural and synthetic sources (the petitioner claims it is difficult and can only be determined by assaying the N isotopes)? In addressing this question please consider the distinction between ease of chemical analysis in a laboratory and the realities of distinguishing between ammonia sources in a commercial setting where fertilizer blending is common.

2. What are the impacts of ammonia extract application on soil organic matter content, the microbiome of the soil, soil faunal diversity and other soil "health" indicators?

3. Is the description presented in the petition defining ammonia products sufficiently precise to classify all ammonia-based products? If not, provide a more precise and inclusive over-arching definition.

4. Are there any other issues with ammonia use in organic crop production that the NOSB should be aware of?

Subcommittee Vote:
Motion to accept the petitioned material discussion document on ammonia extract
Motion by: Dave Mortensen
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Jesse Buie, Crop Subcommittee Chair, to transmit to NOP August 4, 2020

National Organic Standards Board
Crops Subcommittee Material Discussion Document
Biodegradable biobased mulch film
August 13, 2020

Summary of biodegradable biobased mulch film

The Crops Subcommittee (CS) is re-issuing this discussion document with updated links and questions below. The CS is now planning to vote on an annotation addressing biodegradable mulch film that is not 100% biobased in Spring 2021.

Past discussion:

Biodegradable biobased mulch film has been on the National List of approved synthetic substances since September 30, 2014, based upon an October 2012 NOSB recommendation. Historical information on this material is as follows:

Reference on the National List: 205.601(b) As herbicides, weed barriers, as applicable (2) Mulches (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.
Technical Report: 2012 TR; 2015 Report; NOP Policy Memorandum 15-1; Supplemental Technical Evaluation Report 2016
Petition(s): 2012
Past NOSB Actions: 10/2012 NOSB Recommendation; Memo to the NOSB with Report on Biodegradable Biobased Mulch Films in Organic Crop Production (Michigan State University, September 2019) (pdf).
Recent Regulatory Background: Final Rule published 09/30/14 (79 FR 58655); Sunset renewal notice published 10/08/2019, 84 FR 53577

I. Background from Subcommittee:
Biodegradable biobased mulch films were approved for placement on the National List of approved synthetics (Biodegradable Mulch Film Made from Bioplastics) without detailing if non-biobased content would be allowed. The vast majority of mulch films in this category contain 20% or less of biobased materials, with the remainder consisting of polymers, colorings, and other synthetic materials. There are some products that might meet the biobased aspect of this material's definition at § 205.2 but are either not biodegradable or are not used widely in production due to brittleness or other production issues.

In January 2015, the National Organic Program issued Policy Memorandum 15-1, to clarify that biodegradable biobased mulch film must not contain any non-biobased synthetic polymer feedstocks. The NOSB requested a limited scope Technical Review in 2016. The questions asked for this limited scope TR from 2016 were as follows:

1. What is the effect on overall soil health, including soil biology, when this material biodegrades?
2. What is the cumulative effect of the continued use of this biodegradable biobased mulch film, on soil nutrient balance, soil biological life, and soil tilth, when used in the same area of

the field for 3-5-10 years?

3. What effect does the breakdown of these polymers have on soil and plant life as well as livestock that would graze either crop residues or forages grown the subsequent year after this mulch film was used?
4. Are there different cropping systems, climate, soil types or other factors that affect the decomposition rate (Examples would be long cold winters, or exceptionally dry conditions, such as found in a desert)?
5. Are there metabolites of these mulches that do not fully decompose, and if so, is there an effect upon soil health or biological life?

The TR focused upon biobased biodegradable mulches which contain polymers and the soil and crop health effects they may have as they biodegrade. This supplemental TR was inconclusive, since research on these materials is currently limited, and the questions above were not answered to the NOSB crop subcommittee's satisfaction. In addition, there are fossil-based synthetic fertilizers, used extensively in nonorganic agriculture, that break down in the soil and provide nutrients for plants. The reliance on natural fertility inputs is one of the areas where organic agriculture is different from nonorganic agriculture.

An argument can be made that even though the non-biobased polymers degrading into the soil originate from petroleum (a nonrenewable fossil fuel), the use of this product could be considered environmentally friendly since it replaces plastic mulches that are currently removed at the end of the harvest season and end up in landfills that do not breakdown for decades if not centuries. The biodegradable mulches from petroleum-based polymers save labor and time, as the mulch does not have to be removed from the field and transported for disposal.

The NOSB reviewed this material for its five-year sunset renewal in 2017, and decided to relist it as written, with the understanding that there were no products on the market that were commercially viable made from 100% biobased (no petroleum) materials. The crops subcommittee needed more information that addressed our questions above to consider a change to the annotation. If it remained on the National List, perhaps manufacturers would be able to develop a product that met that requirement of 100% biobased "ingredients", which was the preferred outcome.

The National Organic Program reached out to Dr. Ramani Narayan, a researcher with the Department of Chemical Engineering and Materials Science at Michigan State University, to provide more information beyond the Technical Review that had been done in 2016. The focus of Dr. Narayan's report is the biodegradability of both biobased and petroleum-based mulch films with limited research on the effect of these products degrading into the soil over time. Section 2.7 of the report (available here) states:

> *Environmental studies have not shown any adverse impacts associated with the incorporation of biodegradable mulch films (BDMs) into the soil to date. More research is needed to monitor any potential formation of terrestrial micro and nanoplastics from biodegradable mulch films and ensure that there is no residual soil ecotoxicity. There is need for tuning the physicochemical properties of the biodegradable mulch films with the needs of specific cropping systems and climates. The biodegradable mulch films could provide additional environmental benefits by formulating them to deliver macro and micronutrients to the crop as they biodegrade in soil, or deliver pesticides directly into the soil. Sintim et al. showed that there was no significant effect on soil health over two years of monitoring and that the soil microbial communities did not differ much either. They found significant enrichment in*

bacterial and fungal gene copies under BDM treatments over 2 years, but no significant change under PE and no mulch. Another important observation was that repeated tillage of BDMs into the soil across 4 years did not impact crop yield significantly and had no major effect on crop quality.

While this section points out possible negative issues with some polymers used in the biodegradable mulch, the vast majority of the report focused on the positive aspects when the mulch does biodegrade. There is discussion that the current regulation protects organic integrity and would not allow the use of excluded methods (some of the polymers are extracted from petroleum through the use of bacteria created through excluded methods), and does not allow materials to be used that "contribute to contamination crops, soil or water." Organic producers in the European Union are allowed to use this petroleum based biodegradable mulch with no requirement on the percentage of bio-based ingredients. The EU will be reviewing these mulches in 2024 with possible changes to their annotation. The Crops Subcommittee has reviewed Dr. Narayan's report, but feels there are questions that still need to be answered and invites the public to provide input on these issues.

The NOP also rescinded policy memorandum 15-1 in October 2019, stating that it was redundant with current regulations. The requirement for 100% biobased feedstocks is articulated in the preamble of the final rule (79 FR 58655) and the status quo remains. Removal of the policy memorandum provides an opportunity for the NOSB to revise the current definition (§ 205.2) to reduce the biobased content requirement. The NOSB, through this discussion document, hopes to gain insight from the public on possible approaches.

II Questions:

1. Is the biodegradability of the mulch film the main issue, or should a future annotation include other issues?
2. Is there information on the toxicity or effect of all secondary metabolite residues as the product breaks down?
3. What is your opinion on mulch films that could be engineered to include macro or micro-nutrients or pesticides that would then make the mulch film provide more benefits than just a mulch?
4. Is the risk/benefit of keeping plastic mulches out of landfills part of the Organic Food Production Act criteria the NOSB should consider when reviewing this material?
5. Are there any studies that track the impact on livestock or wildlife (terrestrial, avian and aquatic) that might be attracted to consume pieces of the biodegradable plastic before it has completely degraded in 2 years or secondary metabolites that remain in the soil and are taken up by crops?
6. Should a future annotation try to include consideration that different soils and climates might not be able to meet the biodegradability standard set in the annotation, and how would certifiers be able to verify the use of the material met the biodegradability standard?

Supplemental information and questions requested:
New research includes publications reported by the Small Fruit Horticulture Department, Western State University (WSU), Mount Vernon, WA 98273. Links to publications include: https://smallfruits.wsu.edu/plastic-mulches/

https://ag.tennessee.edu/biodegradablemulch/Pages/Publications.aspx

Additional Questions:

1. Is there any new research on BDM film use that has not been previously submitted to the NOSB?
2. Is there any evidence that BDM films contribute to microplastic pollution in soils and freshwater or marine ecosystems?
3. Are their adequate sampling and laboratory methods available to determine whether BDM film use contributes to microplastic pollution in soils and freshwater or marine ecosystems?
4. Is the availability of biodegradable mulch a make-or-break situation for the viability of your organic system? Why?
5. Plastic films are heavily used in organic berry production systems. What other organic production systems are dependent on plastic films?
6. Are any conventional growers using BDM and what is their experience with these materials?
7. If the NOSB recommended off-site composting of BDM, would municipal compost facilities want to receive BDM since a large proportion of the mass is supposed to be converted to CO2 within 2 years (based on the international standard)?
8. Do non-biodegradable polyethylene or other films used in organic agriculture contribute to organic farm soil microplastics pollution even if removed at the end of the growing season?
9. Would it be feasible to gather up and remove BDM film at the end of the season for on-farm or off-farm composting?

Please comment on which of the following mutually exclusive options for regulating BDM films that are not 100% biobased you think is best:

1. Continue with the current annotation with no change;
2. Allow BDM film use followed by ploughing into soil (with some consideration for off-site transport), with monitoring and assessment to determine whether there are adverse impacts; or
3. Allow BDM film use but require that it be gathered up at the end of the season followed by on-farm or off-farm composting, if feasible; or
4. Allow BDM film use but restrict its use in certain environments where biodegradation may not occur in a reasonable time.

The Crops Subcommittee looks forward to reviewing any new information and your comments.

Vote in Crops Subcommittee:
Motion to accept the biodegradable biobased mulch film discussion document
Motion by: Asa Bradman
Seconded by: Rick Greenwood
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jesse Buie, Crops Subcommittee Chair, to transmit to NOSB August 13, 2020

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Low Acyl Gellan Gum
June 2, 2020

Summary of Petition (petition, 8/8/19; petition addendum; 3/6/20):

On August 8, 2019, the NOP received a petition from CP Kelco U.S., Inc. to add low acyl gellan gum (CAS# 71010-52-1) to the National List. The initial petition requested addition to 7 CFR 205.605(a), however the NOP requested the petition be revised to request addition to 7 CFR Part 205.605(b). The petition was provided to the Handling Subcommittee September 17, 2020 reflecting this change.

Upon initial review of the petition, on January 6, 2020 the Subcommittee sent additional clarification questions to the petitioner and a response was received March 5, 2020. On March 17, 2020 the Subcommittee found the petition sufficient.

Regulatory Background

In 2004, CP Kelco U.S. petitioned to add gellan gum to the National List. In 2007, upon completion of its review, the NOSB recommended gellan gum be added to the National List. A proposed rule was published in 2009 and in 2010, gellan gum was added at 7CFR Part 205.605(a) with an annotation that limits its use to the high acyl form. Outside of USDA organic regulations, there is no differentiation between low and high acyl gellan gum made in regulatory approvals, e.g. the CAS numbers are identical and they are treated the same.

In the 2010 final rule publication, the NOP responded to a comment that references the Board's discussion during its review of gellan gum at its November 2007 meeting:

> The comment stated that low-acyl gellan gum is chemically modified by alkali treatment prior to alcohol precipitation and is, therefore, synthetic. The comment indicated that a restriction of the exemption to the high-acyl form aligns with the intent of the NOSB as conveyed during the November 27-30, 2007 meeting discussion.
>
> There are 2 forms of gellan gum: High- and low-acyl. To manufacture the low-acyl form, an alkali is added, and the temperature is raised to remove acetyl groups. A strong acid is then used to lower the pH and the gum is recovered from solution by clarification and precipitation. The high-acyl form is not subject to deacetylation with an alkali salt. After fermentation, the high-acyl form is precipitated out of solution with isopropyl alcohol.
>
> We believe the different manufacturing processes for high- and low-acyl gellan gum merits a revision to the proposed amendment to clarify that only the high-acyl form of gellan gum may be classified as nonsynthetic. Deacetylation, the removal of acetyl group(s) from molecules, results in chemical change. Thus, in accordance with the NOP definition of synthetic, the resulting substance would be synthetic. Based upon this reasoning, we agree with the comment that the recommendation to add gellan gum as a nonsynthetic substance pertains only to the high-acyl form. Therefore, we have amended the listing by adding the annotation "high-acyl form only."

Use

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

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

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

The petitioner offers a number of unique properties that they feel make gellan gum essential:

- Gellan gum fluid gels are very good at suspending particulate matter since the suspension will remain stable, esp. in products containing pulp or jelly pieces.
- It is heat stable in acid systems unlike carrageenan, which breaks down under acid conditions.
- Gellan gum, unlike carrageenan, can be used in fruit fillings, retorted gels, or low pH beverages.
- Use of low acyl gellan gum in hard and soft capsules gives a functionality that cannot be achieved with most materials currently on the National List. Carrageenan is the only material currently listed which offers producers of hard and soft capsules the necessary technical function/properties.
- Consumers are putting pressure on manufacturers to deliver options that are not animal- or carrageenan- based.
- Gellan gum is used at significantly lower levels (<20%) than other gums on the National List.

Manufacture

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

The petitioner provides the following detail specific to their manufacturing.

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

and potassium glycerate are removed from the low acyl gellan gum during the precipitation and recovery of the low acyl gellan gum with isopropyl alcohol.
- The gum is recovered by precipitation with isopropyl alcohol.
- The precipitate is then dried and milled to a fine powder.
- The powdered form of the product is packaged.

In response to a question from the Subcommittee regarding the use of excluded methods in the production of gellan gum, the petitioner stated that the three low-acyl gellan gums they produce (KELCOGEL® [E], KELCOGEL® CG-LA [E], KELCOGEL® F[E]) are Non-GMO Project certified.

International Use:
Canadian General Standards Board Permitted Substances List (Updated in November 2015)
On Table 6.3 (Ingredients Classified as Food Additives) of the Permitted Substances List, gums are listed with the annotation, "The following gums are permitted: Arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum. Shall be derived using substances listed in Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums" (CGSB, 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
CODEX provides Guidelines (CODEX Alimentarius Commission, 2013) for use of food additive gums as follows: Gellan gum (418). CODEX General Standard for Food Additives (GSFA) provides a highly detailed range of uses and specifications for each of these substances (CODEX Alimentarius Commission, 2017).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008
Gellan gum is not listed.

Japan Agricultural Standard (JAS) for Organic Production
Gellan gum is not listed as allowed or prohibited. (Japanese MAFF, 2012).

International Federation of Organic Agriculture Movements (IFOAM)
Gellan gum is neither listed as allowed nor prohibited.

Summary of Review:
Gellan gum, in a high acyl form as a nonsynthetic substance is already included on the National List at 205.605(a) and has been recommended by the Board for relisting through two rounds of sunset review. The low acyl form of gellan gum is technically a synthetic substance as described above but is viewed from a regulatory and food safety perspective as identical to the high acyl form.

The tenets of organic production tend to favor nonsynthetic options when available. However there do not appear to be significant differences between the nonsynthetic high acyl and synthetic low acyl forms of gellan gum. If a distinct functional property is sought from the use of a low acyl form, a difference in impact to human health and the environment through the use of the low acyl form is negligible. If use of low acyl gellan gum contributes to the increased growth and consumption of an organic crop and subsequent processed product, the gains to human health and environment over a conventionally produced crop and product appear to favor its compatibility with organic handling.

Category 1: Classification

1. Substance is for: __X__ **Handling** _______ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _______ **Agricultural** or __X__ **Non-Agricultural?**
      Describe reasoning for this decision using NOP 5033-2 as a guide:

   The substance is a gum, which is explicitly included in the nonagricultural substance definition at 7 CFR Part 205.2.

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __X **Synthetic?**
      Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

   The NOSB has discussed at length and received much public comment regarding the manufacture of products of fermentation and what processes constitute a synthetic or nonsynthetic determination. Most recently this topic was confronted during the Spring 2020 discussion of the reclassification of L-malic acid. Based on public comment from certifiers, manufacturers and the authors of the TR on L-malic acid, a synthetic or nonsynthetic determination can vary based on where in the manufacturing process one begins the determination. *NOP Guidance 5033 Classification of Materials* and the accompanying *NOP Guidance 5033-1 Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* do not provide clarity or guidance on where this determination is to begin.

   The 2018 TR on Gums further describes this determination as it relates to gellan (and xanthan) gum:

   > Gellan gum and xanthan gum are produced by fermentation of a carbohydrate with bacteria. Fermentation is a naturally occurring biological process. The bacteria strains are not an agricultural source, although agricultural materials may compose the substrate media. After fermentation, further processing is used to separate (recover) the gum from the fermentation media and purify the gum for commercial use. Additional processing steps, as described in *Evaluation Question 1,* may include the following:
   >
   > - Gellan gum and xanthan gum undergo pasteurization.
   > - Gellan gum and xanthan gum undergo alcohol precipitation (with ethanol or isopropanol), similarly to guar gum and locust bean gum. Maximum levels of residual solvents are described in *Approved Legal Uses of the Substances.*
   > - Xanthan gum may be washed with a salt solution.
   >
   > In order for post-fermentation extracted materials to be classified as nonsynthetic, NOP Guidance 5033 on the Classification of Materials requires that at the end of the extraction process, the material: 1) has not been transformed into a different substance via chemical change; 2) has not been altered into a form that does not occur in nature; and 3) that any synthetic materials used to extract the substance have been removed from the final substance such that they have no technical or functional effect on the final product. Reviewing the post-fermentation processing steps described above against NOP Guidance 5033, the following conclusions are made:
   >
   > - Heating of biological materials is not considered a synthetic process.

- Alcohol precipitation, as described above, may be considered a nonsynthetic process provided that any residual solvents are removed such that they do not have a technical or functional effect.

The 2018 TR on Gums appears to determine low-acyl gellan gum as potentially nonsynthetic. However the 2010 NOP response to comments on the proposed rule to list high-acyl gellan gum clarifies the view of the Program on this substance:

> "Deacetylation, the removal of acetyl group(s) from molecules, results in chemical change. Thus, in accordance with the NOP definition of synthetic, the resulting substance would be synthetic. Based upon this reasoning, we agree with the comment that the recommendation to add gellan gum as a nonsynthetic substance pertains only to the high-acyl form."

3. For **LIVESTOCK**: Reference to appropriate OFPA category
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   N/A

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   It does not appear that gellan gum has detrimental chemical interactions with other materials.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   The 2018 TR on Gums notes that dues to its low toxicity, the EPA exempted gellan gum from the requirement for a tolerance limit when used as an inactive ingredient in pesticide formulations.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

   The TR notes the Safety Data Sheets for the solvents used to precipitate gellan gum do not indicate specific impacts on the environment or biodiversity.

   The petitioner notes that any waste from the fermentation media will be discharged to the municipal sewage treatment plant and will be present in only trace amounts. A recovery procedure is used to reclaim isopropyl alcohol.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

   The 2006 technical report on gellan gum cites one Joint FAO/WHO Expert Committee on Food Additives (JECFA) study indicating no adverse human health impacts. This same study notes that gellan gum acts as a bulking agent and decreases serum cholesterol.

   The 2018 TR states the effect of food additive gums on the nutritional quality of foods varies depending on the type and amount of gum ingested because of their varied properties. The gums' physiological and nutritional effects occur during transit through the stomach, small intestine, and colon, by reducing and mixing actions in the gut and by their effect on the interaction between nutrients, enzymes and mucosal cells, and finally, as a result of their fermentation, by the colonic microflora. Digestion of sugars and fats may change when foods containing gums as food additives are ingested.

   Gellan gum is not affirmed as GRAS. It is listed at 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Humans, Subpart G, Gums, Chewing gum bases and related substances: Gellan gum, 21 CFR 172.665

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   The 2018 TR notes no sources were identified that discussed environmental contamination resulting from the commercial manufacturing of any of the six gums. The solvent used to separate the gums at the dissolution phase of the process is typically isopropyl alcohol and residual solvent levels are established.

   The petitioner notes that because gellan gum is a polysaccharide, it is broken down by microorganisms found in the soil and therefore, would have a beneficial effect on soil organisms which in turn would benefit crops.

6. Are there any adverse impacts on biodiversity? (§205.200)

   The 2018 TR on Gums notes the Safety Data Sheets for the solvents used to precipitate gellan gum do not indicate specific impacts on the environment or biodiversity. The gum itself does not appear to impact biodiversity.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

   As noted in the 2018 TR on Gums, there are many natural hydrocolloids which can be substituted for any one of the gums currently listed on the National List. The choice of gum for a particular food application is dictated by the functionalities required. Some of these functionalities are unique to a particular gum or combination of gums. The 2018 TR goes into great detail on these various functionalities.

Alternatives do exist but may not provide the same functionality for a particular product. For instance, gelatin could be used as an alternative to gellan, but gellan can withstand higher temperatures. An alternative practice could be to make the product without the additive, resulting in products with different consistencies and textures.

The high acyl form of gellan gum can be produced nonsynthetically. However as noted above, this form may not provide the same functionalities as low acyl gum. The 2018 TR found no information was indicating that organic forms of gellan gum are available commercially.

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   N/A

Classification Motion:

Motion to classify low acyl gellan gum as nonagricultural, synthetic
Motion by: Scott Rice
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 1 Absent: 0 Recuse: 0

National List Motion:

Motion to add low acyl gellan gum to the National List at §205.605(b)
Motion by: Scott Rice
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOP August 13, 2020

National Organic Standards Board
Handling Subcommittee Proposal
Review of the Ion Exchange Filtration Process and Materials Used
August 4, 2020

Background:
In an August 27, 2019, memo the National Organic Program requested the NOSB provide recommendations related to the process of ion exchange filtration in the handling of organic products. It has become clear that there is inconsistency between certifiers in how they approve or disapprove this type of process. Some certifiers require only the solutions that are used to recharge the ion exchange membranes be on the National List at § 205.605. Others require that all materials, including ion exchange membranes and resins be on the National List.

The National Organic Program provided clarification to certifying agents in an email sent on May 7, 2019, that nonagricultural substances used in the ion-exchange process must be present on the National List. This would include, but is not limited to, resins, membranes and recharge materials. Originally, the NOP asked all operations to come into compliance with the statement above by May 1, 2020. However, in response to requests for clarification of NOP's rationale, as well as requests to extend the timeline for implementation, the NOP delayed the implementation date in order to gather more information and requested that NOSB review the issue.

Manufacturers and certifiers who wish to continue allowance of the ion exchange process disagree with some of the findings of the NOP on this complex issue. The different opinions of the need for resins, recharge materials and membranes to be present on the National List, as well as how they interact with each other and the liquid run through the process, is complicated and the NOP therefore asked the NOSB to take on this issue.

A simplified summary of ion exchange, provided in the past from OMRI is as follows:

> Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.
>
> Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).
>
> Other processing aids that are considered secondary food additives required petitions in order to be considered. In addition to the filtering / clarifying / fining agents mentioned above, these also included the boiler water additives, antifoaming agents, and certain enzymes. Other additives that are considered 'de minimis' in conventional processing—such as disinfectants and

> atmospheric gases—also required petitions, reviews, and recommendations to be added to the National List. Ion exchange resins are known to leak from columns and thus become incidental additives in the food.

Subcommittee Review:
The question before the Handling Subcommittee essentially boils down to whether only the recharge materials for the resins must be on the National List or whether both the resins and recharge material must be reviewed and added to the List.

The 2020 Technical Review (TR) provides a thorough review of ion exchange filtration and should be referred to for details on this process. It is clear that there is widespread use of ion exchange filtration in organic processing whether it be for removal of off-tastes, heavy metals, or clarification of the final product, among others. Alternatives to ion exchange filtration are not generally available.

As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product – ions (either cations or anions depending on the resin and desired outcome) that were present on the resin have been substituted in the final product while ions that were initially found in the product are left attached to the resin. This is not just a physical removal of material or a reaction whereby another material is used to help process the initial substance and then removed after that process. The 2020 TR cites various research articles and states:

> …ion exchange filtration requires the replacement of bound ions (ions initially present in the filtration material) by others with the same charge and requires electroneutrality…
> …ion exchange filtration is based on the principle that if an ion is removed from the treated substance by the filtration material, it is replaced by an ion of the same charge that began in the filtration material (e.g., removal of positive ion from treated substance is replaced by a different positive ion from the filtration material). The ion exchange process is a result of electrostatic attractions between the ion of interest (ion to be removed from the treated substance) and the charged functional groups incorporated into the filtration material.

The final product, by passing through the ion exchange filter, does have a different ionic makeup than the initial product. In the case of removing "hardness" from water, the substitution of sodium for the original calcium in the water does not change that it is still water, per se, but it can change how that interacts with other materials. Thus, it seems difficult to argue that ion exchange filtration does not cause a chemical change in the final product, even though the chemical change may be beneficial. There is a different ionic makeup in the final product as compared to the initial product and the final product may behave slightly differently than the initial product.

The next question is whether the ion exchange membranes and resins are secondary food additives or food contact surfaces. If they are food contact surfaces, then, based on past NOP guidance, they may be used unless explicitly prohibited. If they are secondary food additives, then they must appear on the National List. It is beyond the capacity of NOSB members to investigate the nuances of FDA rules and regulations. The NOSB received a number of public comments from our Spring 2020 discussion document with a number of viewpoints, however the comments from the Organic Trade Association gave the most details of FDA rule history on this topic:

> In a policy statement issued on December 12, 2002, after consultation with FDA, NOP clarified which substances are subject to review and recommendation by NOSB for inclusion on the National List. According to the policy, substances that are listed in 21 CFR Part 173 as secondary direct food additives are subject to review, unless the substances are classified by the FDA as a

food contact substance. In 2002, FDA clarified that ion exchange resins were food contact substances, therefore ion exchange resins under the 2002 policy were not subject to the National List process. The 2002 food contact substance policy was archived when the NOP Handbook was created; however it has never been formally rescinded and remains in use by some certifiers.

FDA references are as follows:

- Ion exchange resins and membranes are listed in 21 CFR Part 173 as secondary direct food additives, which are substances that have a technical effect in food during processing but not in the finished food.
- According to FDA guidance, some secondary direct food additives also meet the definition of a food contact substance, which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.
- Prior to 1997, FDA regulated ion exchange resins under 21 CFR 173.25. Once Congress established the term "food contact substance" in the Federal Food, Drug, and Cosmetic Act and initiated the Food Contact Notification Program (FCN) in 1999, all ion exchange petitions were converted to this approval method. There was no need to alter or change prior approvals under § 173.25, so they were left as is. Since that time, FDA has directed all new approvals of ion exchange resins through its FCN program. This clearly reflects FDA's stance that they are food contact substances.
- FDA maintains a database of approved Food Contact Substances, which include ion exchange resins that have been classified and approved by FDA as food contact substances.

Additionally, Ingredion submitted comments that echoed the comments from the Organic Trade Association:

> The regulatory classification for ion exchange resins is both a food contact substance AND a secondary direct food additive. https://www.fda.gov/foodjfood-ingredientspackaging/food-ingredient-packaging-terms:
>
> - Food Contact Substance (FCS) - Section 409 of the FD&C Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.
> - Secondary Direct Food Additive (SDFA) - This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance.

There were no other comments received that contradicted that materials could be listed as both a secondary direct food additive and food contact surface. It would seem that, even though a material might be listed both ways, the fact that they are listed by FDA as a food contact surface, exempts those materials from needing to be reviewed by the NOSB and placed on the National List.

Finally, there is the question of whether the resins or membranes themselves contribute to a change in the final organic product or whether, as food contact substances, they are simply a structure that holds the ions to be exchanged. The 2020 TR states that there are studies that demonstrate that the resins do degrade over time, however that degradation is generally in terms of their loss of resin activity or efficiency or capacity. In other words, the resins are simply not as good at holding ions to be exchanged and thus need to be recharged sooner than they would when they were new. In some cases, this loss of efficacy may be because of a loss of functional groups that were originally present, however the citations referenced in the TR note that this loss seems to primarily occur during the recharge process. Thus, the loss of those functional groups would not be into an organic product, but rather into the recharge material. The 2020 TR further states that there were no published studies on the human health effects of the degradation of the resins found by the TR writers. Based on the findings of the TR and no public comments that provided scientific evidence that the resins degrade and cause changes in the final product it would seem that the resins act in the capacity of food contact surfaces and not primarily as direct food additives.

Subcommittee Recommendation:
The inherent nature of ion exchange leads us to the conclusion that recharge materials used to recharge ion exchange resins must be on the National List if they are used in the processing of organic product. These recharge materials leave ions on the resins and those ions will ultimately end up in the final organic product. The public comments received at the Spring 2020 NOSB meeting support this recommendation.

There is less consensus on the question of whether the resins or membranes themselves must be reviewed and included on the National List. From comments received, the resins and membranes appear to be classified as food contact substances. There was no compelling evidence in the 2020 TR or public comments that the resins or membranes degrade and alter the final organic product. Based on this review, it is the recommendation of the NOSB that the recharge materials, but not the resins or membranes themselves, must be reviewed and included on the National List.

Subcommittee vote:
Motion to approve the recommendation on ion exchange materials
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOP August 13, 2020

Sunset 2022
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2020

Introduction

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

Request for Comments

Written public comments will be accepted through October 1, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2020

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

§205.605(a) Nonsynthetics allowed:
Kaolin
Sodium bicarbonate
Waxes (Wood resin)

§205.605(b) Synthetics allowed:
Ammonium bicarbonate
Ammonium carbonate
Calcium phosphates: monobasic, dibasic, tribasic
Ozone
Sodium hydroxide

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Carnauba Wax
Colors (18)
Glycerin
Inulin-oligofructose enriched
Kelp
Orange Shellac - unbleached
Starches: Cornstarch (native)
Starches: Sweet potato starch for bean thread production only.
Turkish bay leaves
Whey protein concentrate

Kaolin

Reference: 205.605(a)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Filtering of organic juices, and for personal care products

Manufacture:
Kaolin is a soft white clay consisting principally of the mineral kaolinite.

International:
Allowed by Canadian Standards, CODEX, European Economic Community (EEC), Japan Agricultural Standards (JAS), and International Federation of Organic Agriculture Movements (IFOAM).

Ancillary Substances:
Unknown

There were minimal comments about kaolin during the Spring 2020 Board meeting. Two certifiers commented that six entities list Kaolin in their organic system plan. The subcommittee felt this material was relatively benign with no significant environmental or health concerns.

Subcommittee Vote:
Motion to remove kaolin from §205.605 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Kim Huseman
Seconded by: Asa Bradman
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Sodium bicarbonate

Reference: 205.605(a)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

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

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

International Acceptance:
Sodium bicarbonate is approved for use in the following organic standards:

Canadian General Standards Board Permitted Substances List: allowed

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999): not specifically mentioned but sodium sesquicarbonate is allowed

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: may be grouped under "sodium carbonates" and if so is allowed

Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, beverages, vegetable products, processed fruits or for dairy products as neutralizing substance.

International Federation of Organic Agriculture Movements (IFOAM): may be grouped with "sodium carbonates" and if so is allowed

Environmental Issues:
Since sodium bicarbonate is derived from sodium sesquicarbonate, a mined material, and the usual environmental issues of mining would be present. However, no major issues have been raised in past reviews.

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

The Subcommittee discussed the importance of sodium bicarbonate, its common usage, and general support for re-listing. Production from Trona deposits vs. the Solvay process was discussed, and the HS strategized around how best to address developments in the manufacturing process. The question was raised as to whether requesting a work agenda item to annotate Sodium Bicarbonate to limit use to non-synthetic production forms and/or whether the decision tree could use some adjustment to capture updated manufacturing processes.

Written and oral comments support the re-listing of sodium bicarbonate. Stakeholders confirmed wide usage across many categories of products. A commonly used item, stakeholders did not report major environmental concerns; one cited sodium bicarbonate as a great example of a National List eligible substance due to its non-toxic, home kitchen use as a leavening agent.

Certifiers raised a classification question regarding the material produced from Trona deposits versus the use of the Solvay process for formulating Sodium Bicarbonate. Support was expressed for considering re-classifying and/or adding an annotation or some other guidance for clarifying the allowed process for Sodium Bicarbonate production.

Subcommittee Vote:
Motion to remove sodium bicarbonate from 205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Mindee Jeffery
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Waxes (Wood rosin) (sic. resin)

Reference: 205.605(a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR Carnauba Wax; 2014 TR - Wood Rosin
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation: 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Uses:
According to the 2014 TR, wood rosin is used in organic processing and handling primarily as a component of fruit wax, most commonly applied to citrus fruit.

At the most basic level, wood rosin, when formulated as part of a fruit wax, reduces the gas exchange between the surface of the fruit and the atmosphere, which in turn reduces the respiration rate and resulting weight loss. The reduced gas exchange is considered to happen in two different ways: the wax forms a physical barrier that the gas must permeate, and the coating also fills openings in the fruit peel (Hagenmaier and Baker 1993). Hagenmeier and Baker (1993) found that some factors such as thickness of coating, and the waxiness vs. resinous qualities of the coating, also affect the action of fruit waxes. For example, coating thickness is as important as type of coating for resistance to water vapor. Wood rosin, when formulated with carnauba wax at differing percentages, only offers limited resistance to water vapor unless carnauba wax consists of approximately 90% of the formula (Hagenmaeier and Baker 1994) (2014 TR, Lines 120-128).

Manufacture:
Wood chips are passed through a series of extractors where each batch of new chips is extracted with several portions of solvent in succession. Each portion of solvent is used on several different batches of chips. This is a counter-current process where fresh solvent is used on the final extraction of the wood chips, and then it is successively used on the chips that receive one, two or three more extractions. Thus, the oldest solvent is used on the freshest wood chips. After the wood chips have received the final solvent extraction wash, the solvent is drained, and the chips are pressure-steamed to recover any residual solvent. The solvent from the terpene oil-rosin solutions leaving the extractors is recovered by vacuum-distillation separation and reused for subsequent extraction processes. The resulting terpene oils are separated by fractional distillation into refined terpentine, dipentene, and pine oil. The remaining residue is the non-volatile extract and is considered to be crude wood rosin (not food grade). The crude wood rosin is further refined and purified by a liquid fractionation process. It is placed into refining towers where a proprietary polar solvent (Merck 2013) is used to extract the darker components. According to the EPA Toxic Release Inventory (2013), methanol is the likely solvent used in this process step. The solvent is evaporated off, recovered and reused. The resulting lighter wood rosin is called Vinsol and the remaining, darker grade (Grade K) wood rosin is that which is considered 'food grade' and permitted as an ingredient in citrus fruit waxes (Merck 2013). The manufacturing process may only differ by the solvents used, but this is the only known method for manufacturing wood rosin. No chemical changes occur during the extraction and refinement of wood rosin. (2014 TR, Lines 230-248)

International:
Allowed under the Canadian Organic Standards

Ancillary substances:
Raw wood rosin is sold directly to further formulators of fruit wax and other products without any additional ingredients such as stabilizers or preservatives (Pinova 2013) (2014 TR, lines 141-142)

Discussion:
According to the 2014 TR, wood rosin is erroneously listed at 205.605(a) as "wood resin". FDA regulations clearly permit and define only wood rosin and do not define or permit wood resin as a direct or indirect food additive. Wood resin is the raw material produced by coniferous trees prior to distillation of any terpene, tall oil, and other components.

In terms of harm to the environment, wood rosin is derived from two pine species including Longleaf pine which is categorized as endangered by the IUCN Red List of Threatened Species (2013). While wood rosin is considered a by-product of the timber industry (derived from the remaining tree stumps) the conversion of farmland for timber use has contributed to the decline of Longleaf pine which due to its slow growth cannot economically compete with other pine species for replanting.

The solvent extraction of wood rosin from the wood chips has potential to negatively affect human health. Although the specific solvents used by Pinova, Inc. are proprietary, the EPA Toxic Release Inventory (2013) suggests that methyl isobutyl ketone (MIBK) is the likely solvent used for the initial extraction, and methanol for the further refinement. According to the EPA (2003), human studies of acute inhalation exposures to MIBK indicated "transient sensory irritation, neurological effects, and/or strong odor sensation during exposure". Another study showed some nose and throat irritation at an exposure rate of 100-200 mg/m3. A study by the National Institute for Occupational Safety and Health on the other hand did not find any changes in neurological or irritation systems after a 2-hour exposure to MIBK at 100ppm (EPA 2003). For the second extraction step, methanol is considered to be environmentally preferable to other solvents of similar properties (Capello, Fischer and Hungerbuhler 2007). However, workers repeatedly exposed to methanol have experienced headaches, sleep disorders, gastrointestinal problems and optic nerve damage. Exposure to large amounts of methanol can result in death or severe abdominal, leg and back pain (EPA 1994). No information is available on the carcinogenic, reproductive, and developmental effects of methanol in humans, but birth defects have been observed in the offspring of rats and mice exposed to methanol by inhalation (EPA 2000) (TR 2014, Lines 393-414)

Most commenters from the Spring 2020 meeting are in support of relisting wood rosin. Commenters also suggested the addition of an annotation to include 'not extracted using volatile synthetic solvents; contains only ancillary substances approved for organic production'. The Subcommittee supports the option of having multiple waxes which allows for more market share as some countries do not allow the use of certain formulations of waxes. The Subcommittee also recommends a technical correction to the listing - wood **rosin** is the accurate listing and **resin** should be removed.

Subcommittee Vote:
Motion to remove waxes (wood rosin) (sic. resin) from §205.605 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Kim Huseman
Seconded by: Scott Rice
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Ammonium bicarbonate

Reference: 205.605(b) - for use only as a leavening agent
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Ammonium carbonates are used as leavening agents, and may be used in baking where yeast is not used. Ammonium bicarbonate has critical functionality as a raising (leavening) agent in certain cookies and crackers. Compared to baking soda it produces more gas and in the finished baked goods, ammonium bicarbonate completely decomposes into water and gaseous products that evaporate during the baking process. It does not leave behind the salty or soapy taste that sodium bicarbonate may leave when used at higher concentrations. Since ammonium bicarbonate completely breaks down in heat it has no effect on the pH of the baked product. Ammonium bicarbonate cannot be used for moist baked goods since if there is more than 5% moisture in the baked good, the ammonia gas will dissolve in the water and give an ammoniacal flavor to the baked good. Ammonium carbonate may also help provide certain characteristic textures (such as in crackers), as well as aids in controlling cookie spread.

Since this is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process, there are no organic alternatives to replace ammonium bicarbonate.

Manufacture:
Ammonium carbonates are made from ammonia and carbon dioxide. Ammonium bicarbonate is made when carbon dioxide is bubbled through an ammonia solution. Crystals of ammonium bicarbonate precipitate from this saturated solution. It is a component of what was formerly known as sal volatile and salt of hartshorn. The ammonium carbonates are considered Generally Regarded as Safe (GRAS) by the FDA.

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

Canadian General Standards Board Permitted Substances List: Allowed as a leavening agent

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999): Not specifically mentioned but "ammonium carbonates" are allowed for food of plant origin

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: May be grouped under "ammonium carbonates" and if so is allowed for food of plant origin

Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for processed foods of plant origin

International Federation of Organic Agriculture Movements (IFOAM): May be grouped with "ammonium carbonates" and if so is allowed only for cereal products, confectionary, cakes and biscuits

Environmental Issues:
The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Ammonium bicarbonate can be an irritant to the skin, eyes, and respiratory system. There may be short term health effects after exposure and long term exposure may cause lung damage.

The original TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. These two substances have been reviewed together during their subsequent two sunset reviews. The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that this material is still critical for organic food processing, especially for baking crackers and similar baked goods.

Stakeholders reflected mixed reviews on Ammonium Bicarbonate. Some certifiers reported little or no handlers known to be utilizing the substance. A trade association reported that it is essential as a leavening agent and alternatives have not been identified. Other certifiers support re-listing and reported common usage. An environmental group recommended delisting due to the emission of ammonia and carbon dioxide during manufacture or use.

Subcommittee Vote:
Motion to remove Ammonium Bicarbonate from 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Mindee Jeffery
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Ammonium carbonate

Reference: 205.605(b) –for use only as a leavening agent
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Ammonium carbonates are used as leavening agents. Ammonium carbonate is used as a raising (leavening) agent for flat baked goods, such as cookies and crackers. It is often referred to as "*Bakers Ammonia"* in cooking recipes and by chefs. Ammonium carbonate is also used to make breadsticks, cookies, and crackers because it helps to make them both lighter and crispier. It is also used in many traditional Greek cooking recipes. Ammonium carbonates are heat activated, so baked goods will not rise until whatever is being baked actually goes into the oven, thus helping with food preparation and time requirements. This is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process. There are no organic alternatives to replace ammonium carbonates.

Manufacture:
Ammonium carbonates are made from ammonia and carbon dioxide. Ammonium carbonate is made when carbon dioxide is passed through an ammonia solution and by then allowing the vapors to distill, thus the resulting solid is ammonium carbonate. It is a component of what was formerly known as sal volatile and salt of hartshorn. Ammonium carbonates are considered Generally Regarded as Safe (GRAS) by the FDA.

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

> Canadian General Standards Board Permitted Substances List: allowed as a leavening agent
>
> CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999): allowed for food of plant origin
>
> European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: allowed for food of plant origin
>
> Japan Agricultural Standard (JAS) for Organic Production: Limited to be used for processed foods of plant origin
>
> International Federation of Organic Agriculture Movements (IFOAM): allowed only for cereal products, confectionary, cakes and biscuits

Environmental Issues:
The original TAP, previous subcommittee reviews, public comments, and historical information indicated no environmental concerns. Ammonium carbonate can be an irritant to the skin, eyes and respiratory

system. There may be short term health effects after exposure and long term exposure may cause lung damage.

The original TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. These two substances have been reviewed together during their subsequent two sunset reviews. The original TAP, previous subcommittee review, public comments, and historical information indicated few environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that this material is still critical for organic food processing, especially for baking crackers and similar baked goods.

The Handling Subcommittee discussed the material, noting that Ammonium Carbonate has low levels of concern in both environmental and human health areas.

An Environmental group supported delisting due to emissions of ammonia and carbon dioxide during manufacture and use. Certifiers listed little to no record of usage. One farm group supported relisting.

Subcommittee Vote:
Motion to remove Ammonium Carbonate from 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Mindee Jeffery
Seconded by: Steve Ela
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)
Technical Report: 1995 TAP; 2016 TR (Phosphates)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

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

Additionally, it is used as a food source for yeast in bread making, as an anti-caking agent in dry powders, such as in spices, and as a thickener, stabilizer, and sequestering agent for some dairy products. Calcium is derived from either mined limestone or from oyster shells.

Manufacture:
Calcium and phosphorus are sourced from limestone and phosphate rock, respectively. The food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides (TR 2016 43-44).

International:
Calcium phosphates are allowed for use in Canada, IFOAM and JAS.

Subcommittee Review:
The NOSB Subcommittee Review of Calcium Phosphates for the 11/27/2017 review process raised concerns regarding the cumulative effect on human health associated with the use of phosphorous additives in foods. These concerns were raised by stakeholders during both the oral and written comment process. However, some of the oral and written comments also refuted these same health concerns.

The Handling subcommittee was instructed to look into the concerns and come back to the full NOSB with further findings. This was done, and included a broader look at all phosphates with the following conclusion:

> No single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population. Given the new information and research since the last Sunset Review, the Handling Subcommittee requested a new Technical Report (TR) which it received in 2016. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but no long term impacts are fully understood.

In reviewing all of the comments from the Spring 2020 meeting, no further concerns were expressed with the exception of the original concerns stated above. There were also several specific references to calcium phosphate as having a positive impact on bone health.

The Board is always concerned about allowing exceptions that could stifle innovation. However, it is our determination that calcium phosphates have no real substitute, particularly in baked products.

Subcommittee Vote:
Motion to remove calcium phosphates from §205.605 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N?A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0   No: 5 Abstain: 0   Absent: 2   Recuse: 0

Ozone

Reference: 205.605(b)
Technical Report: 1995 TAP
Petition(s): N/A **Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Ozone is a powerful oxidant with many industrial and consumer applications related to oxidation. Ozone, which has approximately 150% of the oxidizing potential of chlorine, is used as an equipment and food disinfectant and in post-harvest treatment for produce to retard spoilage in cold storage or in wash water. It is an effective and environmentally benign substance used to reduce and control microorganisms for food safety purposes.

Manufacture:
Ozone, or trioxygen, is an inorganic molecule with the chemical formula O_3. It is a pale blue gas with a distinctively pungent smell. It is an allotrope of oxygen that is much less stable than the diatomic allotrope O_2, breaking down in the lower atmosphere to O_2 (dioxygen). Ozone's odor is reminiscent of chlorine, and detectable by many people at concentrations as low as 0.1 ppm in air.

Ozone is an unstable gas in the air and even more so in water. Because of this, it must be produced onsite. To do so, typically an oxygen supply is fed to a corona discharge system which uses ambient air to produce ozonated water that is used as a liquid disinfectant.

International:
Canadian General Standards Board Permitted Substances List
Included as an ingredient classified as a food additive, and as a processing aid, as a food-grade cleaner, disinfectant and sanitizer.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
While section 5 outlines criteria for the inclusion of substances, the guidelines do not include a permitted substance list.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The regulation does not specifically address the use of ozone.

Japan Agricultural Standard (JAS) for Organic Production
The standard limits ozone use to processed foods of plant origin, animal intestine disinfection, or as egg cleansing.

International Federation of Organic Agriculture Movements (IFOAM) Norms for Organic Production and Processing
The norms allow ozone as an equipment cleanser and disinfectant.

Ancillary Substances:
N/A

Environmental Issues and Human Health Impacts:
According to the U.S. Environmental Protection Agency, ozone exposure in the air we breathe can be harmful to human health and the environment. However, the application of ozone directly into water as a disinfectant minimizes this exposure. Once introduced into water, ozone decomposes into elemental oxygen in a brief amount of time. Exposure to atmospheric ozone generated from on-site production can be minimized through equipment maintenance.

During its first review at the April 2020 meeting, the Board received comments voicing broad support for the continued listing of ozone. Comments from certifiers noted 51 operations list this material in their organic system plans (OSPs). Numerous comments pointed to ozone's importance as a disinfectant and sanitizer for food contact surfaces. Many noted the material's essentiality in reducing microbial loads on finished produce and grains.
One group acknowledged ozone's strong oxidizing properties and usage that does not leave toxic residues. However, they noted the potential risk to workers from leaks in irrigation water treatment when the material is not transferred to the water and is released as a gas. The group encouraged the Crop and Handling Subcommittees to review ozone in the context of all sanitizers.
The Handling Subcommittee considers that the positive attributes of ozone and its role in food safety programs outweigh the manageable risks to worker safety and supports relisting at this time.

Subcommittee Vote:
Motion to remove ozone from §205.605 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Sodium hydroxide

Reference: 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.
Technical Report: 1995 TAP; 2020 TR IN PROGRESS
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Sodium hydroxide is a highly caustic substance, used as a processing aid in cocoa manufacture, as a caustic bath for pretzels that makes the pretzel surface smooth and helps it to develop brown color during baking and for removing bitterness from olives. It is also used as an alkali to peel fruits and vegetables, but this use is specifically prohibited in organic foods by an annotation. Sodium hydroxide is used to manufacture soaps, oral care products and detergents, and can be used as an ingredient in food preservatives to prevent the growth of mold and bacteria. Soda ash ($NaCO_3$), Magnesium Oxide (MgO)

or Sodium Hydroxide can be used in the production of sugar to increase the pH and alkalinity of the sugar cane juice. It is highly soluble in water.

Manufacture:
Sodium hydroxide is derived from saltwater brine, and manufactured by the electrolysis of this salt brine solution. During the electrolysis process, the water (H_20) is reduced to a hydrogen gas (H) and a hydroxide ion (OH). The hydroxide ion bonds with the sodium to form sodium hydroxide (NaOH). Chlorine is also produced during this process.

International Acceptance:
Sodium Hydroxide is listed on the Canadian General Standards Board Permitted Substances List as an approved food additive. It is approved for use in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) for bakery wares within the food category. It is approved on the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 for the production of sugar, for the production of rape seed and for the surface treatment on pretzels and pretzel breads. It is not listed in the Japan Agricultural Standard (JAS) for Organic Production. It is listed as approved by International Federation of Organic Agriculture Movements (IFOAM) for sugar processing and the surface treatment of traditional bakery products. IFOAM also has sodium hydroxide on its list of allowed cleansers and disinfectants, with the annotation that an intervening event or action must occur after this type of use, to eliminate risks of contamination.

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

Environmental Issues:
Must be handled by personnel according to manufacturer guidelines because of caustic nature. Concentration of sodium hydroxide is routinely monitored in pretzel production to verify complete conversion to sodium bicarbonate during baking. The EPA allows sodium hydroxide for use in treating sewage systems to control tree roots, and as a fungicide and algicide on water well casings. Effluent containing sodium hydroxide is not to be discharged into lakes, streams and other public waters without a NPDES (National Pollutant Discharge Elimination System) permit. Well water casing treatment would result in minimal exposure of birds, mammals and other organisms. The EPA states that current product labeling helps to protect wildlife from undue exposure to sodium hydroxide.

The recent Technical Report states there are no alternatives that provide the desired browning properties of pretzels. Baking soda can be used but is not sufficiently alkaline to result in distinctive crust and flavor. Certain varieties of olives rely on sodium hydroxide to remove bitterness, as salt or water curing does not result in acceptable product. Potassium carbonate, potassium bicarbonate, sodium carbonate, sodium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium hydroxide, magnesium carbonate and magnesium oxide, as well as sodium hydroxide can be used to alkalize cocoa. Each type of alkalizing agent results in different flavors and functional attributes. The label claim "processed with alkali" is used when these alkalis are used in cocoa production. It appears sodium hydroxide is the only alkali in use when an alkali is needed in sugar processing.

The Subcommittee discussed the wide usage of sodium hydroxide in organic systems. Several brands, certifiers, and a trade association listed wide usage of sodium hydroxide. A trade association further noted that alternatives are insufficient and, if removed, products would lose organic certification as reformulation is not an option.

Several commenters suggested an annotation to limit use solely for essential purposes. An environmental group noted that the current annotation only lists prohibitions and requested that the Board investigate essential uses of sodium hydroxide and move towards allowance of essential uses exclusively.

Subcommittee Vote:
Motion to remove sodium hydroxide from § 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Waxes (Carnauba)

Reference: 205.606 Waxes – nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR - Carnauba Wax
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Used as a component in fresh fruit coatings, as a candy coating, and as component of an edible coating for nuts. Other uses include a base for chewing gum and in soft drinks. It can also be used as a processing aid, as a releasing agent, and in defoamers. It's Generally Regarded as Safe (GRAS) listing doesn't provide any limitations on its use as an ingredient in food.
When formulated as part of a fruit coating, carnauba wax functions to reduce gas exchange between the surface of the fruit and the atmosphere, thereby reducing the respiration rate and weight loss of the fruit. It also has antifungal properties beyond the creation of a gas barrier.

Manufacture:
The production of carnauba wax begins with leaves cut from the carnauba palm tree during Brazil's dry season. They are dried in the sun and then beat or scraped until the wax falls off as a fine powder. The wax is collected and then either melted via steam or a solvent. The wax is then cooled and filtered via a filter press or through filter cloth, and then cooled and dried. The wax may also be clarified by centrifugation or with hydrogen peroxide.

International:
Allowed by Canadian Standards, CODEX, European Economic Community (EEC), Japan Agricultural Standards (JAS), and International Federation of Organic Agriculture Movements (IFOAM).

Ancillary substances:

According to the 2014 TR, raw carnauba is sold to formulators without any additional ingredients such as stabilizers or preservatives. While formulations containing carnauba as the only wax are available, it is more common to combine it with other waxes and coasting materials, such as beeswax, candelilla wax, wood rosin, or shellac.

Discussion:
Carnauba wax was originally listed at §205.605(a) of the National List. In October 2015 the NOSB passed a recommendation to reclassify the substance as agricultural and move it to §205.606.

The 2014 TR did not find the manufacture or use of carnauba wax to be harmful to the environment or human health.

Unlike other fruit coating materials like orange shellac and wood rosin, carnauba wax is available organically. There are 19 listings in the USDA's Organic Integrity Database.

The Spring 2020 comment period presented arguments both for and against delisting carnauba wax at § 205.606. Some commenters referenced the sufficient availability of organically produced carnauba wax and therefore supported the delisting. Others suggested the organic form does not provide a satisfactory result when used as a processing aid. It was also mentioned through several comments that waxes in general are not always used, but they are important on those occasions when and where necessary; having alternative forms of waxes available allows for more export opportunities due to regulation differences at the respective destination.

The Subcommittee vote was split based on concerns about the use of volatiles in the production of carnauba wax, the possible availability of organic forms, and the issue of an unlabeled ingredient/additive used on produce. The Handling Subcommittee is seeking more information from stakeholders regarding the use of solvents in carnauba wax production.

Subcommittee Vote:
Motion to remove waxes (carnauba) from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of organically produced alternatives.
Motion by: Kim Huseman
Seconded by: Scott Rice
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

Colors Beet juice extract color, Beta Carotene, Black Currant juice color, 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, Pumpkin Juice color, Purple Potato juice color, Red Cabbage Extract 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

(1) Beet juice extract color (pigment CAS #7659-95-2)
(2) Beta carotene extract color
(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)
(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
(13) Pumpkin juice color (pigment CAS #127-40-2)
(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)
(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)
(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); 2011 (Beta carotene); 2012 Supplemental TR
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Added to NL effective 06/21/07 (72 FR 35137); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date (All except beta carotene): 3/15/2022

Sunset Date: Beta carotene extract color: 5/29/2023

Subcommittee Review:
Use:
Colors are added to food products to enhance the attractiveness of the food, to assure uniformity of color, to add back color lost during processing, to intensify existing colors. (TR 12-25).

Manufacture:
Colors can be produced via a number of production methodologies that vary by individual crop and pigment. While most sources have common agricultural crop names, those used for color extraction are often specific varieties that are grown in specific geographical regions using specific production techniques to produce the specific pigments for coloring purposes. Since these items are listed as agricultural – processing is restricted to physical or biological means. The most common types of extraction will be water extraction, milling, pressing, drying, distillation, enzyme treatment, ethanol extraction, or oil extraction. The annotation prohibits the use of synthetic solvents, carrier systems and artificial preservatives.

International:
Colors are allowed on the Canadian, Codex and EU lists but are not listed on the Japanese (JAS) or IFOAM lists.

Subcommittee Review:
It should be noted that §205.600(b)(4), which states "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law," is only applicable to synthetic substances used as a processing aid or adjuvant per §205.600(b). Citing this section is not a reason to delist colors as they are only listed as agricultural, nor are they considered a processing aid or adjuvant.

During the Fall 2015 NOSB sunset review the NOSB ultimately supported relisting all colors. However, the initial Subcommittee review, as well as a statement from the lead reviewer recommended removing all colors but beet, black currant, black/purple carrot, cherry, pumpkin, red cabbage and turmeric juices. The lack of complete information about availability and whether some were available in powdered form was a factor in the Board's decision to relist. The Board noted the emerging presence of certified organic colors and recommended future NOSBs do not renew colors in whole on §205.606. Because of differences in supply of the various colors it is important to review each color individually rather than lumping them as a group. It is also worth noting that since these colors are on §205.606 they are currently subject to commercial availability of organic forms.

Should those stakeholders interested in maintaining a particular color on §205.606 not respond, the NOSB should take that as an indication that the color no longer needs to be listed on §205.606 and vote to remove it.

Public comment received during the Spring 2020 NOSB meeting addressed similar issues as the 2015 sunset review. Arguments were made for and against the renewal of all or some of the colors, but overall there was a dearth of comments given the number of companies that use colors. One commenter stated that the onus was on users of colors covered by this listing to make the case for relisting. If there were few or no comments in support of relisting, the NOSB should vote to remove the color. Several companies noted that they were able to source certain organic colors but there was insufficient supply of other colors. Other companies presented comments that there is sufficient supply of nearly all colors with a few exceptions. One comment came from a company that said they are a large manufacturer of organic colors and can supply market demands, but that price may be a deterrent for some companies. If this is the case, then there is commercial availability and price should not be a reason for relisting. Based on these, often conflicting, comments, the Handling subcommittee has compiled a list of colors where there seems to be sufficient organic supply and should be delisted. The Handling Subcommittee has questions about supply of the remaining colors. In many cases the Subcommittee was split as to whether a color should be relisted or delisted, and would appreciate additional public comment for the Fall 2020 meeting. A listing of each color follows with comments specific to that color.

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

Beet juice extract received conflicting public comments with one large supplier saying they had adequate organic supply and another supplier asking for it to be relisted. There was also a comment from an end user noting they had moved to nearly all organic colors, but this color should be relisted because of difficulties in using the organic color. The 2015 NOSB HS recommended this color be relisted. One commenter noted there were 47 listings for this color in the Organic Integrity Database. The HS recommends that this color should be relisted.

Motion to remove beet juice extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(2) Beta carotene extract color

Public comment, from both manufacturers and end users, from Spring 2020 for beta carotene extract recommended relisting of this color. Without adequate evidence that this color has adequate organic supply, the HS recommends relisting of this color.

Motion to remove beta carotene extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comment from Spring 2020 was mixed with several commenters recommending relisting and one manufacturer recommending that this color be delisted. One end user of this color commented that they had adequate supply of this color in organic forms. The 2015 NOSB HS review recommended relisting of this color. Given that one large manufacturer says they have adequate supply and that cost may be the limiting factor and that the only end user commenting on this color noted adequate supply, but that others comments recommended relisting, the HS had an even split vote as to relisting or delisting.

Motion to remove black currant juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comment from Spring 2020 was mixed. One end user and one manufacturer commented that this color should be relisted while another end user and manufacturer noted there was sufficient organic supply. The end user asking for relisting noted that they were using organic colors for other products but needed this color relisted for another product. Another commenter noted there were 47 listings for this color in the Organic Integrity Database. The 2015 NOSB HS recommended relisting this color. Given the mixed comments, the HS recommends relisting this color.

Motion to remove black/purple carrot juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting this material while another asked for delisting. One end user that uses mostly organic colors in other products asked for this color to be relisted. However, given increase in organic blueberry supply, the HS recommends this color be delisted.

Motion to remove blueberry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

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

Comments from the Spring 2020 meeting were mixed. One manufacturer asked for relisting while another asked for delisting. Similarly, one end user asked for relisting while another noted adequate organic supply. Given that there are commenters, both manufacturers and end users, that commented on adequate supply, HS recommends this color be delisted.

Motion to remove carrot juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability

Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color while another commenter noted 23 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting this color. The HS had an even split vote on whether this color be relisted.

Motion to remove cherry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove chokecherry – aronia juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 1 No: 5 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove elderberry juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS had an even split vote as to whether this color should be relisted.

Motion to remove grape juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS had an even split vote as to whether this color should be relisted.

Motion to remove grape skin extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(12) Paprika color (CAS #68917-78-2) - dried, and oil extracted

Public comment from Spring 2020 were mixed but were more in favor of delisting. One end user and one manufacturer asked for relisting. However, two other manufacturers and one end user commented they had adequate supply. Without comments listing the exact reasons this color needs to be relisted and that there are several manufacturers noting they are able to provide adequate supply, the HS recommends delisting this color.

Motion to remove paprika color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

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

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. Another commenter noted 25 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting. With no other information, the HS had an even split vote as to whether this color should be relisted.

Motion to remove pumpkin juice color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. With no other information, the HS recommends this color be relisted.

Motion to remove purple potato juice extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

(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)

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. Another commenter noted 24 listings in the Organic Integrity Database. With no other information, the HS had an even split vote as to whether this color should be relisted.
Motion to remove red cabbage extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Mindee Jeffery
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

(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

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. One end user that uses organic colors in other products asked for relisting of this color. The 2015 NOSB HS recommends relisting. With no other information, the HS recommends this color be relisted.
Motion to remove red radish extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela

Seconded by: Kim Huseman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(17) Saffron extract color (pigment CAS #1393-63-1).

Public comments from Spring 2020 were mixed. One manufacturer asked for delisting noting they had adequate supply to meet market demands. Another manufacturer that also makes organic colors has asked for relisting on other colors due to difficulties in supply but did not ask for relisting of this color. One end user that uses organic colors in other products asked for relisting of this color. Given conflicting information, the HS recommends this color be relisted.

Motion to remove saffron extract color from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

(18) Turmeric extract

Public comments from Spring 2020 were mixed. One manufacturer asked for relisting while another asked for delisting. Two end users that use organic colors in other products asked for relisting of this color, while a third user says they have sufficient supply of organic product. Another commenter noted 40 listings in the Organic Integrity Database. The 2015 NOSB HS recommended relisting at that time. With no other information and an apparent adequate supply based on comments from a manufacturer and end user, the HS recommends this color be delisted.

Motion to remove turmeric extract from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Steve Ela
Seconded by: Kim Huseman
Yes: 4 No: 2 Abstain: 0 Absent: 1 Recuse: 0

Glycerin

Reference: 205.606(h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).

Technical Report: 1995 TAP; 2013 TR

Petition(s): 1995 N/A**,** Glycerin (2012 Petition to remove)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:

Glycerin is used in food as a binder, humectant, solvent, and carrier. It is widely used in natural flavors. It is used in alcohol-free applications as an alternative to ethanol (as a carrier or solvent). It is also used in cosmetic and personal care products as an emollient, carrier, lubricant and filler. It has a neutral to sweet taste. (TR 24-25)

Manufacture:

Glycerin can be manufactured from a variety of sources using a variety of means. Glycerin exists in nature as part of triglycerides as a backbone glycerin molecule with three fatty acid chains. The product must undergo processing to break the fatty acids from the glycerin. The processing of glycerin will determine if it is agricultural or non-agricultural and the organic certification status of the raw materials, processing plant, and compliance with the National List would determine if the product could be organic or not. It should be noted that it is possible to produce an organic glycerin that would be classified as non-agricultural. Common practices are high-pressure hydrolysis (considered agricultural), saponification (considered synthetic but possible to be certified organic if origin materials are organic and the caustic material is on the national list), methyl esterification (product of biodiesel, considered synthetic), and fermentation of carbohydrates (considered agricultural, but uncommon). Common feedstocks to produce glycerin are palm oil, soy oil, tallow, canola oil, and rapeseed oil. Fermented glycerin is produced from carbohydrates with the common source being corn. When produced from a fat, the glycerin yield is generally 1:10 glycerin to fatty acid.

International:

Glycerin is allowed in the EU (from vegetable sources), Canada (From hydrolysis of fats and oils), and CODEX. It is not on the Japanese (JAS) or IFOAM lists.

In 2012 the NOSB received a petition to remove glycerin from §205.605(b), reclassify it as agricultural, and move its listing to § 205.606. The petitioner stated as follows: "….An important reason that glycerin produced by hydrolysis of fats and oils should have been included at § 205.606 is that items listed at § 205.606 are subject to the restriction that they can be used "only when the product is not commercially available in organic form." Certified organic glycerin is currently available, but there is no "commercial availability" requirement to incentivize processors to use it or certifiers to require it. Consequently, glycerin should be removed from the National List in order to encourage organic agricultural production."

This matter was discussed at length by the NOSB and received considerable public comment over a period of two years, including presentation at the NOSB meetings in Spring and Fall 2014 and Spring of 2015.

The NOSB proposal dated October 21, 2014, included the following:

"….Because of the confusion around classification of glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced glycerin, the Handling Subcommittee, after significant discussion, is proposing the listing of glycerin at §205.606 and removal of glycerin from §205.605(b). …"

In April 2015 the NOSB voted to remove glycerin produced by hydrolysis of fats and oils from § 205.605(b). In December 2018 the NOP finalized rulemaking on the NOSB recommendation, moving glycerin from § 205.605(b) to § 205.606 and changing the annotation to read "produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a)"

During the Spring 2020 NOSB meeting, held virtually from April 29 to May 1, 2020, and during subsequent Handling Subcommittee (HS) discussions, the issue of "commercial availability" was discussed and there was general agreement that, given the wide use of glycerin as a binder, humectant, solvent, and carrier, there is currently no suitable commercially available alternative. During this same time period, the HS addressed the question about the make-up of the remaining 1% left over from the "99% pure" claim attributed to glycerin? In reviewing the 2013 TR and through review of several stakeholder written comments, it is generally held that glycerin is at least 99% pure with the balance of the remaining material being water and fatty acids that, perhaps, support processing.

Subcommittee Vote:
Motion to remove glycerin from § 205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jerry D'Amore
Seconded by: Kim Huseman
Yes: 2 No: 3 Abstain: 1 Absent: 1 Recuse: 0

Inulin oligofructose enriched

Reference: 205.606(j) Inulin-oligofructose enriched (CAS # 9005-80-5)
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 recommendation; 2010 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)

Sunset Date: 6/27/2022

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

Manufacture:
IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin, however, the most common commercial method to produce oligofructose for use in IOE production is from inulin. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), agave, and other plants. Chicory inulin is the most commercially available inulin, however in organic production, inulin is generally derived from Agave (Mexico) and Jerusalem artichokes (China). Chicory inulin is produced by shredding chicory roots, which are treated with hot water, juiced, and filtered to remove the raw inulin. The raw inulin is purified by treatment with calcium hydroxide, carbonated, and filtered and spray-dried. The resulting

inulin polymers range in chain length from 2–60 units. The shortest polymers range from 2–10 fructose units and are called oligofructose. The longer polymers range from 10–60 units. 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 indicated no ancillary substances but noted that IOE could contain up to 20% glucose, fructose, and sucrose left over from the chicory source material or enzymatic conversion. 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 following 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 standards.

In the Fall of 2015 the NOSB voted to sunset IOE based on the availability of alternatives like inulin derived from organic agave and the continued listing of conventional FOS. However, in the public comment period for the proposed rule a processor and trade association asserted that IOE from chicory was still needed. The USDA decided to renew the listing for IOE even though these same comments were received in the Fall 2015 meeting during oral comment, and were considered by the NOSB.

During the Spring 2020 public meeting the NOSB received about 25 public comments, mostly written, with about 75% in favor of relisting. Of the remaining 25% about 60% expressed strong opposition citing commercial availability, with 40% expressing some concern, again, centering around commercial availability. Many of the entities in favor of relisting provided compelling documentation regarding the widespread use of IOE as well as examples of its unique functionality. Most of those opposed to relisting referenced adequate supply with little or no supporting documentation.

Regarding the acceptability of using organic inulin + conventional FOS (already listed at §205 606), there were numerous public comments asserting that this alternative has a distinct lack of functionality, mostly concerning fiber and sweetness.

Subcommittee Vote:
Motion to remove inulin-oligofructose enriched from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Jerry D'Amore
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Kelp

Reference: 205.606(k) Kelp—for use only as a thickener and dietary supplement.
Technical Report: 1995 TAP; 2016 TR (Marine Plants & Algae)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
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. 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.
Manufacture:
Kelp 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.

International:
Kelp is allowed in Canadian General Standards Board Organic Production Systems under aquatic plants and aquatic plant products, Table 4.2. It is also listed in the European Union Annex IX 1.1.3 Algae, including seaweed, permitted in non-organic foodstuffs preparation. It is also listed in the Japanese Agricultural Standard for Organic Plants-Dried Algae, including the powdered form.

Environmental Issues and Human Health Impacts:
Kelp is a renewable resource. It is also a keystone species, and there are concerns over responsible harvest of kelp beds. Climate change is also impacting the distribution of kelp populations. For example, Northern California populations of kelp have been reduced by 90% due to sea urchin populations that exploded after disease killed local sea stars, which are natural predators of the urchins. The bacteria affecting sea stars may be increasing due to warmer water temperatures resulting from global warming. The impact of the loss of kelp on the California coastal marine ecosystem is potentially catastrophic, and the Handling Committee would like more information on the impact of harvesting on kelp populations. There are also concerns over contamination of kelp from ocean radiation.

Subcommittee Discussion
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 has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds.

The NOSB asked several questions of the organic community. The questions were:

1. Are there organic supplies of kelp available? If so, are there enough organic supplies available to meet commercial demand?
2. How is organic kelp's use in livestock production different from uses for human consumption?
3. Are there organic supplies of kelp available for human consumption?
4. Is the availability of organic kelp enough to supply both livestock and human consumption demand in handling?
5. What are the handling (human consumption) needs of kelp as a thickener and dietary supplement?

Several commenters requested the delisting of kelp because of the ambiguity of the listing and suggested a relisting of kelp under §205.607(b) - the wild crop certification. Other commenters suggested relisting with an annotation. The Subcommittee also discussed, in relation to the listing of kelp, the NOSB's discussion document regarding marine materials. Because the marine materials document will ultimately affect all marine materials, including kelp, there remains some uncertainty about how to proceed with kelp and other seaweeds that will have to be better defined, preferably at once, since many of the terms such as kelp can include other separate listings.

Subcommittee Vote:
Motion to remove kelp from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: A-dae Briones
Seconded by: Steve Ela
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Orange shellac

Reference: 205.606(o) 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; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Orange shellac is used to coat fruits and vegetables to reduce water loss and retain firmness. It is an ingredient in lozenges, capsules and tablets, and is a part of confectionary glazes on candy, chocolate and coffee beans. A dye from shellac is used as a food color. It is a natural bio-adhesive polymer that is soluble in alkaline solutions such as ammonia and in solvents such as ethanol. Shellac is water insoluble.

There are also numerous non-food uses: on wood, in cosmetics, in clothing, on seeds, and in adhesives, varnish, and polishes.

Manufacture:
Orange shellac or "shellac" as it is commonly known is the purified product of the natural resin lac, which is the hardened secretion of the small, parasitic insect *Kerria lacca*, popularly known as the lac insect. These insects suck the sap of certain host trees, and when digested by the insects the sap undergoes a chemical transformation and is eventually secreted through the pores of the insect. When this secretion comes into contact with the air, if forms a hard shell-like coating over the larger swarm of insects. The main areas of the world where it is produced are India, Thailand, and Myanmar.

International Acceptance:
Orange shellac is not listed on the Canadian General Standards Board Permitted Substances List, on the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999), on the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, on the Japan Agricultural Standard (JAS) for Organic Production, nor by International Federation of Organic Agriculture Movements (IFOAM). Therefore, these international organic standard bodies do not allow this substance in or on organic foods.

Ancillary Substances:
From the 2014 Technical Report (TR), there are a number of substances that are used to process the orange shellac for use in fruit coatings. Some are allowed in organic production and some are not, they include: isopropyl alcohol, morpholine, oleic acid, candelilla wax, fatty acid soaps and fast drying solvents, wood rosins, paraffin wax, petroleum wax, carnauba wax, sugar cane wax, polyethylene emulsions, castor oil, triethanolamine, ammonia, sodium o-phenyl phenate, stearic acid, alkyl naphthalene sulfonates, sodium hydroxide, bentonite, borax, potassium hydroxide, glycerol, palmitic acid, luric acid, and stearic acid. Fungicides, growth regulators, and preservatives could be added as well as plasticizers such as castor oil, vegetable oils (corn, soy, etc.), acetylated monoglycerides, fatty acids, etc. that are not soluble in water can be used in formulating shellac products. Plasticizers are additives that increase the plasticity or fluidity of material. Coloring agents such as dyes, titanium dioxide, iron oxide, natural colors and other materials such as talc, calcium carbonate and alumina may be used. Only items allowed on the National List can be included in orange shellac used in or on organic products.

Environmental Issues:
The TR states there are no major adverse environmental effects on the production and processing of orange shellac. However, wash-water originating from processing units contain water soluble dye, fragments from insect bodies, proteinaceous matter, vegetable glue, and some sugars. These effluents collect in a pit outside factories and putrefy, generating an offensive smell. This may be a potential environmental hazard for which further studies are required. During washing of sticklac to seedlac, the effluents of lac factories are allowed to flow and collect in reservoirs. This accumulated water is treated with acid, precipitating all solid matter called lac-mud. Lac-mud is also a source of lac dye and lac wax (Baboo and Goswammi 437 2010).

Discussion:
At the previous sunset review, public commenters expressed the desire to add an annotation that would require labeling of fruits and vegetables that may have had orange shellac applied. This option would be a future work agenda item, since annotations are not changed at sunset. The TR states: "There have been no reports showing adverse effects on human health due to orange shellac. Some individuals may show allergic symptoms and some vegetarians may consider it an animal product not suitable for their consumption." Corn zein and starch are alternative materials for shellac that provide a high gloss to some food products. For example, zein is a protein of the prolamine group occurring in maize and used

in food coating. Carnauba wax has been used commercially to coat apples but has less gloss than shellac. There are primarily four different non-synthetic substances that may be used in place of orange shellac as a component of citrus fruit waxes: wood rosin, carnauba wax, beeswax, and candelilla wax. Each has their own positives and negatives for handling purposes, including shine, permeability, cost, etc.

Limited public comments were presented during the Spring 2020 meeting; however, all the comments supported relisting orange shellac. Public commenters again suggested adding an annotation that would require labeling of fruits and vegetables that may have had orange shellac applied. As noted above, this would be a future work agenda item since annotations are not addressed during the sunset review. A petition is currently under review by the Board for corn zein, an alternative material to orange shellac that also provides a high gloss finish to some foods. The Subcommittee was split over relisting orange shellac. There is lack of information about whether its use in organic products is widespread or necessary as well as the absence of comments on this ingredient.

Subcommittee Vote:
Motion to remove orange shellac from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Alternatives, 7 U.S.C. 6518(m)(6)
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 3 No: 3 Abstain: 0 Absent: 1 Recuse: 0

Starches: cornstarch

Reference: 205.606(s) Starches.
(1) Cornstarch (native).
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 recommendation on cornstarch; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420);
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
"Starches are used in many foods as thickeners, formulation aids, to make corn syrup, and as bulking agents and moisture adsorption agents. Cornstarch is made from special strains of corn that are high in amylose and amylopectin" (prior review).

Manufacture:
Cornstarch is obtained from the endosperm of the kernel. The corn is steeped for 30 to 48 hours, which ferments it slightly. The germ is separated from the endosperm and those two components are ground separately (still soaked). The starch is then removed by washing. The starch is separated from the corn steep liquor, the cereal germ, the fibers and the corn gluten mostly in hydrocyclones and centrifuges, and then dried. This process is called wet milling. Finally, the starch may be modified for specific uses.

Ancillary substances:

None noted.

International acceptance:

Canada: Yes, with restrictions on materials used for manufacture.

Codex: Not listed.

EU: From corn, not chemically modified.

Japan: Not listed.

IFOAM: Not listed

Environmental/Health Issues:

Cornstarch poses no acute health hazards from ingestion or dermal absorption. Dusts produced during production may pose inhalation risks, and potentially a fire hazard if levels in air reach critical combustion concentrations. Cornstarch that is not organic may be produced from conventional corn that was grown with synthetic fertilizers and pesticides that pose risks to human health and the environment.

Discussion:

There are organic starches on the market, but they are not necessarily suitable for all uses. "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". During the 2017 review, public commenters indicated that some types of organic cornstarch are not available. A recent search of the Organic Integrity Database identified 55 suppliers of "cornstarch" or "corn starch", including many in the United States. Cornstarch is listed under §205.606, so non-organic material should be used only when organic cornstarch is not available. The Handling Subcommittee requested public comment on the need to list cornstarch under §205.606.

During the Spring 2020 NOSB meeting, many certifiers, trade organizations, and food manufacturers supported relisting of cornstarch on §205.606. Although various forms of organic cornstarch are available and abundant, many commenters noted that some organic forms were not functional to manufacture their products or there was not enough specialized organic material available to meet their needs. Overall, certifiers and producers reported non-GMO derived cornstarch, albeit not organic, was readily available. Several organic cornstarch manufactures reported production of thousands of metric tons of organic cornstarch and also possible alternatives derived from pea starch or other products. One commenter recommended an annotation limiting cornstarch on §205.606 to specialized forms that are not available organically and thus encouraging broader use of available organic cornstarch when it meets production requirements. Note that an annotation is beyond the scope of the sunset review and would have to be considered as a separate work agenda item. The Subcommittee wanted to encourage policies that increase use of organically sourced cornstarch and there was debate about whether this could be accomplished by an annotation as described above or by removing cornstarch, as listed, from §205.606, and encouraging direct listing of any specialized forms that are not available organically. The Subcommittee ultimately voted to recommend removal of cornstarch from §205.606 because of an abundant supply of organic cornstarch.

Subcommittee Vote:
Motion to remove starches: cornstarch from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Asa Bradman
Seconded by: Scott Rice
Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Starches: sweet potato

Reference: 205.606(s) Starches.
(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; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Sweet potato starch is specifically used as a formulation aid for bean thread production.

Manufacture:
The sweet potatoes are crushed, and the starch is washed out and dried to a powder.

Ancillary substances:
None noted.

International acceptance:
Canada: Not listed.
Codex: Not listed.
EU: Not listed.
Japan: Not listed.
IFOAM: Not listed

Environmental/Health Issues:
Sweet potato starch poses no acute health hazards from ingestion or dermal absorption. Dusts produced during production may pose inhalation risks. Sweet potato starch that is not organic may be produced from conventional sweet potatoes that were grown with synthetic fertilizers and pesticides that pose risks to human health and the environment.

Discussion:
A recent search of the Organic Integrity Database identified two suppliers of "sweet potato starch", including one in the United States and one in China. Sweet potato starch is listed under §205.606, so non-organic forms can be used only when organic cornstarch is not available. The Handling Subcommittee requested public comment on the need to list cornstarch under §205.606 and whether

current supplies are adequate to meet demand for organic bean thread products.

Public comment on sweet potato starch was very limited, with only a few reported users of this project. One organic starch manufacturer suggested pea starch provided a workable alternative to sweet potato starch, although this claim was not addressed by food producers currently using sweet potato starch. Another commenter noted that taking sweet potato starch off §205.606 would likely increase availability of organically sourced material. The Subcommittee wanted to encourage policies that increase use of organically sourced sweet potato starch and ultimately voted to recommend removal of sweet potato starch from §205.606 to encourage use of organically sourced material.

Subcommittee Vote:
Motion to remove starches: sweet potato starch from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Turkish bay leaves

Reference: 205.606(u) Turkish bay leaves.
Technical Report: N/A
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)
Sunset Date: 6/27/2022

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 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:
None noted

Discussion:
During the review of 2017 sunset materials conducted in 2015, the NOSB requested information from the public to assess commercial demand, commercial availability, alternatives, necessity and use in organic production. At that time, the original petitioner noted a source of Turkish bay leaves but believed the supply was too fragile to have the listing removed. Searches of publicly 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 three spice companies were contacted, and all had sources of Turkish bay leaves from Turkey, India or both.

One commenter noted concern regarding impacts of pesticide use and residue when a conventional agricultural ingredient is used. Products certified to the "made with organic…" may use non-organic agricultural ingredients that are not listed on §205.606 and have not undergone a review for compliance with OFPA criteria. However, these ingredients are still required to comply with §205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or with 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.

Based on the availability of organic sources, the NOSB recommended at its October 2015 meeting to remove Turkish bay leaves from 205.606. In an August 7, 2017 final rule, USDA noted it received public comments opposing the remove of Turkish bay leaves from the National List. These extensive comments stated that Turkish bay leaves are not available in the quantity or quality needed to meet organic handling needs. Comments explained that while organic whole bay leaf may be commercially available, ground organic bay leaves provide a different flavor profile, are not presently commercially available, and removal of Turkish bay leaves from the National List would negatively impact finished products containing ground bay leaves. Comments requested that USDA maintain the allowance for nonorganic Turkish bay leaves while suppliers pursue sources of ground organic Turkish bay leaves in sufficient quality and quantity to meet industry needs.

In response to these comments, USDA determined that nonorganic forms of Turkish bay leaves are essential to organic production and handling and should remain on the National List. At the time of this decision, USDA noted that organic handlers are permitted to use the nonorganic substance only if the organic substance is not commercially available. Handlers need to demonstrate, and certifiers need to verify, that the organic substance is not available in the form, quality or quantity needed.

In a December 2019 review of the Organic Integrity Database, the Handling Subcommittee found 62 records of certified handlers and crop producers listing "bay leaf," 86 records listing "bay leaves," and four records listing "Turkish bay leaves."

During its Spring 2020 review, the Handling Subcommittee heard overwhelming support to remove Turkish bay leaves from the National List. As noted above and attested to in public comments received, there appears to be a sufficient quantity of organic Turkish bay leaves in the market to support this removal. Of the certifiers that submitted comments on §205.606 sunset materials, only one noted the inclusion of nonorganic Turkish bay leaves in 4 organic system plans. One trade association noted one organic operation they surveyed used Turkish bay leaves in a wide range of canned soups but stated there is full availability of organic forms. The operation further noted there would be no impact from removal of this material because organic forms can be used and are available.

Based on these comments and the apparent wide availability of organic sources, the Handling Subcommittee recommends the removal of Turkish bay leaves from §205.606 of the National List.

Subcommittee Vote:
Motion to remove Turkish bay leaves from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Commercial availability
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

Whey protein concentrate

Reference: 205.606(w) Whey protein concentrate.
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 05/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241)
Sunset Date: 6/27/2022

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. 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 may be added as an "instantizing" ancillary substance.

Environmental Issues and Human Health Impacts:
In most jurisdictions, environmental regulations now prevent disposal of untreated whey on agricultural land or discharging in municipal sewage system or surface water. Whey composition (high solids, lactose and salt content) makes disposal practices a problem. Rodenberg, 1998 reported that the five day biochemical oxygen demand (BOD5) is a measure of the organic pollutant concentration in the wastewater, and is proportional to the amount of milk or whey lost to the sewer (TR lines 629-631).

Normal dairy production plant wastewater is in the range of 2000 to 3000 mg/l which is 10 times the strength of domestic sewage. The BOD5 can go much higher if a milk spill occurs and the pH can fluctuate widely if spent cleaning in place chemicals are discharged as well. Dairies manage their wastewater discharge to avoid upsetting their biological treatment process or a publicly owned treatment system. With recent advances in technology, as well as increasing awareness of the environmental and financial costs of whey disposal, the dairy industry has found it profitable to process whey into high value added protein products for use as ingredients in food systems. Whey proteins are generally recognized as safe (GRAS) and are considered a label-friendly ingredient. A large portion of the energy used at a typical cheese making operation is devoted to processing whey powder or concentrate. Falling-film type evaporation systems are used to concentrate whey liquid. To fully dry the whey to a powder form, condensed whey from an evaporator is fed to a spray dryer. Both of these processes are highly energy intensive due to the thermal energy required.

Subcommittee Review:
During the Board's previous review in 2015, the NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, and (5) use in the industry. In the past, 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 organic whey protein concentrate. Given the availability of organic whey protein concentrate and the absence of information on continued commercial unavailability from industry, the Handling Subcommittee recommended this item be removed from the National List in 2015 (2015/Fall - Rec to Remove). To date, NOP has not removed WPC from the National List. A petition to remove whey protein concentrate from the National List (https://www.ams.usda.gov/sites/default/files/media/Addendum1_PetitionforRemovalofWheyProteinConcentrate_2019.pdf) is currently under review by the Handling Subcommittee, and review of the Organic Integrity Database indicates several suppliers of whey protein concentrate.

Public comments received during the Spring 2020 NOSB were overwhelmingly in support of removing whey protein concentrate from the National List. The Handling Subcommittee specifically requested information as to whether there were any forms of whey protein concentrate that were not available organically. In response to this explicit request, no public comments were received indicating that there were organic forms that were not available. Furthermore, several commenters replied that they had adequate supply of all forms and actually had so much supply that they were having to sell some organic product on the conventional market. These comments included:

> CROPP Cooperative: Organic Whey Protein is fully available in form and volume. The processing infrastructure has grown dramatically since whey protein concentrate was placed on the National List. Processors are established throughout the United States for both finished products and condensed whey. Roughly sixty percent of our whey is processed into whey powders, with future plans to utilize our entire whey stream. Our whey supply could produce 1.4 million pounds of WPC annually. Today there is an ample supply of organic whey protein concentrate on the market and the supply will continue to grow. In fact, our WPC supply is greater that market demand, where large volumes of our supply are sold on the conventional market.
>
> Western Organic Dairy Producers: We have more than adequate product available to meet the current demand for Organic Whey Protein Concentrate. Given this availability, there is no need to utilize a conventional product for products labeled as organic. The removal of the

conventional Whey Protein Concentrate further supports organic dairy producers and organic dairy product utilization.

Milk Specialties Global: As outlined in the petition, the decision to allow nonorganic whey in organic products may have been necessary in 2007, but no longer meets the threshold of necessity today. We urge the NOSB to remove Whey Protein Concentrate from the National List as part of the mandated sunset process.

Furthermore, at least one organic certifier notes that all of their handlers are currently using organic forms of whey protein concentrate and a number of suppliers were identified on the Organic Integrity Database. Another commenter also noted that organic whey-based products are also offered from international partners, making the supply chain quite robust.

As noted above, the NOSB has also received a petition to remove whey protein concentrate from the National List. The reasoning given in the petition is similar to the reasons listed above. There is adequate organic supply. Despite questions that have been directed towards identifying any forms that are not available organically, there has been no public comment received indicating that the organic supply is inadequate. In fact, there has been comment that at this point the supply exceeds the demand. For this reason the Handling Subcommittee recommends removing whey protein concentrate from the National List.

Subcommittee Vote:
Motion to remove whey protein concentrate from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Alternatives (availability of organic whey protein concentrate), 7 U.S.C. 6518(m)(6)
Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion
Whey Protein Concentrate
August 10, 2020

Summary of Petition (Original petition 9/30/19; petition addendum #1 12/2/19; petition addendum #2 3/21/20):

A petition to remove whey protein concentrate from the National List was received by the NOSB on September 30, 2019. This petition was received at the same time the NOSB is conducting the sunset review for whey protein concentrate. The reasons for removal in the petition are similar to the reasons cited by the handling subcommittee in its recommendation to remove this material through the sunset process. There is adequate organic supply of both form and quantity. Given the commercial availability of organic why protein concentrate, this material no longer appears to meet the criteria for inclusion on the National List as defined in the Organic Foods Production Act, (7 U.S.C 6518(m)(6)).

Summary of Review:
In response to questions to stakeholders requesting if there are any forms not available organically, no public comment received indicated that the organic supply is inadequate. In fact, comments detailed the organic supply, both in quantity and form, exceeds the organic demand. As noted above, the Handling Subcommittee has recommended whey protein concentrate be removed from the National List. For a complete description of the review of whey protein concentrate, please refer to the Handling Subcommittee's fall 2020, sunset review for this material.

The Handling Subcommittee has decided to defer action on this petition until the actions on the sunset review are final. If the NOSB votes to delist whey protein concentrate as part of the sunset process and rulemaking for delisting becomes final, the need for this petition is moot and the petition could be withdrawn. However, if in light of new public comment that a specific form or forms of whey protein concentrate are not available and the sunset vote or rulemaking does not result in delisting of this material, the NOSB could resume work on this petition. The petition process could allow for annotation whereby the NOSB could determine that whey protein concentrate be delisted except for a specific form or forms that the NOSB might determine are not available organically.

Public comments received during the Spring 2020 NOSB were overwhelmingly in support of removing whey protein concentrate from the National List. The Handling Subcommittee specifically requested information as to whether there are any forms of whey protein concentrate that are not available organically. In response to this explicit request, no public comments indicated that there are organic forms that are not available. Furthermore, several commenters replied that they had an adequate supply of all forms and actually had so much supply that they were having to sell some organic product on the conventional market. These comments included:

> **CROPP Cooperative:** Organic Whey Protein is fully available in form and volume. The processing infrastructure has grown dramatically since whey protein concentrate was placed on the National List. Processors are established throughout the United States for both finished products and condensed whey.
> Roughly sixty percent of our whey is processed into whey powders, with future plans to utilize our entire whey stream. Our whey supply could produce 1.4 million pounds of WPC annually.

Today there is an ample supply of organic whey protein concentrate on the market and the supply will continue to grow. In fact, our WPC supply is greater that market demand, where large volumes of our supply are sold on the conventional market.

Western Organic Dairy Producers: We have more than adequate product available to meet the current demand for Organic Whey Protein Concentrate. Given this availability, there is no need to utilize a conventional product for products labeled as organic. The removal of the conventional Whey Protein Concentrate further supports organic dairy producers and organic dairy product utilization.

Milk Specialties Global: As outlined in the petition, the decision to allow nonorganic whey in organic products may have been necessary in 2007, but no longer meets the threshold of necessity today. We urge the NOSB to remove Whey Protein Concentrate from the National List as part of the mandated sunset process.

Furthermore, at least one organic certifier noted that all of their handlers are currently using organic forms of whey protein concentrate and a number of suppliers were identified on the Organic Integrity Database. Another commenter also noted that organic whey-based products are also offered from international partners, making the supply chain quite robust.

Questions:

1. The NOSB received a number of public comments at the Spring, 2020 public meeting that there is an adequate supply of organic whey protein concentrate to meet all the market demands for this material. To best inform its final sunset review decision at its Fall 2020 meeting, the Board is interested in hearing feedback on the following questions. Are there any specific forms of organic whey protein concentrate that are not available in organic form or quantity?

2. Are there any reasons that there is not an adequate organic supply of whey protein concentrate to meet the market demand?

Subcommittee Vote:

Motion to accept the discussion document on whey protein concentrate
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOP August 13, 2020

National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Fenbendazole
July 21, 2020

Summary of Petition:

In July 2019, the NOSB received a petition requesting a revision to the annotation at 7 CFR §205.603 (23)(i) to include the use of Fenbendazole for laying hens and replacement chickens intended to become laying hens.

The targeted organisms of Fenbendazole are the parasitic roundworms *Ascaridia galli* and *Heterakis gallinarum.* Chickens infected with *A. galli* and *H. gallinarum* become unthrifty, weak and emaciated and exhibit weight loss proportional to the parasite load. Young birds are more susceptible to the parasites than are mature hens, but mature hens will exhibit significant loss of egg production when infected with *A. galli* and *H. gallinarum*.

Histomoniasis, also known as Blackhead Disease, is a disease caused by infection with *Histomonas meleagridis.* The disease was named "blackhead disease" because one of the common symptoms observed in infected birds is a bluish or blackish appearance of the skin on their face, comb and wattles. The discoloration occurs because of excessive concentration of reduced hemoglobin in the blood or cyanosis. Flocks of laying hens frequently are infected during the late summer and fall, following heavy rainfall. This is due to the association of earthworms, who commonly surface from the soil after heavy rains. If the chickens eat earthworms which carry the cecal worm, *Heterakis gallinarum,* they will indirectly become infected themselves.

Fenbendazole is an antiparasitic drug that works at the sub-cellular level preventing cell division. Benzimidazoles bind to the β-tubulin, inhibiting the cell's microtubule assembly responsible for intracellular transport and required for mitotic cellular division. (McKellar and Scott 1990). In effect, it starves the parasite by causing intestinal cell disruption. Studies conducted by Sander and Schwarz 1994; Yazwinski and Tucker 2008, Yazwinski et al, 2013, and Alvardo and Mozisek 2018 showed that the late-stage larvae and adult stages of *A. galli* and *H. gallinarum* treated with Fenbendazole showed significantly increased mortality, but hens treated with Flubendazole passed viable eggs that was not significantly decreased in numbers. According to the Merck Veterinary Manual, "The wide safety margin of benzimidazoles is due to their greater selective affinity for parasitic β-tubulin than for mammalian tissues." (Merck, 2006)

Fenbendazole was first approved in 1983 for use in cattle, including beef animals and dairy cows, as a treatment and control of several types of gastronomical worms, including: lungworms, stomach worms (brown stomach worm, barberpole worm and small stomach worm), and intestinal worms (hookworm, threadnecked intestinal worm, small intestinal worm, bankrupt worm, and nodular worm).

A request was submitted to FDA by Ivervet, Inc. to expand the use of Fenbendazole to chickens. The FDA determined that the ADI (Acceptable Daily Intake) in humans is 40 ug/kg of body weight per day and the tolerance for Fenbendazole is 1.8 ppm expressed as the metabolite fenbendazole sulfone. In October 2015, the FDA gave formal approval for the use of Fenbendazole in treatment and control of adult *A. galli* in broiler chickens and replacement chickens intended to become breeding chickens and for the treatment and control of adult *A. galli* and *H. gallinarum* in breeding chickens. The FDA allowed a total of 2.4 ppm residual of Fenbendazole in eggs with no withdrawal time from application.

On January 15, 2018, the approval was extended for the use of Fenbendazole under the trade name of AquaSol for the treatment and control of adult *A. galli* in broiler chickens and replacement chickens and for the treatment and control of adult *A. galli* and *H. gallinarum* in breeding chickens and laying hens.

Fenbendazole was approved to be administered to conventional laying hens and replacement hens at the following rates:

- 200 mg of fenbendazole/ml for oral administration via drinking water
- Safe-Guard® AquaSol must be administered orally to chickens via the drinking water at a daily dose of 1.0 mg/kg BW (0.454 mg/lb.) for 5 consecutive days.

Conventional poultry producers typically administer Fenbendazole to pullets (age 17 weeks of age) or before outdoor access is given to birds to ensure birds have no internal parasites before starting egg production. When birds receive access to the outdoors they come into contact with soil and in turn come into contact with internal parasites. Many producers find the need to re-treat their flocks after a period when birds have access to the soil and come into contact with many internal parasites.

Organic Summary:

In May 2012, Fenbendazole was added to the National List for use in organic livestock, as specified at 7 CFR § 205.603:

In 2016 the NOSB recommended that the annotation for Fenbendazole be amended to include the following:

- *That parasiticides continue to be prohibited in slaughter stock.*
- *That the milk withholding period after treatment with fenbendazole be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.*
- *That fleece and wool from fiber bearing animals be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life.*
- *That fenbendazole be allowed without written order of a veterinarian.*

On Jan 28, 2019: The NOP issued a final rule:

> *Paragraph (a)(23)(i) is revised to read as follows: Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.*
>
> In addition, paragraph *(b)(2) of § 205.238(b) is revised and paragraph (b)(3) is added to § 205.238(b) as follows: (b)(2) Dairy animals, as allowed under § 205.603; and (b)(3) fiber bearing animals, as allowed under § 205.603. AMS has reviewed and agrees with the NOSB recommendation that § 205.238(b) be amended to clarify its use of parasiticides for dairy animals and for fiber bearing animals.*

In Spring 2018, the NOSB recommended clarifying "Emergency" for use of synthetic parasiticides in organic livestock production. The following language was recommended for a rule change:

> *Emergency treatment to allow synthetic parasiticide use in livestock: A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).*
>
> Add this to § 205.238 (b)*(4) Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent*

or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and re-infestation, forage height diversity, use of allowed non-synthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

In Fall 2019, the NOSB Livestock Subcommittee reviewed the petition to expand the annotation to allow Fenbendazole for use on laying hens and replacement chickens intended to become laying hens and submitted a discussion paper at the Fall 2019 NOSB meeting. Based on public comments from the Fall 2019 NOSB meeting, the Subcommittee requested a technical report (TR) limited specifically to the use of Fenbendazole in laying hens and replacement chickens intended to become laying hens. The Livestock Subcommittee gave ten specific focused questions to the TR team concerning human health issues and regulatory issues, and asked the TR team to research any effective alternative methods to the use of Fenbendazole in controlling *A galli* and *H. gallarinum* worms in laying hens and replacement chickens intended to become laying hens.

A second discussion paper was submitted by the NOSB in Spring 2020 to elicit more public comments on amending the 7 CFR 7 CFR §205.603 (23)(i) annotation to allow fenbendazole for use in laying hens and replacement chickens intended to become laying hens.

Summary of Public Comments

The NOSB Livestock Subcommittee received many public comments during the Fall 2019 and Spring 2020 NOSB meetings.

- Many of the public comments were focused on human health concerns resulting from the FDA allowance of 2.4 ppm residual of Fenbendazole in eggs when there is no withdrawal time. Some questioned the method that FDA used to determine the safety of the 2.4 ppm residual of Fenbendazole in eggs. One commenter was concerned that spent laying hens might end up being used for slaughter in soups, etc. That concern is not valid as the current annotation prohibits the livestock from being used as slaughter animals after treatment with Fenbendazole.
- Some public commenters stated their concerns that the definition of “Emergency” had not been adopted by the NOP. They stated that without “Emergency” being adopted the use of Fenbendazole in laying hens and chickens intended to become laying hens was “ripe for fraud.”
- Some commenters stated that “small producers with hens given more access to pastures” did not have problems with worms. Other producers countered by stating that the problems with worms being presence in hens and their eggs has significantly increased since producers had shifted their practices to meet the increased demand for eggs from hens with humane certifications for Free Range or Pasture Raised production models which requires 2.0-108.9 square feet per bird of outdoor access. When birds are out grazing, they are scratching and digging in the dirt for worms and in return picking up intestinal parasites.

- Certifiers and OTA took surveys of their poultry producers to determine if amending the annotation to allow use for laying hens would be of benefit to them. Results of the surveys suggested that the producers were experiencing issues with worms in eggs and that having the use of Fenbendazole on an emergency basis would be one more tool for them to utilize when needed. Other certifiers stated their clients were not having problems with worms in eggs.

Technical Review Summary

The TR addressed the specific questions asked by public commenters and the NOSB Livestock Subcommittee.

- **Health issues concerning the 2.4 ppm residual of Fenbendazole in eggs with no withdrawal period.** The TR states that the ADI was established by the FDA based on extrapolation from adverse health effects found in a six-month oral toxicity study that fed Fenbendazole fed to laboratory dogs. Prior to the FDA's 2018 approval of Fenbendazole for use in laying hens, the detection of any Fenbendazole residues in eggs was considered a violation (Marmulak et al. 2015).

  The TR found that infants and children are considered at a greater risk from exposure to veterinary drug residues than adults, because of their lower weight, growth and developmental stage which many risk assessment models do not include. The study also indicated increased risks to pregnant women and fetuses exposed to the drug (Boobis et al. 2017). In a study of food safety risks, Fenbendazole was rated as having a medium likelihood of occurrence (Bobkov and Zbinden 2018).

  In one human health study, five adult males were fed the equivalent of 2,500 eggs and 5,000 eggs respectively. There were no relevant changes in blood pressure, pulse rate, symptom list, self-rating scale, and clinical chemistry. (Rupp and Hajdu 1974, reported in Inchem 1998).

  Human trials were conducted in 1976 to determine whether Fenbendazole would be considered as treatment for human hookworms and pinworms. Fenbendazole was found to be effective with minor side effects of constipation and burning when urinating. Nevertheless, since that time Fenbendazole has not commonly been used to treat human infestations.

  Benzimidazoles (Fenbendazole) have been used as cancer chemotherapy agents and has been studied as a potential anti-cancer agent (Duan et al. 2013). Development of Fenbendazole is still in relatively early stages. Nothing was found in the scientific literature to suggest Fenbendazole residues in eggs would interfere with its use as a cancer treatment.

- **Fenbendazole Amounts in Eggs and Poultry**
  The question was asked whether cooking eggs at the recommended cooking temperatures of 144-158 F would eradicate the Fenbendazole residuals. The TR found that Fenbendazole fully degrades with peaks of 222.76 F, 447.24 F, 654.66 F and 862.07 F, all considerably higher than eggs are normally cooked for consumption.
- **Natural Alternatives to using Fenbendazole**
  Organic livestock producers have historically and traditionally used a wide range of botanical and naturopathic remedies to control worms in poultry. One common natural remedy is the use of Diatomaceous Earth fed to the birds. The TR provided a table of several substances and methodologies historically used. Most but not all remedies are derived from plants commonly found in the U.S. The TR states that these remedies do not have efficacy or safety data on file with the FDA and are not labeled for internal use on animals. Many of these botanical remedies do not have scientific evidence of their efficacy and safety specifically to poultry internal parasites. At least one organic parasite management guide questions the scientific evidence supporting the efficacy of homeopathic remedies.

Studies show that sanitation of poultry runs is crucial. Pastures, yards and pens should be rotated frequently. It is not clear how long the rotation period in the runs is needed to break the parasitic cycle. Worm eggs may survive in pastures for over two years, and in some experiments, rotations did not significantly reduce infestation rates. Some studies indicated that DE could more effectively be applied to the litter as ovicides to prevent re-infestation of the parasites rather than fed in the poultry feed. The use of probiotics is showing some promise of helping eradicate the worm populations in poultry.

The TR concludes that there is very little research looking at the effectiveness of the natural practices used by organic farmers to control worm populations. The efficacy and safety of these treatments are based largely on anecdotal information and not supported by peer-reviewed scientific research.

Category 1: Classification

1. Substance is for: _______ **Handling** ___X___ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _______ **Agricultural** or ___X____ **Non-Agricultural?**
      Describe reasoning for this decision using NOP 5033-2 as a guide:
   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __X__ **Synthetic?**
   c. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

The manufacturing process for Fenbendazole was included in the March 2007 petition requesting the addition of Fenbendazole as an approved material under §205.603(a)(23)(i) of the National List. The Fenbendazole in AquaSol is now further processed whereby it is reduced in particle size to create a more stable suspension in drinking water. This further processing subjects the Fenbendazole to a wet-milling process whereby a 40 percent fenbendazole suspension is recirculated between a mixing vessel and wet-mill. Utilizing a rotating axis and milling beads, the wet-mill subjects the Fenbendazole particles to impaction and sheer forces, reducing the particle to a submicron size. Moreover, at the end of the manufacturing process Panacur AquaSol is a 20 percent Fenbendazole suspension whereas Panacur Suspension 10% (Safe Guard in the US) is a 10 percent suspension.

3. For **LIVESTOCK**: Reference to appropriate OFPA category

Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Fenbendazole is petitioned as a parasiticide.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Fenbendazole is insoluble in water and excreted after administration in feces. Because it is not soluble, there is little mobility of fenbendazole in soils, and a low risk of groundwater contamination. Laboratory tests show that radiolabeled fenbendazole is degraded with a half-life of 54 days. Although photo-degradation plays a role, degradation of fenbendazole in soil appears to be microbially dependent rather than photodegradative (Kreuzig et al., 2007).

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   Fenbendazole toxicity was demonstrated in pigeons and doves leading the authors of the study to suggest a toxic etiology for fenbendazole in birds of the order Columbiformes treatment (Howard et al., 2002).

   The fate of Fenbendazole in manure and manured soils has been studied under laboratory and field conditions. In pig manure, benzimidazoles disappear slowly. After a 102-day incubation period, 80% Fenbendazole remains. The latter was accompanied by 4% of the corresponding metabolite fenbendazole-sulfoxide. Fenbendazole-sulfoxide remains in clay soil samples after 54 days (Kreuzig et al., 2007).

   Excreted Fenbendazole and Ivermectin residues in cattle dung pats do not significantly affect adult dung beetles or adult dipteran flies; however, excreted Ivermectin produces toxic effects on the larval development of the same dung-colonizing families of insects, while Fenbendazole lacks such toxic effects (Strong et al., 1995).

   Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

   Fenbendazole is manufactured by a process that requires petrochemicals such as benzene and various amines. These are considered toxic compounds.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

   Fenbendazole is not generally considered toxic to humans at regulated doses (FDA, 1995).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   Fenbendazole is insoluble in water, is not a leachate, binds tightly to soil and is not expected to migrate in soil. The only route for fenbendazole to enter the environment is through animal excretion or spillage. Fenbendazole degrades in soil through microbial and photodegradative processes, taking up to 60 days (Hoechst-Roussel Agrivet, 1995)

6. Are there any adverse impacts on biodiversity? (§205.200)

Fenbendazole can break into albendazole. However, there is a low likelihood of physiologic effects. (pg 5 TAP)

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

   While diatomaceous earth (DE) is utilized widely and effectively as a control for external parasites, its effectiveness as an internal control has not been reputably documented. Diatomaceous earth has no effect on lungworm and is not very appetizing to poultry. It may also be a lung irritant. Given that the level of dust is already quite high in barns, diatomaceous earth does not seem appropriate when the animals are fed indoors. The main motivation for adding diatomaceous earth to rations should not be to control internal parasites.

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   Parasiticide use has been tolerated in organic livestock production on a limited basis to alleviate animal suffering. This has almost been, without exception, part of an integrated system of animal health management and requires documentation of a number of approaches other than intervention.

National List Motion:
Motion to amend the listing for fenbendazole to include: Fenbendazole-for use in laying hens or replacement chickens intended to be laying hens at 7 CFR §205.603 (23)(i).
Motion by: Sue Baird
Seconded by: Kimberly Huseman
Yes: 4 No: 2 Abstain: 0 Absent: 0 Recuse: 0

Approved by Sue Baird, Livestock Subcommittee Chair, to transmit to NOP July 22, 2020

Sunset 2022
Meeting 2 - Review
Livestock Substances §205.603, §205.604
October 2020

Introduction

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

Request for Comments

Written public comments will be accepted through October 1, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 2 - Review
Livestock Substances §205.603, §205.604
October 2020

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Butorphanol
Flunixin
Magnesium hydroxide
Poloxalene
Formic Acid
EPA List 4 - Inerts of Minimal Concern
Excipients

Livestock 205.604 Prohibited nonsynthetic substances
Strychnine

Butorphanol

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(5) Butorphanol (CAS #-42408-82-2) - federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

Technical Report: 2002 TR
Petition(s): 2002 Petition
Past NOSB Action: 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Butorphanol is used in livestock production as a pre-operative treatment of pain before surgery. Butorphanol belongs to a general class of drugs known as opiate agonists. It is commonly used as an anesthetic used to treat patients prior to surgery. Other related drugs in this class include buprenorphine, fentanyl, merperidine, and morphine. Xylazine, acepromazine, and butorphanol serve similar functions but each has its own specific advantages that make it the preferred treatment at the time: acepromazine has no analgesic activity, it is only a sedative; xylazine has both analgesic and sedative properties; and butorphanol is a pain killer with no real sedative activity" (TAP p24.) Although, "there are non-synthetic opiates (refers to a group of drugs used for treating pain), butorphanol is preferred for several reasons: it is associated with fewer adverse effects for the animal; it has less abuse potential in humans thereby reducing unwanted consequences if the drug is "diverted" to illicit use."

Manufacture:
Butorphanol is an opioid analgesic derived from morphine. Known for the ability to reduce the perception of pain without a loss of consciousness, the original opioids were derived from opium, which is a partially dried latex harvested from the opium poppy, Papaver somniferum.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Table 5.3 of the Permitted Substances List includes butorphanol under the entry for botanical compounds, noting it shall be used according to label specifications.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
While butorphanol is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including

antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

Japan Agricultural Standard (JAS) for Organic Production
While butorphanol is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

International Federation of Organic Agriculture Movements (IFOAM) Norms
While butorphanol is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Ancillary substances:
Butorphanol tartrate includes sodium chloride, sodium citrate, and citric acid.

Environmental Issues:
Impacts of manufacture of butorphanol are unknown (TAP p25.) Butorphanol is used by injection. Butorphanol and metabolites are not considered toxic if released. Although the fate of butorphanol in the environment is not known, the metabolites that are excreted via urine and bile are water-soluble which will not likely accumulate in the local environment. Butorphanol disposal in city water drainage/sewer systems is accepted practice (TAP pp19, 25).

Discussion:
Butorphanol has been FDA approved for use as an anesthetic in non-food animals. Its use in food animals is an extra-label use (ELU) governed by the Animal Medicinal Drug Use Clarification Act, which allows animal drugs to be used for ELUs when, "limited to treatment modalities when the health of an animal is threatened or suffering, or death may result from failure to treat." The material must be administered by a licensed veterinarian. If all precautions are followed and the drug is administered appropriately, the NOSB judged that there will be no harm done to humans who consume the meats from these animals—and the livestock are able to tolerate surgery, recover quickly, and grant the farmer economic satisfaction, according to the 2002 TAP.

The withdrawal periods for butorphanol in the organic regulations are twice those in the Food Animal Residue Avoidance Databank (FARAD). FARAD is a university-based national program that serves as the primary source for scientifically-based recommendations regarding safe withdrawal intervals of drugs and chemicals in food-producing animals.

In its last review, the NOSB judged butorphanol to be consistent with consumer perceptions of organic products. The NOSB's 2002 votes were 11 favored, 1 absent, and 2 abstained and the NOSB's 2010 vote was unanimous to retain this material on the NL.

Comments received generally supported the continued listing of butorphanol. Two dairy organizations, one dairy cooperative, and one former NOSB member commented in favor of continued use. One organization requested that the LS determine the impacts of the metabolites of butorphanol in milk and when excreted; and determine the legality of the use under the Animal Medicinal Drug Use Clarification Act (AMDUCA), since labels prohibit the use in food-use animals. With regard to the legality of the use and the presence of butorphanol and its metabolites in milk, USDA did determine that butorphanol is listed in the Food Animal Residue Avoidance Databank (FARAD), and the listed meat withdrawal and milk discard times are twice those listed in FARAD (2007 FR Notice). With regard to the impacts of the excreted metabolites, the TAP review did not consider them problematic.

However, reliance on AMDUCA's exemption of ELUs can be problematic (Wren, 2008), and at the time of last review, the Livestock Subcommittee encouraged the Food and Drug Administration to address these uses directly through labeling.

During its first review at the April 2020 meeting, the Board received a majority of comments that support butorphanol's continued listing. Certifiers provided data that shows a small number of operations using this, but several conveyed its importance as a veterinary medicine tool. Several dairy and dairy organizations advocated for its continued listing to ensure the welfare of their animals and the safety of their vets during procedures. As noted in the last sunset review, one organization indicated that information in the TAP about impacts of butorphanol and its metabolites when excreted were not covered and that additional info would be helpful to understand any impacts that may exist. The commenter proposes that all metabolites be evaluated, as well as the extra-label use as described in the discussion above. Xylazine was noted as an alternative but with a caveat that it is not effective.

Based on the comments received, the Livestock Subcommittee considers butorphanol to still be an important veterinary tool for organic producers and supports its relisting at this time.

Subcommittee Vote:
Motion to remove butorphanol from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Dan Seitz
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Flunixin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA

Technical Report: 2007 TAP
Petition(s): N/A

Past NOSB Actions: 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Flunixin, in its compounded state called flunixin meglumine is a potent, non-narcotic, nonsteroidal analgesic agent with anti-inflammatory and antipyretic activity. Flunixin, in its drug form, Banamine®, exists

for intravenous or intramuscular use in horses and for intravenous use in beef and non-lactating dairy cattle only to treat inflammation and pyrexia.

Banamine® has been used to rapidly reduce the fever and lung inflammation that typically accompany Bovine Respiratory Disease (BRD). As a result of usage, cattle feel better faster and have fewer lung lesions in comparison to treatment with other remedies. Additionally, Banamine® has been used to reduce inflammation associated with endotoxemia.

If all precautions are followed and the drug is administered appropriately, there will be no harm done to humans who consume the meats from these animals - and the livestock are able to cope with the disorder and actually heal from it, quickly recovering, and granting the farmer economic satisfaction.

Manufacture:
Flunixin is a synthetic drug more commonly made into flunixin meglumine, which is the primary component of Banamine® (the injectable flunixin meglumine solution). It has been FDA approved and used in horses for intravenous or intramuscular injections and as intramuscular injections for beef and non-lactating dairy cattle for many years to help cope with inflammation, pyrexia, and colic. Administered intravenously and intramuscularly, flunixin is quickly broken down internally and cleared from the bloodstream in urine

Flunixin meglumine is a potent inhibitor of the enzyme cyclooxygenase and is often classified as a non-steroidal anti-inflammatory drug (NSAID) and it functions by reducing the production of mediators of the inflammatory process. It acts as an anti-inflammatory by inhibiting the effect of prostaglandins by inhibiting cyclooxygenase (COX), the enzyme responsible for the direct synthesis of prostaglandins.

International Acceptance:
Canada - Canadian General Standards Board Permitted Substances List:
http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/permises-permitted-eng.html. Flunixin is permitted in Table 5.3 as inflammatories. Preference shall be given to non-synthetic alternatives to reduce inflammation.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
http://www.organic-world.net/news-eu-regulation.html; http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_189/l_18920070720en00010023.pdf. Flunixin does not explicitly appear in the EU Council Regulation, EC No. 834/2007 or 889/2008. However, EC No. 889/2008 Section 4, Article 24 permits the use of chemically synthesized, allopathic veterinary treatments (including antibiotics) when phytotherapeutic, homeopathic products, trace elements and products listed in Annex V, part 3 and in Annex VI, part 1.1 are ineffective. Flunixin is a drug that has been specifically approved for use in swine.

Japan Agricultural Standard (JAS) for Organic Production;
http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

Flunixin does not explicitly appear in the Japanese Agricultural Standard for Organic Livestock Production; (Notification No. 1608); however, Article 4 allows the use of veterinary drugs including biological drugs and antibiotics. Article 3 defines three types of drugs and incorporates by reference other Japanese laws pertinent to animal health care and drugs.

International Federation of Organic Agriculture Movements (IFOAM)
http://www.ifoam.org/standard/norms/cover.html Flunixin does not explicitly appear in the IFOAM NORM (Version 2014). However, Section 5.6 permits the use of chemical allopathic medical products when natural and alternative medicines and treatments are unlikely to be effective. Vaccines are also permitted

in some cases. The norm also states that operators shall give preference to natural medicines, including homeopathy, Ayurvedic medicine and acupuncture.

Environmental Issues:
Generally, flunixin has been declared fairly safe and the probability of environmental contamination during use or disposal of flunixin is very low. EPA stated in a report on PPCP (Pharmaceuticals and Personal Care Products) that are found in the environment, particularly in the water, flunixin was not among the other NSAIDs (i.e. aspirin, ibuprofen, etc.) that had residues left in the waters.

The Spring 2020 Public Comments were overwhelmingly supportive of keeping Flunixin on the National List. Several certifiers conducted surveys of their clients and reported to the NOSB that their clients used Flunixin on their operations and desired to keep it in their 'toolbox" to use when needed for their livestock's well-being**.** Based on prior Subcommittee review and public comments, the NOSB found flunixin compliant with OFPA criteria, and does not recommend removal from the National List.

Subcommittee Vote:
Motion to remove flunixin from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Sue Baird
Seconded by: Dan Seitz
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Magnesium hydroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(18) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.
Technical Report: 2007 TR
Petition(s): 2002 Petition
Past NOSB Actions: 2002 NOSB recommendation; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. It is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid. Magnesium hydroxide is also used as a fertilizer (in the form of lime) as a substitute for more expensive chemical fertilizers.

Manufacture:
The TR states magnesium hydroxide (Brucite) is found naturally in serpentine, chlorite or dolomitic schists, or in crystalline limestones as an alteration product of periclase (magnesium oxide). It is prepared by

mixing sodium hydroxide with a water-soluble magnesium salt. It is also formed by the hydration of reactive magnesium oxide. Either case produces a white precipitate.

International Acceptance:
IFOAM: Basic standards 2002- not explicitly listed as approved food additive or processing aid.

CODEX: Magnesium hydroxide meets the requirements set forth in the Food Chemical Codex, 3rd ed. Assuming good manufacturing practices, magnesium hydroxide is recognized as an acceptable, safe food ingredient.

NORWAY: Magnesium hydroxide is listed as a chemical requiring a much-reduced discharge rate, despite the full known toxicology of the compound. The discharge of unused chemicals is strictly forbidden and enforced in Norway.

The European Union (EU) and the US vary greatly in their limitations on sludge and how it should be treated to prevent disease in livestock. The EU allows more freedom when considering how sludge will be used for treatment. The US requires disposal classification of the sludge before it can be used for treatment. Magnesium hydroxide/oxide are listed as permitted substances in the EU standards.
JAPAN: not specifically listed in Japanese Rule.

Environmental Issues:
According to the TR, the EPA has deemed magnesium hydroxide environmentally safe. This assessment is based on toxicology reports provided by the Centers for Disease Control. Magnesium hydroxide is not listed on the EPA's list of regulated chemicals.

Subcommittee Review:
Based on the Subcommittee review and public comment, the Livestock Subcommittee finds magnesium hydroxide compliant with OFPA criteria and does not recommend removal from the National List.

Subcommittee Vote:
Motion to remove magnesium hydroxide from §205.603.
Motion by: Jesse Buie
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(26) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat
Technical Report: 2001 TAP
Petition(s): 2000 Petition
Past NOSB Actions: 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:

Poloxalene (chemical formula: $C_5H_{10}O_2$) is a copolymer of polyethylene and polypropylene ether glycol that is a non-ionic polyol surface-active agent. Poloxalene is a fast-acting synthetic material approved under the organic regulations only for emergency treatment of bloat. In conventional agriculture, it is also used medically as a fecal softener and in cattle for prevention of bloat.

Manufacture:

According to the 2001 NOSB TAP review of poloxalene, "There are two principal processes used [to manufacture poloxalene] the traditional chlorohydrin process and indirect oxidation by the hydroperoxide process that uses a molybdenum catalyst. Both processes start with propylene (propene) derived from cracking of petroleum. The chlorhydrin process involves reaction of propylene (CH3CH=CH2) and chlorine in the presence of water to produce two isomers of propylene chlorhydrin. This is followed by dehydrochlorination using caustic soda or lime to produce propylene oxide and salt. The hydroperoxide process involves oxidation of propylene to PO by an organic hydroperoxide, producing an alcohol as a co-product. One of the possible alcohols (tert-butanol, TBE) produced as a by-product from this process is used as feedstock for MTBE, a gasoline additive. (Kirk-Othmer 1996b)"

International acceptance:

- Poloxalene is not mentioned specifically in *the Codex Alimentarius; however, the Codex states* that in certain defined circumstances "veterinary drugs or antibiotics may be used under the responsibility of a veterinarian" provided that "withholding periods [are] double of that required by legislation with, in any case, a minimum of 48 hours."
- Poloxalene is not mentioned in specifically the Canadian standards; however, "the standards encourage the use of alternative treatments (e.g., homeopathy and herbal treatments) over regular veterinary drugs. However, if the animal is not responding to alternative treatments or if alternatives are known to be ineffective, the use of antibiotics, parasiticides and other medications is allowed with the additional restrictions outlined here. 'Chemical, allopathic veterinary drugs' refer to synthetic drugs used in mainstream veterinary practice."
- The Japanese Agricultural Standard for Organic Livestock etc. does not specifically mention poloxalene; however, like the Codex and Canadian standards, the is some allowance for use of allopathic veterinary drugs when organic approaches are not effective.
- According to the 2001 TAP:
  - EU 2092/91 – Similar to Codex, with an additional proviso that animals treated more than 2 times or maximum of 3 times per year with chemical veterinary drugs can no longer be marketed as organic (Annex I, Section B 4).
  - IFOAM – similar to Codex and EU, natural products and preventive methods preferred, but use of veterinary medicines is permitted under control of certification agency.

Ancillary substances:

No clear information on ancillary substances was available.

Environmental/Health Issues:

According to the 2001 TAP review, "The production of organic polymers from petroleum sources is a large volume chemical manufacturing process that has significant environmental impact." The 2001 TAP also states that the "FDA does not list any withdrawal times or residue tolerances for poloxalene. (21CFR)" and also the following in regard to human health: "Poloxalene is listed by USP for use as pharmeuceutic aid. It is reported to have no known toxicity (Winters, 99) and is not listed in the National Toxicology Program Database."

Discussion:

The 2001 TAP review stated that "Clearly, there are many preventive measures that can be taken to avoid pasture bloat. Organic farmers seeking to establish a pasture based system for ruminants may occasionally experience unforeseen incidence of pasture bloat that requires an emergency remedy. Use of this synthetic material could be justified to alleviate animal suffering on a very occasional basis."

The following was the conclusion stated in the 2001 TAP review: "Poloxalene is clearly synthetic and prohibited unless added to the National List for medical use. The TAP reviewers are divided and do not have a consensus recommendation. Two of the reviewers favor its allowance for emergency use only based on a need to prevent suffering and promote animal welfare. The third reviewer finds the rare emergency use not to be a compelling reason for considering as a permitted synthetic and does not see it as indispensable given that other treatments are available for cases of mild bloat, and other emergency treatments are called for in life threatening circumstances. This is supported by the lack of historic allowance, or demonstrated need by existing certification agencies. The two reviewers who favor limited allowance also suggested either an extended withdrawal time, or a limited allowance for a permitted number of emergency treatments per year for organic animals. No data to support an extended withdrawal time has been presented, but the NOSB may want to consider an overall policy for frequency of emergency treatment or develop criteria for emergency use medication in general."

Altogether, about a dozen written comments on poloxalene were submitted prior to the April 2020 NOSB meeting. The large majority of comments either supported continued listing of the substance as necessary in emergencies when natural approaches to treating bloat are not effective, or stated that the substance was used by organic farming operations for emergency situations. The general consensus was that while poloxalene is rarely needed, in certain emergency situations it is essential. Two commenters stated that the NOSB should not relist poloxalene unless there is strong evidence of need; however, these commenters did not offer any conclusions in this regard.

Based on the comments received, the Livestock Subcommittee considers poloxalene to still be an important veterinary tool for organic producers and supports its relisting at this time.

Subcommittee Vote:

Motion to remove poloxalene from §205.603(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Dan Seitz
Seconded by: Nate Powell-Palm
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives

Technical Report: 2011 TR
Petition(s): 2010 Petition
Past NOSB Actions: 2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Added to National List, effective August 3, 2012 (77 FR 45903); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:

Formic acid is a pesticide employed to control Varroa and tracheal mites in honeybee hives. Deployed in the form of a compressed pad inside the hive, the material volatilizes to kill mites throughout the hive including mites attacking broods, and located externally on and internally in the adult bees.

The EPA first registered formic acid as a pesticide in 1999 as material control for Varroa and tracheal mites in honeybees. Formic acid kills mites by asphyxiation while not causing harm to the bees. Typically employed over a 21-day treatment period (per label instructions), the efficacy of formic acid in killing mites has been found to be as high as 95%. Label recommendations instruct producers who treat hives with formic acid to not harvest honey from the hive for two weeks after the introduction of the formic acid pads.

Natural sources of formic acid, which include coffee, nectars, some fruits, as well as the stings of ants and bees, have proven insufficient to extract commercially viable quantities.

Manufacture:

Primarily produced through the hydrolysis of methyl formate. Formic acid may be produced as a byproduct of other chemicals (e.g. acetic acid) though these have not proven to be commercially viable.

International Acceptance:

Canada: The Canadian Organic Standards require a 30-day withdrawal time. Also allowed for use silage preservation.

European Economic Community: Formic acid is allowed to control Varroa mites in honeybees. Also allowed for use in silage preservation.

FDA: Formic acid is generally recognized as safe GRAS (21CFR 186.1316)

Environmental Issues:

Due to its localized use inside the beehives, no residue is found outside the hive environment. Human health may be adversely affected if formic acid is inhaled or ingested. Respirators and skin covering personal protective equipment is recommended to protect against applicator contact.

Subcommittee Vote:

Motion to remove formic acid at § 205.603 (b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Nathaniel Powell-Palm
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

EPA List 4 Inerts of Minimal Concern

Reference: §205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 - Inerts of Minimal Concern
Technical Report: 2015 Limited Scope TR Nonylphenol Ethoxylates (NPEs) (one group only of List 4 inerts)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
EPA List 4 Inerts are used for a wide range of applications including surfactants and adjuvants in pesticide formulations.

Manufacture:
As this listing covers a wide range of substances, manufacture varies.

International:
Since this listing covers many different materials, a specific listing of international acceptance cannot be provided. However, it is worth pointing out how other standards address inerts.

Canadian General Standards Board Permitted Substances List
The Permitted Substances List does not individually list inerts, or "formulants" as noted in the Canadian text. Formulants as a class are not subject to the restrictions and prohibitions in the standard.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
While section 5 outlines criteria for the inclusion of substances, the guidelines do not specifically address or include inerts.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The regulation does not specifically address the use of inerts.

Japan Agricultural Standard (JAS) for Organic Production
The standard does not specifically address the use of inerts.

International Federation of Organic Agriculture Movements (IFOAM) Norms for Organic Production and Processing
Section 3.1 of the norms state organic crop production ensure co-formulants (e.g. inerts) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins.

Ancillary Substances:
Given the wide range of substances, presence of ancillaries will vary.

Environmental Issues:
Some of the materials listed on List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of materials listed as to environmental issues is not possible without Technical Reviews of each material.

Discussion:
While the EPA categorized lists (1, 2, 3, 4, 4A, 4B) provided guidance for evaluation of inert substances in organic production, these lists are no longer updated and have limited utility. The NOSB has devoted considerable time to discussing and debating how to address the placement of inerts on the National List. A comprehensive timeline authored by Terry Shistar of Beyond Pesticides is included in the Crops Subcommittee's EPA List 4 Inerts sunset review.

The Inerts Working Group (IWG), made up of NOSB members and NOP and EPA staff, was established in June 2010 and reported to the Crops Subcommittee. The group collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting. At that time, the NOSB and the IWG were working toward a solution to review the inerts that were formerly on EPA List 4 by collaborating with the Safer Choice Program (SCP) of the EPA.

In 2015, the Crops Subcommittee requested a Technical Report (TR) on the class of inerts known as Nonylphenol Ethoxylates (NPEs). The Livestock Subcommittee also reviewed this TR as part of the 2017 Sunset review of the EPA List 4 Inerts of Minimal Concern listed at §205.603. As highlighted in the TR, the US EPA is encouraging industry to eliminate the use of NPEs (TR 2015, line 137) because of toxicity concerns and persistence in the environment. It is unlikely that the NPEs would pass favorably through the SCP screening process. The Crops and Livestock Subcommittees have considered removing NPEs through an annotation, while maintaining the general listing for EPA List 4 while the new SCP review program starts up.

Because of concerns about the adverse health and environmental effects of NPEs, the SCP completed an alternatives assessment for synthetic surfactants, like NPEs, that are not endocrine disrupting chemicals. SCP's goal was to assist in the voluntary phase-out of NPEs used in industrial detergents. The SCP assessment for NPEs reviewed several alternatives to NPE surfactants that are comparable in cost, readily available, and rapidly biodegrade to non-polluting, lower hazard compounds in aquatic environments. Since this assessment, many formulators have reformulated their products without the use of NPEs.

The Crops Subcommittee drafted a proposal outlining the steps for implementation of the Safer Choice Program for inert review. Once initiated, inert manufacturers would have to submit their products to Safer Choice to be reviewed. A long implementation phase would be proposed, so that industry and manufacturers have enough time for submittal of inerts for screening and any required formulation change. The Livestock and Crops Subcommittees have noted that some inerts currently in use in organic products would likely not pass the Safer Choice review, and strongly encourage manufacturers to consider the likelihood of the need for reformulation.

Past public comments at sunset weighed heavily in favor of robust reviews of inert ingredients, due in large part to the fact that the original listing of inerts relied upon an EPA screening process which does not consider the OFPA criteria. Additionally, public comments indicated significant concern that, while inerts are not listed as active ingredients in many pesticide formulations, they nevertheless exert significant impact on the environment, terrestrial and aquatic ecosystems and human health. The Livestock Subcommittee recognizes the public's deep concerns regarding these materials, while also acknowledging the significant impact that wholesale removal of EPA List 4 Inerts from the National List would have on the organic industry.

In the last two sunset reviews, the Board has voted to retain the listing of EPA List 4 Inerts while the organic industry, the NOP, and the EPA worked together to create a path forward that adequately reviews inerts for compatibility with organic production. In October 2015, the Board passed a recommendation proposing an annotation to remove the reference to EPA List 4, and move forward with a formal relationship to work with the EPA Safer Choice Program. The recommendation acknowledges the current nomenclature in use by the EPA regarding FIFRA 25(b) and 40 CFR 180.1122, while laying a framework for some inerts to be reviewed individually.

To date, the 2015 recommendation has not been implemented. The 2015 recommendation presents options for moving forward that are still relevant and necessary. **The board strongly encourages the NOP to move forward on this recommendation and add it to the regulatory agenda.**

During the spring 2020 comment period, the Board again heard overwhelmingly from stakeholders that the inertia around this issue is unacceptable. As one comment noted, "It has now been five years since NOP committed to implementing the NOSB recommendation; ten years since EPA directly requested NOP to remove the reference in its regulations; and about 15 years since EPA Lists became obsolete. Yet the NOP regulations still refer to EPA Lists that were last updated in August 2004." Commenters expressed support for removing the reference in the annotation to EPA List 4 Inerts and moving the 2015 recommendation forward. Several comments provided detailed steps for how the NOP, NOSB and EPA Safe Choice Program can work together to accomplish this.

Though a path forward is well-defined, the timeline required to enact the 2015 recommendation is likely a lengthy one. Many EPA List 4 inerts used in compliant crop and livestock input formulations also appear on the EPA Safer Chemicals Ingredient List (SCIL), thus providing a viable transition to this more relevant list. Other inputs with inerts of known toxicity or other concerns would not move to the SCIL list and require reformulation and the subsequent registration and approval that is required of new regulated inputs. Ultimately, the reformulation of inputs to safer ingredients is a positive direction in which to move, one which meets consumer expectations and strengthens the integrity of the organic label. However, removal of the EPA List 4 reference with no immediate substitute will in the interim cause potential disruption to organic operations that rely on materials formulated with these inerts, removing essential tools in an already limited toolbox.

With these concerns recognized, the Subcommittee on a whole is hesitant to recommend removing EPA List 4 at 205.603(e) from the National list. However, we are unanimous in our request that the NOP immediately initiate steps to implement the 2015 NOSB recommendation to use the Safer Chemical Ingredient List for inerts as an evaluative tool in an expedited manner where possible. It is the intent that the NOP and NOSB work, as recommended by this Board in 2015, with EPA's Safer Choice Program and move to evaluate inerts in a manner that fulfills the requirements laid out in the Organic Foods Production Act.

Subcommittee Vote:
Motion to remove EPA List 4—Inerts of Minimal Concern from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Sue Baird
Yes: 2 No: 4 Abstain: 0 Absent: 0 Recuse: 0

Excipients

Reference: §205.603(f) Excipients—only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
There are more than 8,000 food, drug, and cosmetic excipients available for conventional production; however, excipients currently appear in the USDA National Organic Program (NOP) regulations at §205.603 for use in the manufacture of drugs used to treat organic livestock when the excipient is identified by the FDA as: 1) Generally Recognized As Safe (GRAS); 2) approved by the FDA as a food additive; 3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or 4) Approved by APHIS (Animal and Plant Health Inspection Service) for use in veterinary biologics. Additionally, excipients are allowed in "nutritive supplements" listed at § 205.603(a)(21).

Excipients are defined in §205.2 as "any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance)." Excipients are used in New Animal Drug Applications (NADAs) approved by FDA, and in animal health care products that do not carry NADA registration. They are also used in New Drug Applications (NDAs) in drugs marketed for human consumption that may be administered to animals, such as aspirin.

Excipients are used for a great number of applications in animal drug and health care products but are delineated into broad categories based on the major reasons the excipient is used. "Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained- release matrices, and coloring agents." (§ 205.2)

Manufacture:
Excipients are common in almost all therapeutic products for veterinary use, and in some cases the total amount of excipients used is greater than the active substances in the dose. They are derived from natural sources or are synthetically manufactured by chemicals, derived from genetically modified organisms, or manufactured by other means. They range from simple, whole food products, to highly characterized organic and inorganic molecules, to complex materials that are difficult to fully characterize chemically.

Excipients can be added to the active substance individually or together in a formulated excipient package, depending on the drug. Excipients serve many functions but are typically comprised of suspending and viscosity-modifying agents, pH modifiers and buffering agents, preservatives, antioxidants, chelating agents, sequestrants, colorants, flavors, fillers, and diluents. While it is clear the functions that excipients serve, very few of them have been chemically described in any detail (TR- 54-56).

Because excipients are manufactured for a wide variety of purposes, the source and origin are highly variable. They range from whole food products such as wheat middlings and yeast to synthetic food additives such as sodium benzoate and sodium lauryl sulfate. They may be agricultural, non-synthetic or synthetic. Some are extracted or produced from plants, animals, minerals or microorganisms, and others are manufactured entirely from chemicals.

International Acceptance:
Canada - Canadian General Standards Board Permitted Substances List: http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio- org/permises-permitted-eng.html Excipients are permitted under the Canadian Organic Standards, appearing in Table 5.3 as Formulants (inerts, excipients), and can only be used in conjunction with substances listed in Table 5.3. The listing in Table 5.3 does not specify any criteria for further compliance of such excipients.

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

ftp://ftp.fao.org/docrep/fao/005/Y2772e/Y2772e.pdf 263 Excipients do not explicitly appear in the tables of permitted substances for organic livestock production; however, the use of veterinary medicinal products is permitted under certain conditions according to Health Care, Section 22, including chemical allopathic drugs. Excipients are not specifically mentioned in this section.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
http://www.organic-world.net/news-eu-regulation.html; http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_189/l_18920070720en00010023.pdf 271.

Excipients do not explicitly appear in the EU Council Regulation, EC No. 834/2007 or 889/2008. However, EC No. 889/2008 Section 4, Article 24 permits the use of chemically synthesized, allopathic veterinary treatments (including antibiotics) when phytotherapeutic, homeopathic products, trace elements and products listed in Annex V, part 3 and in Annex VI, part 1.1 are ineffective.

Japan Agricultural Standard (JAS) for Organic Production
http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

Excipients do not explicitly appear in the Japanese Agricultural Standard for Organic Livestock Production; (Notification No. 1608); however, Article 4 allows the use of veterinary drugs including biological drugs and antibiotics. Article 3 defines three types of drugs and incorporates by reference other Japanese laws pertinent to animal health care and drugs.

International Federation of Organic Agriculture Movements (IFOAM)

http://www.ifoam.org/standard/norms/cover.html Excipients do not explicitly appear in the IFOAM NORM (Version 2014). However, Section 5.6 permits the use of chemical allopathic medical products when natural and alternative medicines and treatments are unlikely to be effective. Vaccines are also permitted in some cases. The norm also states that operators shall give preference to natural medicines, including homeopathy, Ayurvedic medicine and acupuncture.

Environmental Issues: The primary mechanism through which excipients appear in the environment is via manure application to cropland. There is little known about the actual effects, adverse or not, on the environment from excipients. Only a handful of studies have even identified the presence of specific excipients in the environment, while most studies focus on pharmaceuticals without making a distinction between active and excipient ingredients. Since most excipients used in organic livestock production are GRAS or FDA approved food additives, the potential for environmental and human health effects has been evaluated by the FDA as part of their legal status. No literature was found to show definitive harmful effects on the environment when excipients are used in animal health care products.

On the other hand, there are environmental concerns related to the manufacture of excipients. Because of the great variety of substances permitted for use as excipients and the methods of manufacture, some of the excipients could have detrimental environmental effects. Raw material extraction of petroleum products, solvents and mined minerals pose negative environmental effects; the FDA has gone as far as recommend to the pharmaceutical industry to avoid certain solvents (e.g., benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethane, 1,1,1-trichloroethane) that pose exceptional environmental and human health risks. Further processing of certain ingredients like starches and starch derivatives can lead to environmental degradation, air pollution, and exploitation of resources. A great number of excipients may be derived from GMOs; i.e., soy, corn, cotton, etc.

Health Issues:
There is no literature to indicate specific human health effects through the use of excipients in livestock health care products; but there is significant literature to show that certain excipients can have detrimental and even lethal consequences when administered directly to human beings, especially infants. This is one reason the FDA assesses the safety of excipients as part of each NADA application, rather than individually in a separate program. New excipients undergo a series of preclinical tests recommended by FDA and the International Pharmaceutical Excipients Council that include acute oral and dermal toxicity, teratology, genotoxicity assays, and skin sensitization studies in rodents. These tests may be conducted on the excipient in combination with the active ingredient, or as a stand-alone ingredient.

The most likely route of exposure of humans to excipients in animal drugs is through consumption of residues in milk and meat products of treated animals. Most of the research on contamination has focused upon traces of antibiotics, but formulations specifically allowed in §205.603 can also appear in milk and meat. Presumably, both the active ingredient and the excipients are cleared from commercial products by the withdrawal times dictated by the NOSB on the active ingredients. However, since the majority of excipients used in organic livestock production are GRAS or food additives, the FDA assessment would include human and animal effects of ingestion of such ingredients, including their metabolism and breakdown pathways. Adulterated excipients pose some potential risk to human health; as a result, the FDA identified a partial list of excipients and active ingredients that may also be adulterated and need further testing.

There were many comments from the public during the Spring 2020 NOSB meeting. Most of the comments addressed inconsistencies amongst certifiers about how to determine which excipients for livestock use are allowable and which are not. The NOSB was asked to commit to identifying and reviewing individual excipients to bring the clarity needed.

Nevertheless, the NOSB heard resoundingly that the public desired that excipients remain on the National List. Several Certifiers sent results of surveys that they had conducted with their clients, and the results showed that the numbers of uses of excipients in livestock health products were in the thousands.

Based on prior Subcommittee review and public comments, the NOSB found excipients compliant with OFPA criteria, and does not recommend removal from the National List.

Subcommittee Vote:
Motion to remove excipients from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Sue Baird
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.
The following nonsynthetic substances may not be used in organic livestock production:
(a) Strychnine
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (crops only); 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Use:
Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It was widely used in poison (toxic) baits to kill rodents and other mammals and is a common adulterant of many illicit (street) drugs. Exposure to strychnine can be fatal. It is colorless, odorless and has a bitter taste.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts very rapidly, producing muscular hyperactivity, which can quickly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I by the EPA, indicating the greatest degree of acute toxicity, for oral and ocular effects; inhalation toxicity is also presumed to be high.

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

Environmental Issues:
According to the EPA, acute toxicity of strychnine to birds is assumed to be very high. Subacute dietary data indicate that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds who may be subject to repeated or continuous exposure from spills.

Mammalian studies indicate that strychnine is very highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occurring within one hour. Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicate that strychnine is moderately toxic to aquatic invertebrates.
Discussion:
In 2017, The Crops Subcommittee determined that strychnine did not meet the OFPA criteria and saw no reason to remove it from its prohibited status on the National List. Both the Crops Subcommittee and the full NOSB voted to not remove strychnine from § 205.604 - non-synthetic substances prohibited for use in organic crop production.

Based on prior Subcommittee reviews and public comments, the NOSB found Strychnine non-compliant with OFPA criteria, and does not recommend removal from the National List §205.604.

Subcommittee Vote:
Motion to remove strychnine from §205.604 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Nathaniel Powell-Palm
Seconded by: Jesse Buie
Yes: 0 No: 6 Abstain: 0 Absent:0 Recuse: 0

USDA National Organic Standards Board
Research Priorities Proposal Fall 2020
Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

1. Evaluation of methionine in the context of a system approach in organic poultry production.
2. Prevention and management of parasites, examining breeds, geographical differences, alternative treatments, and pasture species.
3. Organic livestock breeding for animals adapted to outdoor life and living vegetation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
3. Organic no-till practices for diverse climates, crops, and soil types.
4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
5. Development of systems-based plant disease management strategies are needed to address existing and emerging plant disease threats.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
7. Strategies for the prevention, management, and control of invasive insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of organic synthetic materials, natural materials, and cultural methods, with a request for collaboration with the IR4 project.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

1. Evaluation of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.

3. Develop then implement methods of assessing the genetic integrity of crops at risk in order to quantify the current state of the organic and conventionally produced non-GMO seed.
4. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.

General

1. Examination of the factors influencing access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

National Organic Standards Board
Materials Subcommittee Proposal
2020 Research Priorities
Fall 2020

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2019 board meeting. That substantially updated list arose from public comments received by the NOSB and by concerns raised during the course of the Board's work in the preceding year. Additional input since the Fall 2019 meeting further shaped the current list of research priorities.

BACKGROUND

The list of priorities is revisited each year by the NOSB. The list is made meaningful by input through the written and oral public comments shared with the Board, through the expertise of the Board itself and through interactions throughout the year with those engaged in some dimension of the organic farm to fork continuum. When the NOSB has determined that a priority area has been sufficiently addressed, it is removed from the list of priorities. Priorities are also edited each year to more accurately reflect the existing need for new knowledge. Three new research priorities were added in 2020 while others were significantly rewritten.

The NOSB encourages collaboration with and between laboratories, federal agencies, universities, foundations and organizations, business interests, organic farmers, and the entire organic community to seek solutions to pressing issues in organic agriculture and processing/handling.

PROPOSAL: 2020 RESEARCH PRIORITIES

The NOSB encourages integrated, whole farm research into the following areas:

<u>Livestock</u>

1. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production - Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems; (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine; (3) assessment of management practices for improving existing organic poultry welfare under different conditions; and (4) and with the European

Union as a case study, assess how it is that EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary. The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management.

2. **Prevention and Management of Parasites** - Livestock production places large numbers of cattle, sheep, goats, poultry etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner which approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, it is clear that parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical.

   The research question on prevention and management of parasites must be systems based. What farm systems, bird and animal breeds, herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, diatomaceous earth, or other treatments that have been proven to work overtime? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

3. **Organic Livestock Breeding** - Organic rules require livestock products originate from animals that are not confined and are adapted to outdoor living as well as obtaining feed from living vegetation. A current FAO report states that globally one third of pigs, half of all egg layers, two thirds of milk animals, and three quarters of meat chickens are produced with breeds more suited to confinement or "industrial" production systems than a typical organic farm or ranch. Similar to plant breeding, the organic community sees a great need for regionally-adapted and publicly available livestock breeds that can thrive in organic systems. Heritage, native regional breeds, and breeds used in the EU and other areas of the world that are typically more adapted to organic systems are still present but in small numbers. Increased research on the breeding, production needs, and improvement of these breeds is needed. Traits for good conversion rates from grazing and foraging to eggs, milk or meat, meeting consumer expectations for quality, as well as having the constitution and temperament to thrive outdoors would increase both the profitability and resiliency of organic livestock operations. Animal breeds that may have immunity to a variety of diseases and parasites would be useful traits to research and incorporate in a breeding program.

Crops

1. **Biodegradable Bio-based Mulch Film** - Biodegradable mulch was recently approved by the NOSB but did not specify a required percentage of biologically derived (i.e., bio-based) content. In 2015, NOP

issued a Policy Memo[1] that states that certifiers and material organizations should review biodegradable mulch film products to verify that all (100%) of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers because petroleum-based polymers are present in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions are important to develop more clarity on mulch films and possibly develop an additional annotation to address producer needs for biodegradable mulch films even if petroleum-based polymers are used:

- How rapidly do these mulches fully decompose, to what extent does cropping system, soil type, and climate mediate decomposition rates, and does the percentage of the polymers in the mulch film affect the decomposition rate?
- Are there metabolites or breakdown products of these mulches that do not fully decompose? Do any of these mulches fully decompose?
- Do breakdown byproducts influence the community ecology and ecosystem function of soils, plants, and the livestock that graze on crops grown in these soils?
- As fragments degrade, do they pose a problem to terrestrial and aquatic wildlife? What are the environmental fates of micro- and nano-plastic fragments resulting from biodegradable mulch film degradation, and what hazards do they present to organisms that they interact with on the way to that fate?
- Do the residues of these films accumulate after repeated use?
- Are the testing protocols in place to insure decomposition standards?

2. **Ecosystem service provisioning and biodiversity of organic systems** - How do organic systems impact ecosystem service provisioning, both on-farm and off-farm through the materials and inputs sourced and used for production? For example, life-cycle analysis of environmental costs and benefits of inputs used for organic production, such as manure, seaweed, and fish-based soil amendments, would be beneficial. Additionally, what is the impact of diversified and agroecologically designed organic farming systems on biodiversity and ecosystem services within the farm and in its surroundings? Can farm-mapping be performed to quantify the impact of the location of a farm (in a broader landscape) and the arrangement of fields and non-crop habitat to enhance biodiversity and ecosystem service provisioning?

3. **Organic No-Till and Minimum Tillage** - Organic no-till can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming.

   Farmers are employing a number of different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.

   Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices. Research areas that could be covered include:

[1] Policy Memo 15-1

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
- How does organic no-till influence pest, weed, and disease management?
- What potential pest problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Do these systems affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?

Finally, organic farmers use whole-farm planning when deciding what will be done in each of their fields. Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to “inform” where reduced tillage practices are likely to have their greatest impact.

4. **Managing Cover Crops for On-Farm Fertility** - Growing cover crops and green manures is a foundational practice on many organic farms. In addition to conserving soil, increasing water holding capacity, and providing weed suppression, cover crops supply important plant nutrients and increase soil organic matter. As farmers seek to grow their own fertility, more research is needed on the efficacy of relying primarily on cover crops to meet production needs, particularly for horticultural crops. At present, there is inadequate data on the nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, subsequent planting time of the cash crops, and importantly the preceding practices that define the legacy of individual fields.

5. **Disease Management** - Disease management in organic fruit and vegetable production relies on a systems approach to succeed, but even with current systems plans in place, growers frequently struggle to manage commonly occurring blights and citrus greening. The NOSB underscores the need for systems research that addresses solutions to these and related diseases that are workable for farmers, that reduces adverse health effects on farmers and fieldworkers, and that also limits adverse effects on the soil and water in which the crops grow. To this end, we call for systems research that identifies disease resistant material while at the same time identifying biological controls that limit the use of copper-based compounds where possible.

Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations, including:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Particular research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control, particularly in pears and apples.

6. **Identify Barriers and Develop Protocols for Organic Nursery Stock Production**
   The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants to make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap? Research centered on development of practical organic methods for the nursery industry to implement is needed, including:
   - Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.
   - New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
   - Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.

7. **Management and Control of Invasive Insects and Weeds** - There is a large pool of research on the control of insects and diseases using organic methods. Many controls use a systems approach and are quite effective. The introduction of new invasive species into cropping systems threatens these systems approaches, and in several cases the organic control options are very limited or nonexistent. For example, spotted wing drosophila is a relatively recent invasive insect that infests soft fruits, such as berries, and many other fruits as well. Infestation renders fruit unusable since insect larvae feed inside the fruit and may reach critical levels before fruit is harvested. This insect is particularly problematic in that it has the ability to oviposit in green fruit, and it has multiple generations throughout the summer, creating an extensive control period. There is only one control material available, and it is in danger of overuse. The control period may also extend so long that maximum label rates are used before the season ends. A second invasive insect is brown marmorated stinkbug, and at this time there are no organic control measures beyond attempts at mass trapping. Research into organic control options for both these invasive pests, and others, is critical so that organic growers can integrate controls into their

organic systems. Prevention is critical. Because invasive insect species lack native predators, the organic community needs more information on their biology in order to implement prevention strategies before they become established and are more difficult to control.

Weeds pose one of the greatest barriers to successful organic crop production. Invasive weeds include exotic species that aggressively displace both crops and native plant species, as well as creeping perennial species (exotic or native) that are difficult to control without repeated, intensive tillage. The NOP standards require certified organic producers to use tillage and cultivation practices that maintain or improve soil conditions. Development of integrated, organic management strategies that effectively control invasive weeds without excessive tillage continues to emerge as a top research priority for organic producers.

8. **Nutritional Value of Organic Crops -** How do organic soil health and fertility practices—crop rotations, cover crops, compost and other organic or natural mineral amendments, etc. — affect the nutritional value or "nutrient density" of organically produced crops? How do organic production and shipping methods (including methods of production, handling, and time in transport) influence the nutritional quality, taste, palatability, and ultimately preference for organic vegetables and fruits? There is a lack of sound, rigorously conducted studies of this kind. How can growers and handlers retain nutrition through post-harvest handling and transportation? Additionally, can providing organic producers information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed examining how organic crops compare to conventional crops with regards to nutritional value.

9. **Side-by-Side Efficacy Comparisons Between National List Allowed and Petitioned Synthetic Inputs Versus Non-synthetic Alternative Inputs or Practices**
   During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions. The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

10. **Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments**
    Vendors of organic amendments now offer a large and growing array of microbial inoculants, organic soil conditioners, and other materials claimed to improve soil health, crop vigor and quality, and combat weeds, pests and diseases. There is an urgent need for impartial evaluation of these materials to help producers decide which products to use and to avoid unnecessary expenditures on products that are unlikely to yield benefits.

11. **Pathogen Prevention** - Third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this hypothesis, more research,

extension, and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

12. **Climate Change** - A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although a number of researchers are examining this issue, additional work is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security.

Handling

1. **Chlorine Materials and Alternatives -** Chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. Chlorine materials are also acutely toxic to workers. New sanitizers and disinfectants are regularly petitioned to the NOSB for addition to the National List. FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply.

   Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

   The organic industry needs better information on how either alternative materials or appropriate chlorine materials are best suited for a specific use and control measure. This is especially important in determining if the industry can move away from the use of chlorine compounds in the future.

   Points of consideration for future research activities:
   - Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
   - Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
   - Determination of which of the above-mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
   - Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chorine is the best material to use.
   - Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
   - Research on the absorption of chlorine by produce from its use in wash tanks, including information about the amount of time of exposure, would help inform understanding of human exposure to chlorine and health risks. Are residues from produce washing a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

2. **Alternatives to Bisphenol A (BPA)** - The Handling subcommittee is examining the issue of whether to prohibit BPA in packaging materials used for organic foods in light of direct evidence that these uses result in human exposures and mounting evidence that these exposures may be harmful. There is a need for increased research about alternatives for the linings of cans and jars used for organic products that do not result in human exposures and health risks.

Materials/GMO

In previous years, the Materials subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014). These issues are currently being addressed through a Genetic Integrity of Seeds Ad Hoc Working Group.

1. **Fate of Genetically Engineered Plant Material in Compost -** What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (bacillus thuringiensis) after composting that would result in persistence in the environment or plant uptake?

2. **Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material -** Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. **Assess the Genetic Integrity of Organic Crops At Risk** - Develop then implement methods of assessing the genetic integrity of crops at risk in order to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. **Prevention of GMO Crop Contamination: Evaluation of effectiveness** - How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows? Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen. Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

5. **Testing for Fraud: Developing and implementing new technologies and practices** New technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope

rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

General

1. **Increasing Access to Organic Foods** - What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing to organic food. Research should be funded that builds on an understanding of constraints by asking what community, market, and policy-based incentives would enhance access to organic foods.

3. **Barriers to Transitioning to Organic Production** - What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

Subcommittee Vote:
Motion to adopt the proposal on 2020 NOSB Research Priorities
Motion by: Dave Mortensen
Seconded by: Emily Oakley
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Dave Mortensen, Materials Subcommittee Chair, to transmit to NOSB August 14, 2020

National Organic Standards Board Materials Subcommittee Proposal
Marine Macroalgae[1] in Crop Fertility Inputs
August 11, 2020

Summary:
This proposal brings forward an annotation to marine macroalgae used as crop fertility inputs to provide parameters on harvesting addressing conservation areas, bottom trawling, protecting reproduction of the population and ecosystem functions, biomass and architecture, and bycatch.

Introduction and Use:
Seaweeds are classified into three broad groups based on pigmentation: brown, red, and green; respectively, *Phaeophyceae*, *Rhodophyceae* and *Chlorophyceae* (TR 2016 lines 103-4), and all three classes are used in organic fertilizers[2]. Seaweeds are also called macro-algae, distinguishing them from micro-algae (*Cyanophyceae*) which are microscopic in size and often unicellular (TR 2016 lines 108-110). Seaweeds used in synthetic aquatic plant extracts and in nonsynthetic products, namely meal, are macroalgae.

Marine macroalgae are used in extracts as foliar fertilizers or as soil conditioners. They also are used as a foliar/soil feed or transplant solution and seed treatment. The material is absorbed into the plant and acts as a growth promoter (TR 2006 lines 63-6). Marine macroalgae is widely used by producers. During the most recent sunset review of aquatic plant extracts, certifiers reported high numbers of growers listing these materials on their Organic System Plans.

Background:
In 2015, the board had a lengthy sunset review, and as part of that process reviewed marine materials in the Handling (seaweeds for human consumption), Crops (aquatic plant extracts for fertilizers), and Livestock (kelp for feed) subcommittees. In the Crops Subcommittee, the majority of initial comments were in favor of keeping aquatic plant extracts on the National List. During the fall public comment period, the Subcommittee identified concern about potential overharvesting. Extensive public comment was received on this issue. At the end of the fall 2015 meeting, the board recommended keeping aquatic plant extracts on the National List; however, the vote was divided. The board consequently prioritized review of this topic and determined that a Technical Evaluation Report (TR) was needed on all the marine plants used in organic production across the Crops, Livestock, and Handling Subcommittees.

The board received the limited scope TR on Marine Plants and Algae in summer 2016. Subsequently, the Handling Subcommittee published a fall 2016 Discussion Document for Marine Algae Listings on the National List. In it, the board stated that “it is within this context of a desire to allow use of marine plants and algae in organic production, while at the same time ensuring long term sustainability, that the marine materials on the National List must be reviewed”. The board solicited public comment on addressing naming conventions as well as developing guidelines for wild harvested seaweeds. As a result, a spring 2017 Proposal on Marine Algae Listings was posted in the Crops Subcommittee, which was virtually identical to a similar proposal in Handling, and it tried to address classification and nomenclature. In the Crops section, a proposal was put forth to limit aquatic plant extracts to those

[1] For the purposes of this proposal, the term “marine macroalgae” is used to refer to marine plants, seaweed, and marine vegetation.

[2] The 2016 TR lists species used in fertilizers and their harvest regions. This list can also be found in on page 3 of the fall 2018 Discussion Document on this topic.

derived from brown macroalgae. Public comment revealed there were numerous products containing red, green, and brown macroalgae. In Handling, significant public comment was received stating stakeholders needed more time to address the classification and nomenclature issues. The Handling Subcommittee re-posted the Discussion Document for the Fall 2017 but received no significant additional public comment.

The work agenda item was moved to the Materials Subcommittee, and the board explored new approaches to addressing concerns about environmental impact. The Materials Subcommittee posted a fall 2018 Discussion Document proposing that all marine macroalgal ingredients used in organic crop production be certified organic. The spring and fall 2019 Discussion Document solicited comments on the question of organic certification or an annotation specifying harvest methods. To further explore this complex topic, the board convened an expert Panel on Marine Materials used in crop inputs at the fall 2019 meeting.

The goal of the board's work on this topic is to take a precautionary approach to ensuring that both synthetic and nonsynthetic forms of marine macroalgae used in fertilizers are not "harmful to ... the environment" by adversely impacting the ecosystem provisioning of the marine environment.

Relevant Areas of the Rule, NOP Guidance, NOP Policy Memo, and NOSB Policy and Procedures Manual:

OFPA Section 6517 [National List] (c) [Guidelines for Exemptions or Prohibitions] (1)(a)(i) and (2)(a)(i) which allows for the prohibition of synthetic or nonsynthetic substances, respectively, that would be "harmful to ... the environment."

§205.2 Terms defined.
Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

§205.601 Synthetic substances allowed for use in organic crop production.
In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided that, use of such substances does not contribute to contamination of crops, soil, or water...
(j) As plant or soil amendments.
(1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction.

§205.207 Wild-crop harvesting practice standard.
(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance as set forth in §205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.
(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§205.200 General.
Production practices … must maintain or improve the natural resources of the operation, including soil and water quality.

7 U.S.C. 6518 National Organic Standards Board, 6518 (b) Board composition, (4) three shall be individuals with expertise in areas of environmental protection and resource conservation; (6) one shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry.

NOP 5022, effective July 22, 2011, Guidance: Wild Crop Harvesting provides details to clarify §205.207, including:
Section 205.200 states that production practices must maintain or improve the natural resources of an operation under organic certification. This applies to all types of organic certification, including wild crops. Unmanaged, untrained and uninformed harvesting of wild products from a wild habitat without maintaining or improving the natural resources can disqualify the wild products from organic certification.
Additionally, the Guidance states:

1. A description of the proposed ecosystem management and harvesting practices, the impact of their proposed harvesting on the long-term viability of the wild species and on the area's ecosystem, and information on any equipment planned for use or being used to harvest and manage the wild-crop and ecosystem.
    a. This should include a description of the monitoring system that will be used to ensure that the crop is harvested in a sustainable manner that does not damage the environment, including soil and water quality.
2. A list of any rare, threatened, or endangered terrestrial or aquatic plants or animals that occur in the harvest area.
    a. The presence of rare, threatened, or endangered species in a wild harvest area does not automatically disqualify an operation from organic certification, but any potential or actual impacts need to be described and addressed.
    b. If there are potential or actual negative impacts resulting from the wild crop management and harvesting, actions that address and correct these impacts need to be described, implemented, and monitored.
3. The procedures employed that prevent contamination from adjoining land use or other point or non-point sources contamination.
4. The training provided and the procedures employed to ensure that all collectors harvest crops in accordance with the OSP and in a manner that does not damage the environment.

NOP 5020, effective 1/15/16, Guidance: Natural Resources and Biodiversity Conservation clarifies organic regulations at 7 CFR 205.200 that states, "to maintain or improve the natural resources of the operation….".

NOP Policy Memo 12-1, Production and Certification of Aquatic Plants, issued September 12, 2012 provides further clarification as follows:
This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List of Allowed and Prohibited Substances at 7 Code of Federal Regulations (CFR) 205.601-205.602, as the basis for the production and certification of cultured and wild crop harvested aquatic plants.

While current USDA organic regulations specifically exclude aquatic animals from organic certification, no such exclusion exists for aquatic plants. Further, some parts of the USDA organic regulations specifically address aquatic plant production. For example, some aquatic plants, such as kelps and seaweeds, are listed in 7 CFR 205.606 of the USDA organic regulations, allowing their use in non-organic form when certified organic forms are not commercially available. Producers and certifiers are required to comply with the USDA organic regulations when producing or certifying cultured and wild crop harvested aquatic plants.

The use of ground and surface waters, ponds, streams, or other waterways for aquatic plant production may be regulated by Federal, State, or local authorities. Aquatic plant producers should consult with Federal, State, and local authorities to ensure compliance with all applicable laws, in addition to the USDA organic regulations, regarding the use of synthetic substances and other materials in ponds and waterways. Also, under 7 CFR 205.200, aquatic plant producers must ensure, and certifying agents must verify, that production practices maintain or improve the natural resources of the operation, including soil and water quality.

NOSB Policy and Procedures Manual, Principles of Organic Agriculture Organic agriculture, adopted 2001, 1.1 states: Organic agriculture…is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity.

Public Comments:
Public comments over the past several years have been diverse on this topic and range from support for organic certification as an appropriate tool to address environmental impacts of harvesting, to caution against setting a precedent of certifying an input ingredient, to concerns that certification could amount to greenwashing by inadequately addressing environmental impact, to sentiments that the industry does not need further regulation. A broad review of public comments can be found in the earlier discussion documents referenced above.

The 2019 spring and fall discussion document asked stakeholders to provide feedback on the possibility of requiring organic certification for marine macroalgae input ingredients, presented standards from other certifiers and third-party entities certifying sustainable seaweed, solicited numbers of crop input products approved for use that currently contain certified organic marine algae ingredients, and inquired if farmed algae is used in any products. Public comments covered all questioned posed.

Although several certifiers were skeptical about the ability to certify wild aquatic systems, it was also noted that this is already being done for handling and livestock uses of marine macroalgae. Importantly, material review organizations reported that there are some crop fertilizer products now that formulate with certified organic marine macroalgal ingredients. Farmed algae do not appear to be used, likely given the high cost of seaweed aquaculture compared with the large volumes of material needed for fertilizers[3].

While some worried about increased scrutiny of additional nonsynthetic inputs, others said some natural inputs likely deserve more scrutiny for their environmental impact. Opposition to requiring organic certification was centered on precedent setting and the inconsistency of requiring certification for one type of input but not others (though there were also some who felt marine macroalgae should not be certified organic as its harvest can never meet the standard of not destructive to the

[3] Theuerkauf *et al*. discuss the potential of seaweed aquaculture to mitigate seagrass beds and kelp forests losses globally as a result of overharvesting and other human activities (2019). See Buschmann *et al*. on the prospects of seaweed cultivation to alleviate increasing harvest pressure, particularly of *Macrocystis pyrifera* (2014).

environment). One commenter supporting certification as a tool stated that if organic certification is important for food, the organic community should also see it as viable for inputs. They noted, “we do not believe that requiring organic certification of marine material inputs would create the universal expectation that all crop inputs, such as manure and mulches, be certified organic”. Another commenter shared that “sourcing of inputs, including those from natural resources, can have significant impact on the sustainability of agricultural systems, and NOSB is responsible for making recommendations for inputs on the National List that would not harm the environment”.

Some public comment supported using annotations to the National List and definitions as the best means for developing clear standards rather than requiring certification. NOP guidance would provide additional information on implementation, as well as training areas for inspectors. It was felt that an annotation could specify parameters for harvesting and would be more enforceable than attempting to establish such parameters through guidance complementing an organic certification requirement. A material review organization said they could hire staff capable of reviewing an annotation and conducting on-site inspections.

One public commenter and marine biologist proposed “some key aspects to be considered within the definition of ‘not destructive to the environment’: a) the amount that can be harvested from an area; b) the method and timing of harvest; c) the impact of the harvest on the structure and reproduction of the plants themselves; d) the consequences of the changes in the canopy for other species; e) the direct removal of non-target species (by-catch); and the ability of the ecosystem to f) remain resilient in the face of many challenges (climate change, invasive species) and g) maintain essential functions and services”. Another marine scientist emphasized the need to focus on the habitat marine macroalgae provide when considering the effects of harvesting.

Some stakeholders suggested prohibiting specific species, regions, or harvest methods might be an option. Some felt government regulations are adequate, though it was acknowledged that they do not typically involve on-site verification and enforcement varies. One stakeholder suggested that more information is needed about existing legal frameworks in countries where most marine macroalgae used in fertilizers is harvested.

The board particularly requested industry participation and heard from a number of harvesters in the fall 2019 public comments. Several harvesters stated that the harvest of rockweed, for example, is well regulated and does not negatively impact the marine environment. One harvester explained that they follow biomass assessments, closed areas, minimum cutting heights, and periodic auditing. They indicated that if the wild crop standards for organic certification as applied to marine macroalgae feed for livestock remained the same for certification of macroalgae for fertilizer products, they would support organic certification. Another harvester said that while not against organic certification, they prefer applying the commercial availability clause instead. One harvester and processor stated that annual regrowth of the seaweed extracted exceeds the amount harvested. A company based in Ireland explained its compliance process with each of its harvesters, which includes hand harvesting to preserve “the balance of the ecosystem without damaging environmental issues that could arise from this activity”.

An industry task force was developed by one association to foster discussion around this topic. There was a request for more documentation of the need for monitoring harvests to avoid environmental impact. In addition, the stakeholder said that more information on global harvesting rates is needed. As noted by the Food and Agriculture Organization, “About 25 million tonnes of seaweeds and other algae are harvested annually for use as food, in cosmetics and fertilizers, and are processed to extract thickening agents or used as an additive to animal feed." Unfortunately, accurate global harvest rates for marine macroalgae across all uses is difficult to obtain. Equally, information on the impact of harvests for fertilizers is unavailable on a global level (see the review of the scientific literature below for more information).

One public commenter provided a comprehensive overview of all marine materials used in organic production across macroalgal and fish uses in Crops, Livestock, and Handling. Although some public comment suggested we look at all marine uses across all subcommittees under one work agenda item, there are practical limitations that make that challenging. Significant differences exist between fish and marine macroalgae and between Handling and Livestock uses. Each marine material on the National List represents a discreet use that warrants individual attention. If the work agenda item were too large, it might preclude meaningful progress.

Stakeholders asked the board to create standards that cover existing certified organic marine macroalgal materials. Some were concerned that the board not create a higher standard for crop fertility uses of marine macroalgae than for human consumption and livestock feed. Alternatively, it could be argued that most seaweeds used in organic handling and all used in organic animal agriculture receive some measure of oversight and protection through their certification to the wild crop standard. The inconsistency lies in using the same, unverified input in fertilizers that is certified organic in handling and livestock uses. Additionally, the wild crop standard is necessarily general to cover the wide range of crops it can include. But in its generality, it does not give guidelines for how the standard operates in complex marine environments. As one commenter said, the existing wild crop standards "are very limited" and "do not provide sufficient metrics for certifiers". Given the complexity of this topic, this proposal is intended as a first step, with subsequent explorations of marine macroalgae uses in Handling and Livestock. Annotations for Handling and Livestock uses will be the next area the Materials Subcommittee investigates.

In conclusion, one harvester of certified organic kelp meal noted "agriculture by its very nature causes environmental harm, even organic agriculture disrupts the natural succession of the ecosystem". Organic agriculture is founded on practices intended to minimize its environmental impact and harm. The commitment organic farmers demonstrate to soil and water conservation, fostering biodiversity, and limiting negative impacts of synthetic chemicals through a host of practices relates to a desire by many to source inputs reflecting similar values.

Discussion:

Review of the Literature

A review of the literature on the environmental impact of commercial seaweed harvesting varies in its findings. The 2016 TR raised concerns about the potential for negative environmental impacts on marine ecosystems from macroalgal harvesting. Some examples noted in the 2016 TR were specific to species used in organic crop fertility inputs and aquatic plant extracts. For example, in mechanical harvesting in Iceland, as with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (TR 2016 lines 892-6). The cited paper states "industrial harvesting of the seaweed *Ascophyllum nodosum* in the Bay of Breioafjorour inevitably leads to the death of huge numbers of invertebrates, including species that are important food for birds" (Ingolfsson 2010). In

Nova Scotia, commercial yields of rockweed are maintained. A comprehensive assessment of impacts performed by industry or third-party research proving harvest rates are not detrimental to the rockweed marine community is lacking. Estimated recovery times based on percentages of rockweed removed vary between publications (TR 2016 lines 597-600). Additionally:

> There is one species of red algae and two species of brown algae growing along the coasts of the United States that have gained attention as ecologically threatened in recent years. They are respectively, Irish moss (*Chondrus crispus*), rockweed (*Ascophyllum nodosum*) and giant kelp (*Macrocystis pyrifera*). These plants are economically important and drive several seaweed industries including cosmetic products, nutraceuticals, fertilizers and hydrocolloids. Fertilizer applications are similar to farmyard manure, but may also include extracts and foliar applications (Chojnacka, 2012).
>
> Kelp and rockweed, are foundational species forming large expansive marine habitats supporting a diverse range of wildlife, including other algal species, marine animals and many species of protozoans and bacteria (Seeley and Schlesinger, 2012). Without a good accounting of all of the species present it is hard to predict the effects of harvesting rockweed and kelp on each ecological niche. Thus, it has been important to recognize that sustainable seaweed production perceived as reproducible harvest capacity, may not guarantee the sustained subsistence of each resident species. Although not part of any agricultural waste stream, extracts from wild-harvested kelp and rockweed are allowed for use in organic production as soil amendments (§205.601(j)(1)). [TR 2016 lines 522-535].

Even within the 2016 TR, differences of opinion about the environmental impacts of harvesting were noted within the scientific community. For example:

> One study addressing the major components of the resident fish community in the rocky intertidal zone after rockweed harvest found no evidence linking rockweed harvest to changes in the ichthyoplankton component or the juvenile and adult fish of that community (van Guelpen and Pohle, 2014). In a summarized review of selected work, a researcher at the University of Maine also concluded that the effect of 17% rockweed harvest on some species including seabirds was negligible (Beal, 2015). [TR lines 326-31]

The TR goes on to explain that:

> Notwithstanding, rockweed has an important role as habitat, as food and as a nutrient source supporting a community of organisms that inhabit its "forests." Any cutting of rockweed can produce an effect on the supported eco-communities. Furthermore, many aspects of this ecosystem have not been elucidated, encouraging more precaution as the brown algae "forestry" industry grows into the future (Seeley and Schlesinger, 2012). [TR lines 356-60]

Since 2016, the board has received numerous public comments by marine macroalgae experts and other stakeholders, and these have included myriad references to the academic literature. A reading of the comments and their citations reveals the many views on the environmental impacts of harvesting marine macroalgae. Nevertheless, it cannot be said that removing a wild native species from a wild native ecosystem, as in the case of commercial marine macroalgal harvests, has no impact on the environment. As explained above, the extent to which harvesting causes negative environmental impacts is contested within the literature[4]. There are certainly papers that will state views counter to those cited below, and interestingly, the same papers are quoted to support competing claims[5]. It is not the goal of this proposal to argue over whose science is right.

The literature review on the environmental impacts of harvesting is not intended to suggest that effects cannot be at least partially mitigated or that harvesting should not occur. Rather, the information was requested in public comments, and it is presented to demonstrate the complexity of the issue and to address claims made in some public comments that harvesting has little effect on the environment. While it is not possible to provide a comprehensive analysis of peer-reviewed research here and there are numerous other articles that could have been cited, the following review of the scientific literature provides the technical data to support this proposal.

"Canopy-forming seaweeds, including kelps, rockweeds and many red seaweeds are widely acknowledged as foundation species that form important three-dimensional structure in marine coastal environments which contribute important functions and services" (Lotze *et al*. 2019). These include primary and secondary production, production of detritus, nutrient cycling, carbon storage, nutrient retention, provision of food for biodiversity, biological links between marine ecosystems, habitat for year-round residents, foraging grounds, breeding and nursery areas, refugia from predators, coastal buffers from waves and storms, and filters for runoff (Ibid). "Despite the ecological importance of seaweed canopies and their long history of harvesting, relatively few studies have directly examined the effects of harvesting beyond the resource species itself on ecosystem structure, functions and services" (Ibid). The authors conclude that:

> harvesting canopy-forming seaweeds affects the morphology, canopy structure, standing stock and species composition of the foundation species which in turn affects their ecological roles in marine ecosystems (Table 2). The magnitude and range of ecosystem impacts depend on the species being harvested, the harvest methods employed, the intensity of biomass removal and its spatial and temporal extent (Supplementary Text S2 and Table S2.1). The broader ecosystem effects further depend on the recovery of seaweed fronds and regeneration of seaweed canopies after harvesting, and the ability of associated flora and fauna to recolonize and reorganize associated communities. (Ibid)

Schmidt et al.'s (2011) study of ecosystem services of eelgrass and rockweed found that:

> marine vegetation provides important habitat, nitrogen, and carbon storage services, yet the extent of these services depends on the foundation species and its architecture. Changes in canopy structure will therefore have profound effects on associated food webs and ecosystem services. Thus, as increasing human pressures on coastal ecosystems threaten the continued supply of essential functions and services, the protection of marine vegetated habitats should be a management priority.

Mac Monagail *et al.* (2017) offer a comprehensive analysis of the environmental impacts of marine macroalgal harvesting, including the effects of over-exploitation on biomass and coastal habitats. They state, "as is the case with the use of all natural resources, the wild harvest of seaweeds inevitably has ecological implications for the species targeted, and the associated

[4] For example, Phillippi *et al*.'s (2014) study indicates potential beneficial impacts of *Ascophyllum nodosum* harvesting on invasive crabs. The paper acknowledges that "human utilization of any natural resource involves ecological implications not only for the species harvested, but for its associated community as well" (Ibid).

[5] See for example Sharp and Pringle 1990, Sharp *et al*. 2006, Ugarte 2010, and Ugarte and Sharp 2001, among others.

community of flora and fauna, leading to varying degrees of change" (Ibid). Additionally, "Poorly managing resources, such as opportunistic harvesting, excessive removal of holdfast material (reducing regeneration), trampling and enhanced grazing by herbivores all place additional stresses on the resource, while near denudation of a seaweed bed is perhaps the most extreme case of direct impact on the community (Ibid)". The authors point out that sustainable harvesting practices are possible and collaborations between scientists and harvesters have led to the development of best practices in some places.

The impacts of hand versus mechanical harvesting are contested, but mechanization increases the amount of biomass removal in the same amount of time. In Ireland, review of potential mechanization cautioned that it is "essential to develop a suitable management scheme to ensure sustainable exploitation of natural resources and continuous integrity of marine habitats" (Werner and Kraan 2004). In a separate study in Ireland, even traditional hand harvesting resulted in a difference in cover of associated algal species following the removal of the target species (Kelly *et al.* 2001). Additionally, there were seasonal differences in "the abundance of periwinkle *Littorina obtusata* in hand harvesting (Ibid). Krumhansl *et a*l. (2017) found that small-scale, "artisanal" harvesting of *Macrocystis pyrifera* in the Pacific Northwest had a minimal impact on kelp recovery rates. Lotze *et al.* (2019) note:

> Any harvesting method will affect the extent and three-dimensional structure of a seaweed canopy, but the magnitude and range of consequences will depend on the gear type, the harvest intensity and scale, and the cutting methods applied. While mechanical clear-cutting or trawling will remove most of the canopy with years to decades needed for recovery, even lower level hand-harvesting changes canopy structure through a truncation of larger, older and more voluminous fronds… Cutting height plays a crucial role in frond regrowth, such as for perennial rockweed, and repeated cutting can change the branching, size, and density of seaweed fronds. Such changes in the amount and structure of the seaweed canopy will affect the quantity and quality of habitat provision and community organization".

Calculations of the ecological effects of kelp trawling in Norway

> show that kelp trawling reduces primary and secondary production substantially within the kelp trawled tracks. Primary production is reduced with 45 % and secondary production with 70 to 98 %... Observations indicate that diversity of flora and fauna will be reduced within the trawled area. The diversity will probably not recover until the mean age of the plants reach the mean age of the large kelp plants in untrawled kelp forest. Mean age increases with increasing latitude and is about 7 years in mid-Norway, where the kelp forest has optimal growth conditions and is well developed. With a trawling interval of 5 years, the kelp forest within mid-Norway will not be recovered with respect to species diversity until next trawling. (Rinde *et al*. 2006)

In a study of biomass and productivity of intertidal rockweed, Vadas *et al*. (2004) found significant variation in the length of apical tip growth, estimates of standing crop weight, and annual productivity estimates. Another study measuring the effects of fucoid bioengineer species on the understory along intertidal elevation gradients in Atlantic Canada found "a combined experimental and mensurative approach shows that the same bioengineer species affect overall species richness, diversity, and composition differently along a stress gradient" (Watt and Scrosati 2013). Specifically, they discovered that "bioengineer canopies have different effects on understory communities depending on intertidal elevation", and this is significant to conservation efforts since "the loss of bioengineers is a concern because these organisms often have wide-ranging and cascading effects" (Ibid). Therefore, "biologists need to consider not only whether bioengineers are present, but also the abundance required to elicit positive changes in communities" (Ibid).

One review of the ecological impact of harvesting in the northwest Atlantic concluded that "long-term harvesting has altered the population structure and population ecology of *C. crispus* and *A. nodosum* in some areas" but went on to state that "both target species and associated communities are resistant to perturbation" (Sharp and Pringle 1990). Foster and Barilotti (1990) emphasize "the need for considering the potential effects of seaweed harvesting at both the population and community level, and the utility of approaching these effects in a comprehensive manner". They explain that considering the harvest type, procedures, and ecological effects on the target population, community, and ecosystem are essential for maintaining harvestable marine macroalgal resources. In an experimental study of the ecological effects of harvesting kelp in Chile (in this case for alginates), the researchers concluded there were significant impacts on both the harvested and related species:

> Experimental studies of *Lessonia nigrescens* and *L. trabeculata* have revealed several ecological effects of harvesting that ought to be considered when managing wild stocks of these species. In both kelps, the removal of the upper canopy eventually leads to death of the plants. The invertebrate fauna does not abandon the holdfast of pruned *L. nigrescens*. Therefore, both partial and complete plant removal has similar mortality consequences for the kelp and for the invertebrate fauna associated with the kelp.
>
> The most important population effects of removal are the increments in inter-plant distances and the resulting increasing access of grazers to the kelp holdfast and to inter-holdfast surfaces. Increased grazing reduces recruitment of both *Lessonia* species and modifies the morphology of *L. trabeculata*, rendering individuals of the latter species more susceptible to being removed by water movement. (Vasquez and Santelices 1990)

In a review of global kelp forests, Wernberg *et al*. (2019) state that "kelp species show global declines and, like so many other marine ecosystems, they are under pressure from direct and indirect anthropogenic activities". These include climate change (warming waters, acidification, and increased storm activity), fishing (when urchin predators decline due to fishing, urchins increase grazing on kelp), and direct harvesting of kelp. However, when species-specific biology is understood and respected, sustainable harvests are possible (Ibid). In another global review of kelp forest change, Krumhansl *et al*. (2016) note that "kelp harvesting accounted for recent kelp declines in Central and Northern Chile despite a regional cooling trend".

Sharp *et al*. (2006) explain that "harvesting can affect the structure of these marine plant habitats by changing branching structure, canopy height, distribution of biomass and overall density of plants and fronds". Vasquez (1995) states that "if the disturbance (e.g. harvest) is strong enough, changes occur in the abundance of harvested and/or associated species, and in availability of some resources (e.g. space and light)".

Boaden and String's (1980) study abstract in Northern Ireland provides a quantitative overview of ecosystem effects of harvesting *Ascophyllum nodosum*, though it must be noted that the study cut rockweed "within 10-15 cm of the base, rather shorter than normal harvesting practice":

> In 1976 an attempt to establish harvesting in Strangford Lough, Northern Ireland, was opposed on mainly theoretical conservation grounds. The attempt began and stopped within a single small bay leaving a sharp boundary between cut and uncut areas. A subjective survey apparently confirmed the predicted loss of cryptic fauna, decline through predation and the resorting of interboulder sediment. In April 1979 the cut and uncut areas were examined in detail to determine whether any of these effects had persisted and were demonstrable scientifically. Beach and boulder transects and various other studies showed some increases in the cut area.

There was significantly more *Fucus*, *Enteromorpha* and *Ulva*; *Cirratulus* (inhabiting *Rhodochorton*-bound sediment on boulder surfaces) had a greater biomass. Some changes in *Littorina* colour morphs were apparent. Sediment in the cut area was coarser and had significantly more crustacean meiofauna. *Ascophyllum* internodal length and lateral branching were increased but it still provided 20 % less shore cover than in the uncut area. There were significant decreases in the cover of *Cladophora* on the sides of boulders and of *Halichondria*, *Hymeniacodon* and *Balanus* on undersurfaces. Indeed on the habitable underside of boulders total animal cover had been reduced by nearly two-thirds and the average number of species per boulder by one-third. It is concluded that *Ascophyllum* harvesting has a significant and persistent effect on shore ecology. Littoral algae are a valuable commercial asset, but it is important that some fairly large intertidal areas should be left unharvested for general conservation purposes.

Defining overharvesting is potentially subjective, yet the consequences are not. "Over-harvesting can lead to a reduced density of seaweed thalli, skewing the population mix and increasing impurities (i.e. other, unwanted seaweed species) in the harvested seaweed loads" (Mac Monagail *et al*. 2017). "In Atlantic Canada, a shift from Irish moss to coralline algae has been observed multiple times over past decades due to overharvesting and did not easily or rapidly reverse" (Lotze *et al*. 2019). Some stakeholders have noted a "tragedy of the commons" associated with harvest areas. In Chile, research on the effects of fishing pressure found that Territorial User Rights for Fisheries "areas could be important ancillary conservation instruments in kelp forest ecosystems, if key processes of the subtidal community assemblages (e.g., interactions between grazers and reef fish) are maintained" (Pérez-Matus 2017).

An example of differing views on the harvesting *Ascophyllum nodosum* causing a deficit of detritus and the response reiterating the finding can be found in Garbary *et al*. (2017). The authors affirm that harvesting creates a "'missing' biomass … primarily in the form of detritus never produced because of the nature and timing of the harvest" and state their original paper underestimated the deficit (Ibid). Ugarte and Sharp (2012) assert that the consistent yields of *Ascophyllum nodosum* is "is proof of good management practices and an ecologically sustainable harvest in the Canadian Maritimes". However, Halat *et al*. (2015)state that while previous research demonstrates the regeneration of *Ascophyllum nodosum*, it "does not address wider ecological issues associated with overall environmental impact". Detrital deficits in *Ascophyllum nodosum* could be of concern due to "the role of the 'missing' detritus that should be serving coastal fertility in the form of dissolved and particulate nutrients for both planktonic and benthic organisms from primary producers through to detritivores" (Ibid). "This detritus is typically released through epidermal shedding, and if not consumed by herbivores or microbes before reaching the upper intertidal zone, it contributes to coastal, terrestrial fertility" (Mac Monagail *et al*. 2017). For kelp, Krumhansl and Scheibling (2012) found that:

Detritus settles within kelp beds or forests and is exported to neighboring or distant habitats, including sandy beaches, rocky intertidal shores, rocky and sedimentary subtidal areas, and the deep sea. Exported kelp detritus can provide a significant resource subsidy and enhance secondary production in these communities ranging from tens of meters to hundreds of kilometers from the source of production. Loss of kelp biomass is occurring worldwide through the combined effects of climate change, pollution, fishing, and harvesting of kelp, which can depress rates of detrital production and subsidy to adjacent communities, with large-scale consequences for productivity.

A study measuring the biomass removal of *Ascophyllum nodosum* found that natural storm occurrences removed a significantly higher percentage of holdfast material than commercial harvestings (Ugarte 2010); however, this point (one made frequently in public comments) must bear in mind that storms are a natural part of the ecosystem whereas harvesting and removal of the species from the ecosystem is not. As the same paper notes, "environmental concerns will continue influencing marine resource management in Canada, especially when the harvested resource is also a habitat" (Ibid). Any amount of harvesting will have some ecological impacts, and in Nova Scotia "because Rockweed harvesting disturbs habitat through alteration of the canopy structure and has high levels of bycatch, unharvested Rockweed beds, which are likely more common on the Eastern Shore, have a substantially higher habitat value than those that are harvested" (Jeffery *et al*. 2020).

In a three-year study in Norway, the multitrophic effects of kelp harvesting were investigated by Lorensten *et al*. (2010):

> Coastal kelp forest ecosystems provide important habitats for a diverse assemblage of invertebrates, fish and marine top-predators such as seabirds and sea mammals. Although kelp is harvested industrially on a worldwide scale little is known about the multi-trophic consequences of this habitat removal. We investigated how kelp fisheries, which remove feeding and nursery grounds of coastal fish, influence local food webs and the availability of food to a marine top predator, the great cormorant (*Phalacrocorax carbo*). We conducted experimental harvesting of the canopy-forming kelp (*Laminaria hyperborea*) during a 3 year period (2001–2003) in an area at the coast of Central Norway while synoptically monitoring fish occurrence and cormorant foraging parameters. Our results demonstrate that cormorants preferentially foraged within kelp-forested areas and performed significantly more dives when feeding in harvested versus un-harvested areas suggesting lower foraging yield in the former case. In kelp areas that were newly harvested the number of small (<15 cm) gadid fish was 92% lower than in un-harvested areas. This effect was persistent for at least 1 year following harvest. To our knowledge, this is the first time that the ecological consequences of kelp harvesting have been tested at a multi-trophic level. The results presented strongly suggest that kelp harvesting affects fish abundance and diminishes coastal seabird foraging efficiency. Kelp fisheries are currently managed in order to maximize the net harvest of kelp biomass, and the underlying effects on the ecosystems are partly ignored. This study calls for re-assessment of such management practices.

In a twenty-year study of *Ascophyllum nodosum* in Iceland, Ingólfsson and Hawkins (2008) concluded that full canopy recovery after harvest took seven to eight years, but community recovery could take as much as twenty years. When *Ascophyllum nodosum* was removed but understory algae species were left undisturbed, some of those species died and did not return to the study sites (Ibid). In the southwest English Channel, Migne *et al*. (2014) found that while "the number of species [and] their distribution among trophic groups" was unaffected by canopy removal of *Fucus serratus* "and the algal community was only slightly affected", the "abundance and biomass of mobile invertebrates … were greatly reduced in the absence of canopy".

The importance of harvesting method is underscored in Waage-Nielsen *et al*. (2003) whose study showed that leaving kelp holdfasts was significant to associated kelp fauna. "The remaining holdfasts were the best refugia or alternative habitat in this study, as they contained a fauna very similar in composition to the fauna associated with the natural kelp plants" (Ibid). Alternative harvesting methods for *Ecklonia maxima* in South Africa, in which only the fronds were cut rather than the whole plant, "shows considerable promise in that the required commercial yield can be achieved from much smaller areas than if whole plants are harvested" as plants remain living and recover more quickly (Levitt *et al*. 2002). Nevertheless, "the possible effects of disturbance on the benthos, together with the short lifespan of suspended kelp zoospores …, may negatively affect *Ecklonia* recruitment, particularly if it is strongly episodic" (Ibid). In their study of the effects of commercial harvesting of *Fucus serratus*, *Palmaria palmata*, and *Porphyra* on ecosystem biodiversity and functioning, Stagnol *et al*. (2016) found that the hand harvesting methods employed had the greatest impact "on the diversity of the animal community and the metabolism of the studied area", largely due to the opportunistic settlement of *Ulva* spp. (2013). Steen *at al*. examined kelp regrowth after harvesting in Norway and found that the target species "had regained its dominance at the harvested sites, however, plant age, sizes and epiphytes were still below pre-harvesting levels". While *Laminaria hyperborean* biomass recovered after four years, this was due to high density of the recovering kelp vegetation; "the density of understory kelp recruits 4 years after harvesting was significantly lower than it had been prior to harvesting, and this may lead to a slower recovery if future harvests occur before the stocks of understory kelp recruits are restored" (Ibid). In their research of the impact of harvesting on canopy-forming macroalgae, Stagnol *et al*. (2016)

> found that patterns of recovery following the harvesting disturbance were variable and matrix specific, suggesting that local factors and surrounding habitat characteristics mediated the influence of harvesting. The greatest and longest effects of harvesting were observed for the targeted species that created a dominant and monospecific canopy on their site prior to the disturbance. Another relevant finding was the important natural spatiotemporal variability of macrobenthic assemblages associated with canopy-forming species, which raises concern about the ability to discriminate the natural variability from the disturbance impact.

Although certain countries have developed marine macroalgae management plans and regulations, others have not (Rebours *et al.* 2014). As harvesting:

> increases, there is also an urgent need to develop and implement ecosystem-based management models and integrated coastal zone planning. Policy makers must develop regulations and directives that enable a sustainable exploitation of the natural resource, not only to preserve marine and coastal ecosystems but also to ensure social stability and economic income of local communities (Ibid).

Lotze *et al.* (2019) "outline potential ecosystem-based management approaches that would help sustain productive and diverse seaweed-based ecosystems" for harvesting. They specify areas reflected below in this proposal, including "maintaining high canopy biomass, recovery potential, habitat structure and connectivity, limiting bycatch and discards, while incorporating seasonal closures and harvest-exclusion zones into spatial management plans" (Ibid). Stagnol *et al*. (2016) note their "results support the need to implement ecosystem-based management, assessing both the habitat conditions and ecological roles of targeted commercial species, in order to insure the sustainability of the resource". In the case of *Ascophyllum nodosum*, Seeley and Schlesinger (2012) state "besides setting the removal rate at the right level, other critical parameters that need to be considered in defining an ecologically sustainable harvest include recovery of preharvest rockweed morphology, rockweed bed structure, rockweed community structure and function, and ecosystem function". Similarly, in another study of *Ascophyllum nodosum*, Kay *et al*. (2015) found that "plant and canopy structure, including length, circumference and density, were much better predictors of associated community structure than rockweed biomass, which is often used for single-species monitoring".

The precautionary approach is not new to marine macroalgae harvesting and was used to development a management strategy for in Atlantic Canada following public concern over negative impacts of exploitation of marine resources and in recognition of its habitat function for invertebrate and vertebrates (Ugarte and Sharp 2001). Similarly, "the European Union has defined an organic label for macroalgae, which implies that the commercial harvest of algae shall not cause a significant impact on ecosystems" (Stagnol *et al*. 2013). In the absence of adequate baseline measures of existing macroalgal stands, "robust and precautionary management measures should be adopted" (Lotze *et al*. 2019).

<u>Regulatory Oversight</u>

"The current wild seaweed harvesting methods, regulations and management regimes vary widely across species and countries" (Lotze *et al*. 2019). Government regulatory agencies acknowledge the environmental impact of seaweed harvesting through various restrictions. For example, in Nova Scotia, the Rock Weed Harvesting Regulations of the Fisheries and Coastal Resources Act describe permitted harvest areas, allowable harvesting methods and quotas, leases, and record-keeping. Specifically, the "Harvest Manner" specifies harvest cannot interfere with re-growth, cannot harvest "in such a way that representative harvest samples contain more than 15% holdfast by weight", and must leave an upright shoot with "an absolute minimum length of 127 mm (5 in.) above the holdfast in non-leased areas" or as indicated in the lease management plan (Rock Weed Harvesting Regulations 1996)[6]. In Maine, a Fishery Management Plan for Rockweed makes recommendations for minimum cutting height, designated no-harvest areas, and harvester training (Maine Department of Marine Resources 2014); however, the plan has not been enacted to date. Washington Department of Natural Resources is responsible for marine macroalgae harvests, where harvest for sale or barter is not allowed on public or private land; in other words, the commercial harvesting of macroalgae is prohibited. Rules for hand harvesting, daily per person weight limits, and cutting heights are listed. Harvest of kelp and other marine macroalgae are regulated by the California Department of Fish and Wildlife and require a license. Regulations designate 87 kelp beds, some of which are open to all harvesters, some are available for lease, and some are closed. Eelgrass and surfgrass are prohibited from harvest. Harvesting is prohibited in state marine reserves and state marine parks. Regulations stipulate that harvesters "may not cut attached kelp at a depth greater than four feet below the surface of the water at the time of cutting", and that the kelp harvest plan must identify how harvesters will avoid "1. repetitive harvest from individual giant kelp plants; 2. harvest of bull kelp from those portions of kelp beds that contain both giant kelp and bull kelp; and 3. harvest of giant kelp near sea otter rafting sites used by female sea otters with dependent pups" (CDFW 2014).

In Scotland, "licensing of wild harvesting activities … provides a means to manage negative environmental impacts" (Scottish Government 2016). The absence of accurate assessments of marine macroalgae biomass can impede efforts to determine harvest volumes that would have limited environmental impact. "To our knowledge, there are no recent estimates of the wild seaweed standing stock of the UK nor of the potential stock that could be sustainably harvested" (Capuzzo and McKie 2016). Similarly, "very little research has been carried out in Northern Ireland on the direct and indirect effects of harvesting on biodiversity and coastal processes" (Environment and Heritage Service 2007). There is a "lack of specific information on the carrying capacity of marine ecosystems to support seaweed harvesting and mariculture" (Ibid).

[6] Some of these provisions, such as minimum cutting height and holdfast content for *Ascophyllum nodosum*, have been noted as potentially inadequate to protect not only regeneration of the target species, but also to mitigate ecosystem-wide effects of harvesting. "An overharvest of Ascophyllum could lead to an undesirable level of habitat loss at a landscape scale. This is an important perspective which has not been stressed in earlier assessments of the Ascophyllum harvest in Nova Scotia." (Vandermeulen 2013)

In Norway, regulations state that "importance shall be attached to the following in the management of wild living marine resources and genetic material derived from them: a) a precautionary approach, in accordance with international agreements and guidelines, b) an ecosystem approach that takes into account habitats and biodiversity, and c) effective control of harvesting and other forms of utilisation of resources" among other factors (Marine Resources Act 2008). The Act states in Section 16 The Conduct of Harvesting Operations:

> All harvesting and other utilisation of wild living marine resources shall be carried out as in such a way as to minimize impact.
>
> The Ministry may adopt regulations on the conduct of harvesting operations, including provisions on the following:
>
> a) the periods when harvesting is permitted and times for departure from port,
>
> b) the number of vessels from different vessel groups that may harvest at the same time in an area,
>
> c) prohibition of harvesting in certain areas, of certain species or using certain types of gear,
>
> d) the design, marking, use and tending of gear and other devices used in connection with harvesting,
>
> e) the maximum or minimum permitted sizes of individual organisms, and requirements for part or all of the harvest to consist only of males or females,
>
> f) permitted bycatches,
>
> g) the design and use of harvesting gear to reduce damage to species other than the target species. ((Directorate of Fisheries 2008)

It should be repeated that some countries have limited or no regulations on macroalgal harvests, and the extent to which countries with regulations have the capacity to fully enforce them is not known. The United States has no specific federal regulations on macroalgal harvests.

A number of third-party standards on sustainable seaweed harvesting offer non-regulatory options for verification of environmental stewardship goals, and these were outlined in the board's previous discussion document on this topic. The Aquaculture Stewardship Council-Marine Stewardship Council (ASC-MSC) sustainable seaweed standards indicate that there are environmental impacts to harvesting seaweed, hence the need for/benefit to certification. Their guiding principles state that "seaweed harvesting … must be conducted in a manner that does not lead to depletion of the exploited wild populations". Harvesting must additionally "allow for the maintenance of the structure, productivity, function and diversity of the ecosystem (including habitat and associated dependent and ecologically related species) on which the activity depends." (ASC-MSC 2020)

It is important to note that the regulations typically focus on regrowth of the harvested species, with such conditions as cutting height, holdfast restrictions, or repeat harvest guidelines. While those parameters are important, "generally, the management focus is on the regeneration of the seaweed resource itself, with no or limited consideration of other species that are associated with the target species and may therefore be affected by bycatch or habitat loss and alterations" (Lotze *et al*. 2019).

<u>NOSB Fall 2019 Marine Materials Panel</u>

In order to gain a deeper understanding of the topic from a range of stakeholders, the board convened an expert panel in fall 2019 panel to evaluate the environmental impacts of marine macro algae harvesting for crop fertility inputs and to explore possible means of mitigating harm. The panel was composed of 2 scientists specializing in marine ecology and seaweed, 1 certifier, and 1 harvester. The questions posed to were synthesized from public comment and NOSB members. Panelists were asked to identify and focus on those questions that best related to their experience and expertise.

Questions for the Scientists and a Summary of Their Responses in Italics:

1. Stakeholders have pointed out the need for a definition for the term "sustain". Current NOP standards for protecting environmental resources rest largely on the terminology of "maintain or improve", while the wild crop standard uses the word "sustain". The NOP regulations do not define this term. §205.200 requires that crop producers "maintain or improve the natural resources of the operation". §205.207(b) requires that wild crops be "harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop". How can the NOP define, measure, and verify the phrases "not destructive to the environment" and "sustain the growth and production" as related to wild harvested marine macroalgae?
    a. *Biomass is indicative of abundance of dependent organisms and measurable; architecture is more challenging to assess, but could be done intermittently.*
2. Could practice standards or guidelines be created that are sufficiently broad to cover the wide geographic distribution and differences in marine ecosystems while being simultaneously specific enough to provide adequate protection of marine algae and the ecosystem functions they afford?
    a. *Conservative guild level guidelines, but may require species specificity.*
3. What are the environmental implications of taking no action?
    a. *Given the rate of ocean change, the paucity of data on many of these systems, and tendency for overexploitation of marine resources, a cautionary approach is warranted. Additionally, aquaculture is an alternative to meet demand.*
4. Define an efficient, science-based method for measuring existing biomass to establish a baseline. How would this be measured post-harvest? Is there existing data from established harvest regions?
    a. *We reviewed several developing remote sensing and genetic techniques, in addition to standard visual assessments. Validation and training required.*
5. For all algae, what are the best methods for harvesting that minimize the impact on the recovery of the population of the harvested species and maintain ecosystem function and services? What would be measured and what benchmarks would be set? Who should determine the methods/benchmarks?
    a. *Benchmarking of harvesting approaches (e.g., holdfast minimums, no trawling).*
6. Are there some species that are so important to ecosystem structure and function that harvest should not be permitted at all?
    a. *Coralline algae should be considered as off-limits to harvesting because of their life history characteristics and ecological importance.*
7. Should there be protected areas that are off limits to harvesting? Should seasonal restrictions be considered?
    a. *Yes and Yes!*
8. What is an acceptable level of bycatch? Should this be assessed on a species by species basis? Are there any bycatch species that could prevent harvesting in an area altogether?
    a. *Harvest using least destructive and most selective gear; implement bycatch monitoring.*

Questions for the Certifier and Harvester:

1. What methods are currently being used by certifiers and harvesters to verify environmental goals and avoidance of harm when certifying marine algae to the wild crop standard for livestock feed, human consumption, or as a crop input?
2. Are certifiers adequately trained to certify marine algae? What could be done to address any deficiencies in knowledge and training?
3. What concerns exist regarding the NOP's regulatory authority to require organic certification of a crop production input ingredient?
4. Are government regulatory structures in place to ensure habitat protection from over-harvesting of marine algae? Should marine algae harvesting be permitted (under the organic regulations) where those regulations are weak or non-existent?
5. If biomass assessments are made pre- and post-harvest, who should perform them?
6. Who would monitor compliance and enforce management standards?
7. Should the NOSB propose requiring organic certification of marine macro algae crop input ingredients, create an annotation, or explore other methods to ensure that environmental criteria are met?

The expert panel provided the board with much-needed information on harvesting methods, certification concerns and areas for standards, the biology and ecology of marine macroalgae, and recommendations on future work. The harvester testified about his company's many years of research on harvesting impacts and management plans enacted to minimize them. Annual surveys are conducted to establish proper harvest quotas. The certifiers addressed current certification of "kelp" as an agricultural product in organic livestock feed and emphasized that additional training for certifiers is needed, as was proposed in NOP 5027-1. They certify six operations to the wild crop standard for "kelp" harvesting.

The scientists testified that marine macroalgae are ecosystem engineers providing habitat to other species, that harvesting reduces biomass and structure, and the extent of impact depends on harvesting methods. In some cases, seaweeds can recover. When clear-cut, it can take decades for recovery. They suggested a balanced view of desired ecosystem services from marine macroalgae. They affirmed that it was possible to create generalizable harvest parameters that could include baseline biomass assessments, minimum cutting heights and holdfast removal, and prohibitions on trawling.

Proposal:
Through its previous discussion documents, the board variously explored either requiring organic certification of macroalgae ingredients as a means of monitoring the environmental impact of harvests or an annotation in the National List that would achieve a similar result. There is resistance among some stakeholders to requiring organic certification due to concerns about a slippery slope for other natural inputs. On the other hand, there are species that are currently being certified organic for human consumption or livestock feed that are also used for crop fertility inputs. Additionally, there has been concern that requiring organic certification without specifying additional harvest parameters could lead to excessive variation in interpretation of the wild crop standard between certifiers.

Some were apprehensive that verification could increase the cost of these inputs for farmers. Public testimony by one certifier noted that of the 19 crop inputs they approve containing aquatic plant extracts, 7 already contain certified organic plant extracts. A quick search for certified organic kelp meal revealed a number of products containing certified organic *Ascophyllum nodosum*. When compared with kelp meal products containing the same species that was not certified organic, there were instances in which the product containing certified organic *Ascophyllum nodosum* was cheaper than the product containing *Ascophyllum nodosum* that was not certified organic.

After significant consideration, it was decided that an annotation with specific wording about harvest procedures was a desirable and achievable goal. In consultation with the NOP, it was determined that language requiring verification within the annotation itself was not feasible; however, that does not diminish the requirement to follow the annotation.

Although not a condition of the annotation, some harvesters and/or processor may seek verification. This could be done in a number of ways, including through a "material evaluation program" similar to the material evaluation requirement for High-Nitrogen Liquid Fertilizers (HNLF) explained in NOP Guidance 5012. A sample fee schedule for a material evaluation program can be viewed at the Organic Materials Review Institute and varies according annual gross sales for the company, the type of product being reviewed, and additional situations. Verification could also potentially be achieved through organic certification, with the certifier inspecting to the annotation harvest parameters as well as the wild crop standard.

This annotation applies only to the raw marine macroalgal ingredient, not the resulting product. Companies harvesting the marine macroalgae would be responsible for harvesting according to the annotation parameters. Moreover, if the harvester chose to certify their macroalgae harvest, the ingredient list could state that the marine macroalgae ingredient was certified organic, i.e. "USDA Organic *Ascophyllum nodosum"*. If a producer opted to undergo a material evaluation program, the macroalgae would be product-verified and listed by that material review organization (producers can be individual harvesters or companies hiring independent contract harvesters).

While there would be some increased cost for producers who decided to certify their macroalgae or have it reviewed through a material evaluation program, this is not dissimilar to the cost farmers and handlers bear when electing organic certification for their products. Moreover, a number of harvesters are already certifying all or part of their macroalgal harvests. There may be uncertified harvesters already harvesting to the annotation parameters for whom acquiring verification would not necessitate significant changes to their practices.

This is a complicated subject and one the board has worked on for over five years. Differing views on the need for action exist. Finding the correct means of addressing harvesting has involved important exchanges between the board and stakeholders. The annotation must be broad enough to cover the range of species, geographies, and harvest methods while simultaneously being specific enough to be useful and feasible.

The Materials Subcommittee is proposing an annotation to the organic regulations stipulating harvesting parameters for marine macroalgae used in crop fertilizers, providing a science-based process and parameters to ensure that harvesting limits harm to the environment. The annotation wording came about through review of previous public comments, in looking at the Marine Materials Fall 2019 panel's scientists' recommendations, and in conversations with Dr. Robin Hadlock Seeley (Shoals Marine Laboratory, Faculty, University of New Hampshire and Cornell University). The draft annotation was then sent to the two scientist seats on the panel –Dr. Allison Schmidt (Dalhousie University, Professor, Department of Biology) and Dr. Nichole Price (Bigelow Laboratory for Ocean Sciences, Senior Research Scientist)—and they collaborated to make additional edits.

The draft language was shared with the certifier on the panel, Chris Grigsby (MOFGA Certification Services, Director) and the harvester, Dr. Raul Ugarte (Acadian Seaplants, Senior Manager Resource Science). Comments said the annotation should include not only biomass and architecture, but also the other species in the community. Additionally, it was suggested that a more feasible and ecologically sound metric than biomass and architecture returning to pre-harvest levels might instead be harvest rates below the annual rates of regeneration.

The annotation language was next reviewed, and edits were suggested, by Dr. Michael Graham at Moss Landing Marine Laboratories and Co-/Managing-Editor, Journal of Phycology. The draft annotation language was subsequently sent to 18 different marine scientists across the US, Canada, and Chile to solicit their feedback on feasibility, adequacy, and suggested edits. They came via public and stakeholder comments and recommendations and through referrals from scientists contacted about last fall's expert panel. Those that replied were:

- Dr. Susan Brawley, University of Maine, Professor School of Marine Sciences
- Dr. Dan Reed, University of California Santa Barbara, Marine Science Institute
- Dr. Robert DeWreede, University of British Colombia, Professor Emeritus Botany
- Dr. Thomas Mumford, Marine Agronomics LLC, Retired from the Washington Department of Natural Resources
- Dr. Heike Lotze, Dalhousie University, Professor Department of Biology
- Dr. David Garbary, St. Francis Xavier University, Professor of Biology
- A colleague of Dr. Pam Krone, Monterey Bay National Marine Sanctuary
- Dr. Jennifer Smith, University of California at San Diego Scripps Institution of Oceanography, Professor of Marine Biology
- Dr. Brian Beal, University of Maine, Professor of Marine Ecology & Director of the Marine Science Field Station
- Dr. Alejandro Heriberto Buschmann Rubio, Universidad de los Lagos, Professor
- Glyn Sharp, Retired from Department of Fisheries and Oceans-Nova Scotia

Broadly speaking, there was general agreement about the annotation and suggestions for revisions (with the exception of one scientist who thought it was satisfactory and feasible as written and one who expressed concern that it was too broad to be effectively applied to specific regions or species). Edits were made to the proposed language based careful analysis of the feedback received from the various scientists, including Drs. Schmidt, Price, and Ugarte from the Fall 2019 Expert Panel.

The “prohibited harvest areas” section was amended to specify established public and private conservation areas and to include sanctuaries and preserves. “Trawling” was refined based on near universal feedback to “bottom trawling”. Given a range of views on language referring to “reproductive individuals”, the wording was changed to reflect the diversity of species and their reproductive characteristics by rohibiting practices that prevent reproduction of the population. Additional language was added based on suggested wording from Dr. Ugarte regarding sufficient propagules to maintain the population. Phrasing about maintaining ecosystem functions was also added. Original wording stating that bycatch should be “minimized” was recognized as subjective, and so the wording was changed to “prevented” and “eliminated” in the case of special status species. One scientist noted that the absence of bycatch can demonstrate an unhealthy marine community. Monitoring practices would need to be clarified in guidance.

The language that drew the greatest amount of feedback was that regarding biomass and architecture returning to pre-harvest levels prior to repeat harvesting. Questions arose about how to measure this. Monitoring and data collection to measure biomass and architecture can take place using a variety of methods, including remote sensing, drones, GIS maps, genetic techniques, transect sampling, and visual assessments. Guidance would be needed to clarify how and when sampling should occur. It was recommended that "height" should be an average with some variation. One scientist noted that commercial harvesting affects the architecture of some species, making it challenging to require a complete return to pre-harvest levels. It was suggested that guidance on how different types of species are harvested would be needed. Establishing fully accurate pre-harvest levels was deemed difficult. One commenter said that hand raking of some species is preferred over mechanical harvest as it reduces in incidence of cutting to minimum allowed heights, which can negatively impact the biological community. An initial limited test harvest was recommended, along with subsequent designated strip harvesting. It is not the intent of the language to stop harvesting to establish a baseline measurement. All of these are points that should be evaluated in guidance.

The second version of the annotation with incorporated comments was sent back to all those who originally provided feedback. This time there was more agreement from the scientists that the changes had improved the annotation. Roughly half felt it was adequate as edited. A few had suggestions for additional edits. Thus, a third version of the language was drafted based on feedback and in consultation with four of the scientists, paying close attention to improvements that could gain the broadest degree of consensus within the stakeholder community. Importantly, the scientists represent a range of specialties in marine macroalgae. It was noted that storms and natural succession can impact biomass and architecture. Ice scouring of rock ledges and storm events affect biomass and architecture in the case of *Ascophyllum nodosum*. The earlier annotation language specified a return to pre-harvest levels. Preharvest measures of biomass and architecture in ice-scoured or winter storm-impacted areas may not adequately form the basis of sufficient recovery. Consequently, the wording was further developed to clarify that repeat harvest cannot reoccur until the biomass and architecture approach that of undisturbed natural stands of the target species in that area. This recognizes variability in site specific conditions.

All of the scientists were sent the final annotation wording. The vast majority agreed with the final wording as it was written, as well as the process of developing the language. Three provided additional comments, and most of those were incorporated into the final language. The two outstanding issues raised that will need to be explored in guidance are how to measure architecture (though length and circumference can be measured in a quadrant for intertidal species, this is more challenging for subtidal species; whether estimated measurements are adequate and how to define this should also be considered), and the importance of the relationship between species size and age. The final annotation wording reflects of a diverse spectrum of scientific feedback, collaboration, and support. The subcommittee thanks all those who participated in its crafting, particularly Dr. Allison Schmidt and Dr. Nichole Price for their tremendous time, effort, and expertise in helping guide this language development.

Adoption of this annotation should be accompanied by a NOP-appointed scientific task force to elaborate additional guidance and instruction to certifiers, with particular focus on providing species-specific parameters[7]. The task force could identify the top three to five species used and provide

[7] Modifying existing third-party standards that address environmental impact of seaweed harvesting or using them as a reference point could be explored by the task force.

recommendations for their unique biological and geographical characteristics. A periodically updated living document, reviewed at sunset intervals, would serve to address changes to the annotation as needed and to promote consistency in interpretation and application. Adoption of this annotation should be followed by a lengthy phase-in period of five years to allow for industry adaptation. Material review organizations and certifiers would need to use staff qualified to evaluate the harvest against the annotation parameters, for harvesters seeking certification or product verification. Task force-driven guidance should detail needed areas for training.

These parameters reflect values and science around marine macroalgae harvest the board supports. 1) Protected conservation areas should not be used for harvest of organic fertility inputs. 2) Bottom trawling is prohibited because of its potential for damage to the surrounding ecosystem, thus preventing the harvest of most coralline algae (as recommended by the scientists on the Fall 2019 Expert Panel) because of its slow growth rate[8]. 3) Harvesting should not interfere with reproduction for the continued growth and ecosystem functions of the species. 4) Although harvesting affects the architecture of some species, biomass or percent cover and architecture (density and height) must be allowed to approach the biomass and architecture of undisturbed natural stands of the targeted species in that area before a subsequent harvest so that ecosystem function interruption is minimized, to the extent possible. 5) Prevention and monitoring of bycatch are important to avoiding unnecessary mortalities associated with the harvest.

It is not intended that every harvest be monitored as that would be impossible to oversee, just as organic inspectors are not present for every action taken during a farm's growing season. As with the entire organic label, trust is involved. Finally, harvesters must comply with all local, state, federal, and tribal regulations, permits, and jurisdictions.

§205.601 Synthetic substances allowed for use in organic crop production

1) This proposal suggests an annotation to §205.601 (j)(1) requiring (proposed annotation changes are in red):

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided that, use of such substances does not contribute to contamination of crops, soil, or water...

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction. Harvest Parameters - "Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules[9], holdfasts, and reproductive

[8] In the Mediterranean, Barbera *et al*. (2003) note "that maerl beds are non-renewable resources and cannot sustain direct exploitation", a species and region cited in the 2016 TR as used in organic fertilizers. Lotze *et al*. (2019) state "Trawling and dredging generally entrain a wide range of non-target species and have the most damaging effects on seafloor habitats, including the seaweed canopy".

[9] Definition of a propagule: a vegetative structure that can become detached from a plant and give rise to a new plant, e.g. a bud, sucker, or spore.

structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service."

2) An additional listing is proposed at §205.602 prohibiting marine macroalgae unless produced in accordance with the following annotation (identical to that proposed for §205.601 (j)(1)) in order to address marine macroalgae used in non-synthetic products and therefore not covered by the annotation under Aquatic Plant Extracts. This prohibition, unless harvested in accordance with the annotation, would help safeguard that marine macroalgae harvested for and used in organic crop production do not harm the environment (proposed changes are in red):
§205.602 Nonsynthetic substances prohibited for use in organic crop production.
The following nonsynthetic substances may not be used in organic crop production:
<u>(j) Marine macroalgae (seaweed)--unless harvested in accordance to the following parameters:</u>
Non-commercial harvests for whole and unprocessed seaweed are exempt from these parameters.
Harvest Parameters - "Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules[10], holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service."

Public comment indicated some farmers in coastal regions harvest small amounts of marine macroalgae for on-farm, non-commercial use. Such harvests are exempt from this annotation.

Conclusion:
On issues where universal agreement does not exist, it is the board's aim to pursue a middle ground approach where achievable. Given the strong calls for action on the one hand and statements that action is unnecessary on the other, this proposal reflects the best effort at compromise. Prohibition of the use of marine macroalgae in crop fertility inputs is not viable, nor is inaction on safeguarding marine ecosystems from the impacts of harvesting. This annotation does not prohibit marine macroalgae but provides scientifically sourced harvest parameters to protect the target species and its associated community.

Much of organic agriculture is based on the precautionary principle. Similarly, this proposal prevents possible negative environmental impacts from commercial harvesting of marine macroalgae. The potential for a negative impact is sufficient to warrant a cautionary approach and was recommended by

[10] Definition of a propagule: a vegetative structure that can become detached from a plant and give rise to a new plant, e.g. a bud, sucker, or spore.

the scientists on the Fall 2019 Expert Panel. This proposal furthers the commitment to continuous improvement in organic farming by valuing marine macroalgae not simply as resources but also as integral species within complex ecosystems.

In the presence of conflicting views and given evidence describing the environmental impacts of harvesting, this proposal seeks to ensure that the raw input ingredient, marine macroalgae used in crop fertility inputs, is not harmful to the environment by establishing harvest parameters created in collaboration with marine science experts in the field. The review of the literature demonstrates the possibility for multi-level environmental effects of harvesting marine macroalgae. Even where regulations exist, and they are not legislated in every country, they do not typically address effects on the community and ecosystem functions and instead focus on regrowth and recovery of the targeted species. The organic regulations, as noted in the earlier section on relevant areas of the rule, is concerned not only with single species impacts but also with ecological balance and biodiversity conservation. This proposal helps assure that marine macroalgae used in organic production is consistent with a system of sustainable agriculture.

Subcommittee Vote:

Motion to adopt the proposal on Marine Macroalgae in Crop Fertility Inputs
Motion by: Emily Oakley
Seconded by: Dave Mortensen
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Dave Mortensen, Subcommittee Chair to transmit to NOSB, August 11, 2020

References:

Aquaculture Stewardship Council-Marine Stewardship Council (ASC-MSC) (2020, June 29) "The ASC-MSC Seaweed Standard" [brochure]. Retrieved from https://www.asc-aqua.org/wp-content/uploads/2017/06/BC2146_ASC-MSC_A4_6pp_ARTWORK_LRES.pdf.

Barbera C, Bordehore C, Borg JA, Glémarec M, Grall J, Hall-Spencer JM, de la Huz C, Lanfranco E, Lastra M, Moore PG, Mora J, Ramos-Esplá AA, Rizzo M, Sánchez-Mata A, Seva A, Schembri PJ, Valle C (2003) Conservation and management of northeast Atlantic and Mediterranean maerl beds. *Aquatic Conservation: Marine and Freshwater Ecosystems,* 13, 65–76.

Boaden PJS, Dring MT (1980) A quantitative evaluation of the effects of *Ascophyllum* harvesting on the littoral ecosystem. *Helgolander Meeresuntersuchungen*, 33, 700-710.

Buschmann AH, PrescottS, Potin P, Faugeron S, Vasquez JA, Camus C, Infante J, Hernandez-Gonzalez MC, Gutierrez A, Varela DA (2014) The status of kelp exploitation and marine agronomy, with emphasis on *Macrocystis pyrifera*, in Chile. *Advances in Botanical Research*, 71, 161–188.

California Department of Fish and Wildlife (CDFW) (2014) *Informational Digest to the Regulations Governing the Harvest of Kelp and other Marine Algae in California*. California.

Capuzzo E, McKie T (2016) *Seaweed in the UK and abroad – status, products, limitations, gaps and Cefas role*. Cefas Contract Report FC002I. Centre for Environment, Fisheries & Aquaculture Science. Suffolk, UK.

Environment and Heritage Service (2007) Environmentally Sustainable Seaweed Harvesting in Northern Ireland.

Food and Agriculture Organization of the United Nations (2014) *The State of World Fisheries and Aquaculture 2014*. FAO Fisheries and Aquaculture Department. Rome.

Foster MS, Barilotti DC (1990) An approach to determining the ecological effects of seaweed harvesting : a summary. *Hydrobiologia*, 204/205, 15-16.

Garbary DJ, Galway ME, Halat L (2017) Response to Ugarte *et al*.: *Ascophyllum* (Phaeophyceae) annually contributes over 100% of its vegetative biomass to detritus. *Phycologia*, 5,: 116–118.
Halat L, Galway ME, Gitto S, Garbary D (2015) Epidermal shedding in *Ascophyllum nodosum* (Phaeophyceae): seasonality, productivity and relationship to harvesting. *Phycologia*, 54, 599–608.

Halat, L, Galway ME, Gitto S, Garbary D.J (2015) Epidermal shedding in *Ascophyllum nodosum* (Phaeophyceae): seasonality, productivity and relationship to harvesting. *Phycologia*, 54, 599–608.

Ingólfsson A (2010) The conservation value of the Icelandic intertidal, and major concerns. *Natturufraedingurinn*, 79 (1-4), 19-28.

Ingólfsson A, Hawkins SJ (2008). Slow recovery from disturbance: a 20 year study of *Ascophyllum* canopy clearances. *Journal of the Marine Biological Association of the United Kingdom*, 88(4), 689–691.

Jeffery NW, Heaslip SG, Stevens LA, Stanley RRE (2020) *Biophysical and Ecological Overview of the Eastern Shore Islands Area of Interest (AOI)*. Canadian Science Advisory Secretariat Research Document 2019/025. Fisheries and Oceans Canada. Ottawa.

Kay L, Eddy TD, Schmidt AL, Lotze HK (2016) Regional differences and linkage between canopy structure and community composition of rockweed habitats in Atlantic Canada. *Marine Biology,* 163(251).

Kelly L, Collier L, Costello MJ, Diver M, McGarvey S, Kraan S, Morrissey J, Guiry MD (2001) Impact assessment of hand and mechanical harvesting of *Ascophyllum nodosum* on regeneration and biodiversity. *Marine Resource Series*, 19. Retrieved from http://oar.marine.ie/bitstream/10793/207/1/No 19 Marine Resources Series.pdf.

Krumhansl KA, Scheibling RE (2012) Production and fate of kelp detritus. *Marine Ecology Progress Series*, 467, 281–302.

Krumhansl KA, *et al*. (2016) Global patterns of kelp forest change over the past half-century. *Proceeding of the National Academy of Sciences*, 113, 13785–13790.

Krumhansl KA, Bergman JN, Salomon AK (2017) Assessing the ecosystem-level consequences of a small-scale artisanal kelp fishery within the context of climate change. *Ecological Applications*, 27, 799–813.

Levitt GJ, Anderson RJ, Boothroyd CJT, Kemp FA (2002) The effects of kelp harvesting on its regrowth and the understorey benthic community at Danger Point, South Africa, and a new method of harvesting kelp fronds. *South African Journal of Marine Science*, 24, 71–85.

Lorentsen SH, Sjøtun K, Grémillet D (2010) Multitrophic consequences of kelp harvest. *Biological Conservation*, 143, 2054–2062.

Lotze HK, Milewski I, Fast J, Kay L, Worm B (2019) Ecosystem-based management of seaweed harvesting. *Botanica Marina*, 62(5), (published online) https://doi.org/10.1515/bot-2019-0027.

Mac Monagail M, Cornish L, Morrison L, Araújo R, Critchley AT (2017) Sustainable harvesting of wild seaweed resources. *European Journal of Phycology*, 52(4), 371-390.

Maine Department of Marine Resources (2014) *Fishery Management Plan for Rockweed (Ascophyllum nodosum)*. Maine.

The Marine Resources Act: Act of 6 June 2008 no. 37 relating to the management of wild living marine resources. (2008) Directorate of Fisheries. Norway.

Migné A, Golléty C, Davoult D (2014) Effect of canopy removal on a rocky shore community metabolism and structure. *Marine Biology*, 162, 449–457.

Pérez-Matus A, Carrasco SA, Gelcich S, Fernandez M, and Wieters EA (2017) Exploring the effects of fishing pressure and upwelling intensity over subtidal kelp forest communities in central Chile. *Ecosphere 8*, e01808.

Phillippi A, Tran K, Perna A (2014) Does intertidal canopy removal of *Ascophyllum nodosum* alter the community structure beneath? *Journal of Experimental Marine Biology and Ecology*, 461, 53–60.

Rebours C, Marinho-Soriano E, Zertuche-Gonzalez, JA, Hayashi L, Vásquez JA, Kradolfer P, Soriano G, Ugarte R, Abreu MH, Bay-Larsen I, Hovelsrud G, Rodven R, Robledo D (2014) Seaweeds: an opportunity for wealth and sustainable livelihood for coastal communities. *Journal of Applied Phycology*. 26(5), 1939-1951.

Rinde E, Christie H, Bekkby T (2006) *Økologiske effekter av taretråling. Analyser basert på GIS-modellering og empiriske data*. Norwegian Institute for Water Research.

Rock Weed Harvesting Regulations made under Section 71 of the *Fisheries and Coastal Resources Act*, S.N.S. 1996, c. 25. (1996) Province of Nova Scotia.

Schmidt AL, Coll M, Romanuk T, Lotze HK (2011) Ecosystem structure and services in eelgrass (Zostera marina) and rockweed (*Ascophyllum nodosum*) habitats. Maine Ecology Progress Series 437, 51–68.

Scottish Government (2016) *Wild Seaweed Harvesting: Strategic Environmental Assessment Environmental Report*. Marine Scotland. Edinburgh.

Seeley RH, Schlesinger WH (2012) Sustainable seaweed cutting? The rockweed (*Ascophyllum nodosum*) industry of Maine and the Maritime Provinces. *Annals of the New York Academy of Sciences*, 1249, 84–103.

Sharp GJ, Pringle JD (1990) Ecological impact of marine plant harvesting in the northwest Atlantic: a review. *Hydrobiologia*, 204/205, 17-24.

Sharp GJ, Ugarte R, Semple R (2006) The ecological impact of marine plant harvesting in the Canadian Maritimes, implications for coastal zone management. *ScienceAsia*, 32, 77–86.

Stagnol D, Renaud M, Davoult D (2013) Effects of commercial harvesting of intertidal macroalgae on ecosystem biodiversity and functioning. *Estuarine, Coastal and Shelf Science*, 130, 99–110.

Stagnol D, Michel R, Davoult D (2016) Unravelling the impact of harvesting pressure on canopy-forming macroalgae. *Marine and Freshwater Research*, 67, 153–161.

Steen, H., F.E. Moy, T. Bodvin and V. Husa. 2016. Regrowth after kelp harvesting in Nord-Trøndelag, Norway. *ICES Journal of Marine Science*, 73, 2708–2720.

Theuerkauf SJ, Morris JA Jr, Waters TJ, Wickliffe LC, Alleway HK, Jones RC (2019) A global spatial analysis reveals where marine aquaculture can benefit nature and people. *PLoS One*, 14(10):e0222282, (published online) https://doi:10.1371/journal.pone.0222282.

Ugarte R (2010) An evaluation of the mortality of the brown seaweed *Ascophyllum nodosum* (L.) Le Jol. produced by cutter rake harvests in southern New Brunswick, Canada. *Journal of Applied Phycology*, 23, 401–407.

Ugarte RA, Sharp G (2001) A new approach to seaweed management in Eastern Canada: the case of *Ascophyllum nodosum*. *Cahiers de Biologie Marine*, 42, 63–70.

Ugarte R, Sharp G (2012) Management and production of the brown alga *Ascophyllum nodosum* in the Canadian Maritimes. *Journal of Applied Phycology*, 24, 409–416.

Vadas RL, Wright WA, Beal BF (2004) Biomass and Productivity of Intertidal Rockweeds (*Ascophyllum nodosum LeJolis*) in Cobscook Bay. *Northeastern Naturalist*. 11(Special Issue 2), 123–142.

Vásquez JA (1995) Ecological effects of brown seaweed harvesting. *Botanica Marina*, 38, 251–258.

Vasquez JA, Santelices B (1990) Ecological effects of harvesting *Lessonia* (Laminariales, Phaeophyta) in central Chile. *Hydrobioligia*, 204/205, 41-47.

Waage-Nielsen E, Christie H, RindeE (2003) Short-term dispersal of kelp fauna to cleared (kelp-harvested) areas. *Hydrobiologia*, 503, 77–91.

Watt CA, Scrosati RA (2013) Bioengineer effects on understory species richness, diversity, and composition change along an environmental stress gradient: Experimental and mensurative evidence. *Estuarine, Coastal and Shelf Science*, 123, 10-18.

Wernberg T, Krumhansl K, Filbee-Dexter K, Pedersen MF (2019). Status and Trends for the World's Kelp Forests. Ch. 3 in *World Seas: An Environmental Evaluation*. Elsevier Ltd, 57-78.

Werner A, Kraan S (2004) Review of the Potential Mechanisation of Kelp Harvesting in Ireland. *Marine Environment and Health Series No. 17*. Marine Institute.

National Organic Standards Board
Policy Development Subcommittee
Consent Agenda Discussion Document
July 19, 2020

Summary:
The PDS is discussing the use of a consent agenda for voting on Sunset items that are similar, in an effort to save time at the NOSB meetings.

Discussion:
A consent agenda is a board meeting practice where similar agenda items are grouped into a single agenda item for voting purposes. All items under a consent agenda can then be approved in one action, rather than board members filing motions on each item separately. Using a consent agenda can save time. Many private and governmental boards use a consent agenda for generally non-controversial items that do not require much, if any, discussion before a vote.

For the NOSB, reviews of substances with multiple listings on the National List where the two reviews are essentially the same could be grouped for voting. For example, ammonium carbonate and ammonium bicarbonate, or copper substances, could be grouped. The consent agenda process allows a board member, for any reason, to remove an item from the grouping for further discussion, and possible separate vote. However, if the items are not singled out for discussion they can be grouped for voting thereby saving time. To maintain transparency the process would only be used for similar, non-controversial items.

The Policy Development Subcommittee is seeking feedback from the full Board and public commenters to see if there is support for this change before pursuing it further.

Subcommittee Vote:
Motion to accept the discussion document on the use of a consent calendar
Motion by: Rick Greenwood
Seconded by: Jesse Buie
Yes: 4 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Policy Development Subcommittee Chair, to transmit to NOP August 9, 2020