National Organic Standards Board Meeting

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National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Paper based crop planting aids
January 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 that the current allowance for paper on the National List (i.e., as compost feedstock and mulch) 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 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.

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 the manufacturer has proposed that these fibers be replaced by a natural hemp fiber. The petitioner and public commenters 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 greens, 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 petition, there are numerous other paper pot systems, both to be transplanted as single plants and in chains of pots. 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 15-100%. Synthetic adhesives are also used in the Ellepots, but currently no other synthetics.

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 views 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 TR 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 and Spring 2019 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 one noted in the petition. Approval of this material will probably 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 more non-paper synthetic fiber content are more typically used in the nursery trade, where the 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 between planting into the pot and planting out 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 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 used with the intent of degrading in 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 time of the crop production, and to those aids that would decompose 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 has developed a listing and annotation that it believes 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" to biodegrade into soil, and there are very few differences between the currently allowed paper and the paper as a planting aid we were reviewing, except for the long term use paper pots that have a very high percentage of synthetic fibers.

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, and it is not necessary to annotate paper to exclude these prohibited materials.

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 or glossy inks would be allowed for paper as a crop planting aid, to be in alignment with 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 and type of synthetics, is biodegradable and has no negative effects on human health. The 2019 TR did not indicate 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 and type of synthetics, is not harmful to the environment. The 2019 TR did not indicate 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 approved synthetics 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, to limit the use of this material to activities around planting of seeds or plants.

   The annotation of no less than 85% biobased content meets the needs of current manufacturers, with the possibility of hemp or other fibers capable of providing the strength needed to meet this annotation. Continuing the prohibition on colored and glossy 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. 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 encourages continued innovation to move to 100% biobased content as well as to make sure that these materials are

promptly and economically available to growers of all sizes. The Subcommittee also encourages testing and trials of increased natural and/or biobased synthetic content and believes that manufacturers would be less likely to provide products to organic farmers if this testing were required.

Classification Motion:
Motion to classify "paper-based crop planting aid" as synthetic.
Motion by: Harriet Behar
Seconded by: Steve Ela
Yes: 6 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 primarily of cellulose-based paper, including pots, seed tape, and collars that are placed in or on the soil and are intended to degrade into the soil. Contains no less than 85% biobased content with biobased content determined using ASTM D6866 (incorporated by reference; see §205.3).
Add to 205.601 (o) Production Aids:
Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without colored or glossy inks. If these paper-based crop planting aids are commercially available with 100% biobased fiber content, these must be used."
Motion by: Harriet Behar
Seconded by: Steve Ela
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jesse Buie, Crop Subcommittee Chair, to transmit to NOP January 21, 2020

National Organic Standards Board
Crops Subcommittee Discussion Document
Wild, Native Fish for Liquid Fish Products
November 19, 2019

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 work agenda item is to assess the impact of harvesting wild, native fish for fertilizer and to ensure that liquid fish and other fish-based 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 subcommittee posed questions to stakeholders asking about the number of products using wild fish harvested solely for fertilizer versus products utilizing fish 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 (CS) requested the development of a **Technical Report (TR) on Fish-Based Fertilizers** to investigate this further.

Relevant Areas of the Rule:
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."

In its initial discussions, the subcommittee considered how any negative environmental impacts associated with harvesting wild, native fish exclusively for fertilizer might be addressed in the regulations. We 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 on Section 205.602. Ultimately, the subcommittee agreed that a prohibition on 205.602 alone would suffice as it would cover any products on 205.601(j)(8). There is no intention to exclude the use of farmed fish or invasive species that are harvested to protect native ecosystems.

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, 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 goes on to answer 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)

The TR discusses some species used for meal/oil that have experienced documented declines, though not always exclusively as a result of over-fishing. It addresses the effects of large-scale harvesting on fisheries and ecosystems, though 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.

Discussion 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.

Vote in Subcommittee

Motion to accept the Wild, Native Fish for Liquid Fish Products discussion document
Motion by: Emily Oakley
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jesse Buie, Subcommittee Chair, to transmit to NOSB November 21, 2019

National Organic Standards Board
Crops Subcommittee Material Discussion Document
Biodegradable biobased mulch film
January 7, 2020

I Summary of biodegradable biobased mulch film

This material 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 on 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, since 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 to the NOSB. 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 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 our 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 invite the public to provide their input on these issues.

The NOP has 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 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. This discussion document hopes to gain insight from the public and possibly lead to a work agenda item for the NOSB to work on this issue.

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?

III Vote in Crops Subcommittee

Motion to accept the biodegradable biobased mulch film discussion document
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jesse Buie, Crops Subcommittee Chair, to transmit to NOSB January 7, 2020

Sunset 2022
Meeting 1 - Request for Public Comment
Crops Substances
April 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

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2020 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2020 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 3, 2020 as explained in the meeting notice published in the Federal Register.

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances under Review:

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

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

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

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

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 3, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 1 - Request for Public Comment
Crops Substances
April 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(j)4
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

Background from Subcommittee:

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.

Discussion:
The Crops Subcommittee voted to delist soap-based algicide/demossers in 2017 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 are still being used by some

producers. Based on public comment they were not removed.

Additional information or questions requested by Subcommittee:
None

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
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

Background from Subcommittee:

Use:
Use for use 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 specifically for fly control. 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 are 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, interaction is unlikely with current annotation. 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 all respondents supported relisting including a number of respondents who voiced strong opposition to other insect pest management chemicals up for relisting. Having said that, the past two sunset reviews of ammonium carbonate resulted in limited stakeholder input attesting to the efficacy and need of the material. To conduct an objective relisting review of ammonium carbonate stakeholder input attesting to the need and efficacy of the compound would be helpful. 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 predators and parasitoids.

Additional information or questions requested by Subcommittee:

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?
3. To what extent is the population or behavior of beneficial insects altered by the ammonium carbonate bait?

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).
Technical Report: 1994 TAP
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

Background from Subcommittee:

Use:
Insecticidal soaps are used on organic crops for control of soft bodied insects and hard bodied insects in the larval stage.
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 use 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 Insecticidal soaps 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 coldwater 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 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 that insecticidal soaps are non-toxic to desirable insects such as lady bugs and the coccinellid beetle. A recent technical review (TR) (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 control (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) make one a poor substitute for the other.

Discussion:
In the previous sunset review in 2015 there was overwhelming support for the continued listing of this material. Public commenters 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 commenters stated that these oils are allowed for use world-wide by most organic certifying bodies. In 2020, the Crops Subcommittee confirmed with a major certifying agency that insecticidal soaps were listed on over 100 Organic System Plans (OSPs) and that it is still necessary because of its unique mode of action.

Additional information requested by Subcommittee:

Is this substance still necessary for the organic farming community?

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

Background from Subcommittee:

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 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 183 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 186 publicly available.

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.

Ancillary Substances:
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.

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 EPA 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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Is this product still needed as a rodenticide in organic crop production?
2. Are there any nonsynthetic alternatives to this material with the same functionality?
3. Please provide information on the ancillary substances that may be part of vitamin D3 formulations.

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
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

Background from Subcommittee:

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]

Discussion:

During its preliminary sunset review in 2015, the Crops Subcommittee did not pose any questions to the public, and the majority of comments were in favor of keeping aquatic plant extracts on the National List. Commenters noted that aquatic plant extracts are an important element of fertility programs on many organic farms. During the fall public comment period, the Subcommittee identified concern about potential seaweed overharvesting. Extensive public comment was received on this issue, though the Subcommittee noted the comments were at times regional in nature. The board subsequently 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. At the end of the fall 2015 meeting, the board recommended keeping aquatic plant extracts on the National List, though the vote was divided with 5 to remove, 6 to keep, and 3 abstentions.

In the winter of 2016, the board received the limited scope TR on Marine Plants and Algae. Subsequently, the Crops Subcommittee published a in spring 2017 Proposal on Marine Algae Listings which was virtually identical to a similar proposal in Handling. In the Crops section, a proposal was put forth to limit aquatic plant extracts to those derived from brown seaweeds. Public comment demonstrated that there were numerous products containing red, green, and brown seaweeds. The work agenda item was then moved to the Materials Subcommittee, and the board explored new approaches to addressing concerns about environmental impact. In fall 2018, the Materials Subcommittee posted a Discussion Document proposing that all seaweed ingredients used in organic crop production be required to be certified organic. The next Discussion Document was posted in spring and fall of 2019 and solicited public comments on the question

of organic certification or an annotation specifying harvest methods. Public comments 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, to sentiments that the industry does not need further regulation. Following an expert panel on marine macroalgae used in organic crop inputs at the fall 2019 meeting, the board continues to explore this complex topic.

Additional information or questions requested by Subcommittee:

1. Given the broad range of views on this topic, please describe if/or how aquatic plant extracts should be addressed during this sunset review.
2. Are aquatic plant extracts still needed in organic crop production?
3. The 2006 TR states that aquatic plant extracts can be derived naturally by dehydrating seaweeds and grinding them into meal. Meal can be applied directly to the soil or diluted with water and used as a foliar spray or soil drench. Nonsynthetic products also may be produced using mechanical disruption, or freezing, pulverization, and clarification of the thawed slurry. The relative efficacy of alkali-extracted versus non-alkali- extracted product has not been consistently demonstrated, perhaps partly as a result of a lack of understanding of the mechanism by which aquatic plant extracts exert any purported beneficial effect (lines 205-12). Do the nonsynthetic alternatives to this material provide the same functionality?

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.
Technical Report: 2011 TR; 1995 TAP
Petition(s): N/A, 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

Background from Subcommittee:

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

Manufacture:
There are several processes used for production of lignin sulfonates: sulfite chemical pulping, the Kraft process, acid sulfite pulping (2011 TR 239-258). 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 biological demand (BOD), which affects aquatic organisms through decreased available oxygen. In a previous TR (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 that no harm will result to the general public, infants and children from aggregate exposures to lignosulfonantes.

Alternatives:
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 the landscape can also be used for dust suppression - water sprays, gravel, and no-till farming practices can also be used.

Discussion:
At the last Sunset review in 2017 public comment was supportive of relisting lignin sulfonate as a chelating agent and 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. A petition requesting the addition of sodium carbonate lignin at 205.601(j) is currently under review by the Crops Subcommittee and a limited TR has been requested. This compound is essentially the same as lignin sulfonate and there is the potential that new information about the manufacturing process or environmental or human health issue could be brought forward on these compounds.

Additional information or questions requested by Subcommittee:
None

Sodium silicate

Reference: 205.601 (l) As floating agents in postharvest handling. (2) Sodium silicate—for tree fruit and fiber processing.
Technical Report: 1995 TAP; 2006 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

Background from Subcommittee:

Use:
Sodium silicate, also known as "waterglass", 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 most of 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 U.S. Food and Drug Administration. The 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).

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).

Discussion:
During the previous sunset review, the Crops Subcommittee received no comments in favor of relisting sodium silicate. Even though the previous reviews had concluded that this material was compatible with a system of organic agriculture, based on evidence that it wasn't in use, the Subcommittee voted to delist this material. Several commenters noted that the material was unnecessary and that most fruit packers had already found alternatives, either through mechanical modifications to dump tanks to physically move fruit from the bottom of the tanks to the packing line or through the use of other materials. Contrarily, other commenters voiced concerns that modifications to equipment were expensive and that delisting sodium silicate might prevent smaller packers from converting conventional packing lines to organic use.

One alternative to sodium silicate is lignin sulfonate. During the same sunset review the NOSB voted to remove lignin sulfonate for use in packing operations from the National List. Therefore the question was raised whether sodium silicate should remain on the list as a viable alternative to lignin sulfonate. The Board ultimately voted to relist this material.

Additional information or questions requested by Subcommittee:

1. Are there non-synthetic practices (mechanical, physical or chemical) for pear or other tree fruit handling during the packing process that would be a reasonable alternative to using sodium silicate?

2. Is sodium silicate still used and should it remain on the National List?

3. Is there any use of sodium silicate for organic fiber production?

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

Background from Subcommittee:

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 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). 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.

The standards of OFPA are different from those used by the U.S. Environmental Protection Agency (EPA) to regulate pesticides. 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. Due to the 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 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 that it 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. They 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.

Additional information or questions requested by Subcommittee:

1. Can you provide examples of product development that have been stifled by the lack of clarity on the regulation and approval of inert ingredients in organically approved pesticide formulations?
2. Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?
3. Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?
4. What would be the consequences of a NOSB recommendation to delist List 4 Inerts?

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, unless 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."

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

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.”
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

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

Background from Subcommittee:

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).

Discussion:
Arsenic is prohibited by the Organic Foods Production Act (OFPA) 7 U.S.C. §6508(c)(1) CROP MANAGEMENT — "For a farm to be certified under this title, producers on such farm shall not –

(1) Use natural poisons such as arsenic or lead salts that have long-term effects and persist in the environment, as determined by the applicable governing State official or the Secretary."

The Senate Committee report says, "The Committee recognizes that certain natural materials present environmental and health hazards. An example would be the use of arsenic which, although natural, is known to be extremely toxic, and which is therefore explicitly prohibited from use in organic production under this title."

In the 2017 review, the Crops Subcommittee determined that arsenic did not meet the OFPA criteria and saw no reason to remove arsenic from its prohibited status on the National List. Both the Crops Subcommittee and the full NOSB voted to not remove arsenic from §205.602, non-synthetic substances prohibited for use in organic crop production.

Additional information or questions requested by Subcommittee:
None

Strychnine

Reference: 205.602(h)
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

Background from Subcommittee:

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, 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, 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 §205.602, non-synthetic substances prohibited for use in organic crop production.

Additional information or questions requested by Subcommittee:
None

National Organic Standards Board
Handling Subcommittee Discussion Document
Reclassification of L-Malic Acid
February 19, 2020

Introduction:
The Handling Subcommittee is considering a change to the classification of L-malic acid from a nonagricultural (nonorganic) non-synthetic allowed substance to a nonagricultural synthetic allowed substance and move the substance from §205.605(a) to §205.605(b). This consideration responds to recommendations made in a number of comments submitted during the substance's sunset review at the Spring and Fall 2019 NOSB meetings. Additionally, this responds to the 2019 L-malic acid Technical Report (TR), which found that most commercial quantities of L-malic acid are derived in part via a process of enzymatic conversion of synthetic fumaric acid.

Background:
L-malic acid was first added to the National List in 2006 and its listing has been renewed at each subsequent sunset review. The substance underwent its most recent 5-year sunset review in 2019, during which it received support from stakeholders for continued inclusion on the National List. Several commenters opposed the relisting; these comments are addressed in the discussion section below. At its Fall 2019 meeting, the Board voted 13 in favor, with one member absent, to relist L-malic acid.

However, during the sunset review the Board acknowledged the many comments suggesting most commercial sources of L-malic are synthetic and that the listing for L-malic acid should be at §205.605(b). Because a listing cannot be changed nor can an annotation be added during sunset review, the Board noted it would address the placement of the substance outside of sunset review.

Relevant areas in the Regulation:
§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))."

Reference: 205.605(a) Nonsynthetics allowed: L-malic acid (CAS # 97-67-6).

Discussion:
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice.

In the first round of the sunset review in Spring 2019, a number of commenters questioned whether commercially available L-malic acid is indeed from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process.

Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

1. Production of fumaric acid either synthetically from petroleum or by fermentation of carbohydrates; and
2. Enzymatic conversion of fumaric acid to L-malic acid by immobilized microbes producing the enzyme fumarase.

There are two options for obtaining the fumaric acid in the **first step** in this process; more detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

1. The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., Rhizopus spp.)
2. The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin

Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most if not all, of the L-malic acid on the market is therefore synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).

A number of commenters noted that while there may have been nonsynthetic versions available in the past, it is unlikely that commercially available nonsynthetic quantities exist. As certifiers, material review organizations, and the 2019 TR attest, applying NOP Guidance 5033 and 5033-1 to this full production method would result in classifying L-Malic acid as a synthetic material. Until this material is reclassified, certifiers have been verifying the following for L-malic acid: that it is not made using the "big 3" (genetic modification, sewage sludge, irradiation); that it is L-malic acid (not DL- or D-); and that it is the form with the same CAS# as is identified on the National List.

Commenters opposing the relisting of L-malic acid during the 2019 sunset review believe it should be removed from the National List and then repetitioned for inclusion at §205.605(b), or listed at §205.605(a) with an annotation limiting use to forms produced through nonsynthetic fermentation methods. The Handling Subcommittee is keenly aware of the negative environmental and climate impacts of petroleum use and supports alternatives to its use in organic production. However, as noted by commenters during the 2019 sunset review and indicated in the 2019 TR, it does not appear that commercial quantities of nonsynthetic L-malic acid are sufficient to meet current demand.

Questions:
The Subcommittee is seeking feedback on the following questions to help inform its decision regarding the reclassification of L-malic acid and to gather further information on some of the comments expressed during the 2019 sunset review.

1. There still appears to be some disagreement whether the process described in this document results in a synthetic form of L-malic acid. Is the determination that the two-step process described in this document and in the 2019 TR results in a synthetic form of L-malic acid accurate?
2. Would classification of L-malic acid when manufactured from synthetic fumaric acid as a synthetic substance affect the classification of other substances currently on 205.605(a)?
3. If the Subcommittee recommends an annotation that limits sources of fumaric acid used in the production of L-malic acid to non-petroleum sources, are there sufficient quantities to meet current demand in organic production?
4. How much time would be required for the industry to meet current and expected commercial demand of nonsynthetic L-malic acid produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*?

Subcommittee Vote:
Motion to accept the discussion document on reclassification of L-Malic Acid
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOSB, February 19, 2020

National Organic Standards Board
Handling Subcommittee Discussion Document
Review of the Ion Exchange Filtration Process
January 7, 2020

Summary of Memorandum from the National Organic Program to the National Organic Standards Board, dated August 27, 2019

The National Organic Program has 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 of this type of process. Some certifiers require only the solutions used to recharge the ion exchange membranes be on the National List. 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 processes 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, but have delayed implementation in order to gather more information and give the NOSB a chance to review the issue.

The NOP noted in the 2019 email, and other Materials Review Organizations have agreed, that the ion-exchange process is a chemical one and does affect the food in a way that chemically changes it. This process is different from a physical filtration. In the ion exchange process, the liquid used in the process exchanges molecules with the chemicals used as recharge or resins. The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the food that is run through this process.

Manufacturers and certifiers who wish to continue allowance of the ion exchange process disagree with some of the findings of the NOP. The different interpretations 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 organic product produced through the process, is complicated and the NOP therefore asked the NOSB to take on this issue.

The NOSB has begun its initial review of this issue, including the NOP email of May 7, 2019, the NOP memorandum to the NOSB of August 27, 2019, the applicable FDA definitions, previous NOSB discussions on this matter from 2002, as well as our current National List and OFPA criteria. The NOSB Handling Subcommittee will be discussing this issue in the coming year and seeks to clarify several issues: Whether or not there is a chemical change; if the various items are food contact substances or processing aids; and if this process is fundamentally different from other filtration processes, in which case the definition in the organic regulation may have to be modified. It is understood that while polymers are used in packaging that do not affect chemical change on the products in that package, the polymers used in ion exchange appear to be functionally different.

The Handling Subcommittee has begun its review of this process by learning about the process and the various materials used. A simplified summary of ion exchange, previously provided by 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.

The Handling Subcommittee has requested a technical review of the ion exchange process. The following questions and issues were added to the standard questions typically included in the TR request template:

- Listing of the uses of ion exchange filtration by organic operations or nonorganic operations, as available, including a description of the products where ion exchange filtration may be used, including processed products, crop, and livestock products;
- Function/purpose of ion exchange filtration, including a description of any chemical changes that occur during the process;
- Uses of ion exchange for water treatment, including domestic and agricultural water treatment and treatment of produced water
- Substances or materials used in ion exchange filtration, including resins, membranes and recharging solutions;
- Alternatives to ion exchange filtration, including practices and substances on the National List;
- Regulations related to ion exchange filtration, especially by U.S. FDA, including categorization/characterization of the substances/materials employed in ion exchange filtration and any associated regulatory terms used to describe substances/materials in ion exchange filtration (i.e., definition of food additive, food contact substance, processing aid, etc.);
- Regulatory terms in USDA organic regulations (7 CFR Part 205) or the Organic Foods Production Act (7 U.S.C. 6501 *et seq.)* that relate to ion exchange filtration substances/materials;
- Residues/chemicals that may be transferred from ion exchange materials (e.g., resins, beads, membranes, etc.) to food products;
- Regulatory status or approach to ion exchange filtration under international organic standards.

Questions for Public Comment:

The NOSB would like to hear from the public on the topic of ion exchange, and is seeking answers to the following questions to help inform its discussion and future proposal.

1. What organic products are currently produced through the ion exchange process?
2. Are there other processing methods used to produce these products?
3. What materials are being used in the ion exchange process for current organic products? Please include resins, recharge materials, membranes and any other substances.
4. If you do not agree that there is chemical change to the products run through the ion exchange process, please provide rationale for this belief.

Vote in Subcommittee

Motion to accept the Ion Exchange Filtration Process and Materials Used discussion document
Motion by: Harriet Behar
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent 1 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOSB January 7, 2020

National Organic Standards Board
Crops Subcommittee
Petitioned Material Discussion
Fish Oil annotation change

Summary Work Agenda:
In May 2019, the NOSB requested an annotation for Fish Oil to address environmental concerns be added to its work agenda. Specifically, The NOSB request stated:

> During the sunset review of Fish Oil at the Spring NOSB 2019 meeting the NOSB asked for comment on how to address environmental and conservation concerns raised about the manufacturing of Fish Oil. Public comment was received validating these concerns as well as suggesting annotative language to address this area of concern. These annotations were proposed by industry, trade associations as well as interest groups. The handling subcommittee would like to request a work agenda item to propose an annotation to Fish Oil to address environmental concerns.

In August 2019, the NOP agreed to add the annotation work agenda item to address environmental impact of harvesting of fish directly for their oil. Specifically, the NOP stated:

> You have requested to review the current listing of fish oil and develop recommendations to address the environmental impact of harvesting of fish directly for their oil. Please limit your work to this topic; this work agenda item does not include the organic certification of fish (i.e. aquaculture or wild seafood standards). In your review, please consider how your recommendations would align with other Federal regulations addressing fish harvesting.

Citations:

OFPA § 6517. National List
(c) Guidelines for prohibitions or exemptions
(1) Exemption for prohibited substances in organic production and handling operations
The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—
(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—
(i) would not be harmful to human health or the environment;

OFPA § 6518. National Organic Standards Board
(l) Requirements
In establishing the proposed National List or proposed amendments to the National List, the Board shall—
(1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;

OFPA § 6518. National Organic Standards Board
(m) Evaluation
In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall 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.

7 CFR 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

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

Summary of Review:
Fish oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report (TR) or Technical Advisory Panel Report (TAP). The NOSB 2007 recommendation indicated that the OFPA criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the NOSB final recommendation from May 9, 2007, stated …"pursuant to the judgment in Harvey v. Johanns, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed at § 205.606." These criteria were finalized in the NOSB "Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606" of October 19, 2006. "That recommendation allows for pro-active listing on § 205.606 of materials that may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather, or trade-related issues. "…. After discussion, the Board decided to add an annotation to the recommendation to list fish oil to the National List. The annotation is "stabilized using only allowed ingredients on the National List." The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market." The NOSB (2007) further noted that "There were no public comments specifically opposing the listing of fish oil on §205.606…."

While the NOSB has submitted several recommendations on organic aquaculture standards the NOP has not proceeded with rulemaking on these recommendations. At this time organic fish and therefore organic fish oil cannot be produced under the USDA organic regulations. If fish oil is to be used by organic food manufacturers it must remain on the National List.

In subsequent sunset reviews in 2015 and 2019, public comment indicated that the listing as is left room for concern based on how the fish for the fish oil were harvested. Sustainability of fishing is not a fringe concern and the U.S. has been a leader in managing sustainable fishing. The management of U.S. Fisheries is primarily governed by the Magnuson-Stevens Fishery Conservation and Management Act of 1976. This act recognized the need to manage fisheries to ensure fish stocks would be able to continually produce without depletion. Specifically, it sought to prevent overfishing, rebuild overfished stocks, increase long-term economic and social benefits and ensure a safe and sustainable supply of seafood. NOAA fisheries manages this program and states "U.S. fisheries are scientifically monitored, regionally managed, and legally enforced under 10 national standards of sustainability. Managing sustainable fisheries is a dynamic process that requires constant and routine attention to new scientific information that can guide management actions. Fish and shellfish are renewable resources—they can reproduce and replenish their populations naturally. Because of this, we can sustainably harvest fish within certain limits without depleting the resource. Fishery management is the process of using science

to determine these limits—some fish are caught while some are left to reproduce and replace the fish that are caught." As part of its regulatory duties, NOAA maintains a Fish Stock Sustainability Index. In this index fish stocks by region are classified as:

> Overfishing – The annual rate of catch is too high.
> Overfished – The population size is too small.
> Rebuilt – A previously overfished stock that has increased in abundance to the target population size that supports its maximum sustainable yield.

In its 2018 report to Congress, NOAA noted 28 fish stocks on the overfishing list and 43 stocks on the overfished list.

The United Nations Food and Agricultural Organization (FAO) similarly recognizes the concerns around over exploitation of fish. In its 2016 report, FAO recognized that overfished stocks had increased from 10% of total stocks in 1974 to 33.1% in 2015. The FAO similarly classifies fish stocks around the world. Their definitions include:

> Underexploited Undeveloped or new fishery: Believed to have a significant potential for expansion in total production.
> Moderately exploited: Exploited with a low level of fishing effort. Believed to have some limited potential for expansion in total production.
> Fully exploited: The fishery is operating at or close to an optimal yield level, with no expected room for further expansion.
> Overexploited: The fishery is being exploited at above a level which is believed to be sustainable in the long term, with no potential room for further expansion and a higher risk of stock depletion/collapse.
> Depleted: Catches are well below historical levels, irrespective of the amount of fishing effort exerted.
> Recovering: Catches are again increasing after having been depleted.

Proposed Annotation Discussion
Significant U.S. regulation and International regulation exists to address the environmental concerns of overfishing. In addition, there are numerous private standards established to monitor fishing, including but not limited to: Marine Stewardship Council, Friend of the Sea, Global Standard for Responsible Supply (IFFO RS), and Sustainable Fisheries Partnership. While these private standards may be sufficient to address potential environmental concerns related to fishing, the use of sufficient and recognized national and international standards are preferred not only for their clear legal definitions but also from an enforceability perspective.

We recommend adding three elements to the current fish oil annotation. This first element would state:

1. **Sourced from fishing industry by-product only.**

This would restrict the use of fish caught directly for the sole use of its oil to that of byproducts only. In public comment in 2019 it was noted by industry and trade associations that fish oil is always a byproduct due to economics but this remains a concern by other environmental groups. This restriction was supported by members of the fish oil industry and would make clear that fish oil must be a byproduct.

2. **Where within NOAA's jurisdiction, only from fish species and regions not listed on NOAA's current "Overfishing" or "Overfished" list.**

NOAA has jurisdiction of sustainable fishery management within U.S. waters and therefore it's prudent to defer to NOAA's expertise and classification of species. This work is ongoing, updated quarterly and reported to congress annually. The classifications are available publicly and are easily verifiable. We are recommending prohibiting fish oil from fish species and regions that appear on NOAA's "overfished" and "overfishing" lists. While NOAA regulations restrict fish practices of these stocks in order to rebuild stocks – the high bar for avoiding environmental harm set in OFPA aligns with prohibiting fish oil produced from these stocks from being used in organic products – this would then allow for products within the maximum sustainably yield (MSY) or rebuilt stocks to be used in organic foods.

3. Where outside NOAA's jurisdiction, only from fish species and regions not listed on FAO's "Overexploited," "Depleted," or "Recovering."

Where NOAA doesn't have jurisdiction, we recommend defaulting to similar classifications issued by FAO. FAO's "overexploited," "depleted," and "recovering" classification similarly class fish stock above and beyond their maximum sustainable yield. This annotation was also proposed and supported by members of fish oil industry.

The proposed annotation, in totality, would read:

> 205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. *Sourced from fishing industry by-product only. Where within NOAA's jurisdiction, only from fish species and regions not listed on NOAA's current "Overfishing" or "Overfished" list. Where outside NOAA's jurisdiction, only from fish species and regions not listed on FAO's "Overexploited," "Depleted," or "Recovering"*

Questions:

1. Are these requirements sufficient, insufficient or overly burdensome to mitigate environmental concerns from the overexploitation of fishing?
2. Are there conflicts between the FAO and NOAA classifications of fish stocks that would make using both lists difficult?
3. Are these requirements clear and enforceable?
4. What impacts would these requirements have on the availability of fish oil for organic products?

Citations:

2019 Fall Sunset Review – Fish Oil, NOSB
Public Comments Fall 2019 NOSB meeting
https://www.fishwatch.gov/sustainable-seafood/managing-us-fisheries
https://www.fisheries.noaa.gov/national/2018-report-congress-status-us-fisheries
http://www.fao.org/3/I9540EN/i9540en.pdf
http://www.fao.org/newsroom/common/ecg/1000505/en/stocks.pdf

Subcommittee Vote:

Motion to accept the discussion document on fish oil.
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Sunset 2022
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 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 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
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2020 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2020 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 3, 2020 as explained in the meeting notice published in the Federal Register.

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

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

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

For Comments That Support Substances Under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

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

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

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

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

For Comments on Nonorganic Agricultural Substances at Section 205.606.
For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 3, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 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 606
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

Background from Subcommittee:
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

Discussion:
There is no technical report (TR) or technical advisory panel report (TAP) available for this material. Public comment from the 2015 sunset review was limited to a trade association representing the juice industry, a certifier, and a manufacturer who stated that Kaolin was essential for filtering organic juices. No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by Subcommittee:
1. Is this material essential to organic production?
2. Are there possible alternative materials?

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

Background from Subcommittee:

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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

Is there any new information related to environmental concerns, human health, or use that would cause this substance to be considered for delisting?

Waxes (Wood rosin) (sic. resin)

Reference: (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR - Wood Rosin
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation: 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

Background from Subcommittee:

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)

Additional information requested by subcommittee:
1. Is this material essential to organic production?
2. Are there possible alternative materials?

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

Background from Subcommittee:

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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Is there any new information related to environmental concerns, human health, or use that would cause this substance to be considered for delisting?

2. Are there any other organic uses that, in the future, should be considered for listing beyond the annotation for leavening?

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

Background from Subcommittee:

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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Is there any new information related to environmental concerns, human health or use that would cause this substance to be considered for delisting?

2. Are there any other organic uses that, in the future, should be considered for listing beyond the annotation for leavening?

Calcium phosphates (monobasic, dibasic, and tribasic)

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
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

Background from Subcommittee:
Use:
Calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminum 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, 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.

Discussion:
All phosphates were reviewed in 2016. public commenters noted concern with the use of phosphates in production of processed foods and that phosphorus may not appear on the nutritional panel making it difficult to be informed, although phosphates would appear on the ingredient list. In particular there were concerns about the cumulative health impacts of phosphorous additives in food and in 2015 the NOSB requested a technical review and work agenda item to study this issue further. Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contributed to renal damage and failure, osteoporosis and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal renal function, from cumulative phosphorus. A daily limit of 70 mg/kg/day was recommended in one study. Populations are at risk for bone health, and kidney failure were especially impacted. In 2016 the NOSB Handling Subcommittee published a discussion document on the cumulative health impacts of phosphates and the NOSB decided to address phosphates individually during sunset reviews. Sodium phosphate was reviewed in 2017 and the NOSB came to 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 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 long-term cumulative impacts are not fully understood.

Additional information or questions requested by Subcommittee:
Is calcium phosphate still in use and in what applications?

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

Background from Subcommittee:

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 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 O3. 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 O2, breaking down in the lower atmosphere to O2 (dioxygen). Ozone's odor is reminiscent of chlorine, and detectable by many people at concentrations of as little 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 carona 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 uses 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 EPA, ozone exposure in the air we breathe can be harmful to human health and the environment. However, the application of ozone directly into water as a disinfectant minimizes this exposure. Once introduced into water, ozone decomposes into elemental oxygen in a brief amount of time. Exposure to atmospheric ozone generated from on-site production can be minimized through equipment maintenance.

Discussion:
The most recent Technical Advisory Panel report (TAP) dates to 1995 and does not include the degree of detail of more recent Technical Reports (TR). The Subcommittee suggests that NOP contract an updated ozone TR in advance of the next sunset review.

Additional information or questions requested by Subcommittee:
Are there any commercially available alternatives to ozone that warrant its removal from the National List?

Sodium hydroxide

Reference: 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.
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

Background from Subcommittee:

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.

Discussion:
The TR states there are no alternatives which provide the desired browning properties of pretzels. Baking soda can be used, but is not sufficiently alkaline enough 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 an 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, with each type of alkalizing agent resulting 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.

Additional information or questions requested by Subcommittee:

1. Is this product still needed in the processing of organic products?
2. Are there any nonsynthetic alternatives to this material with the same functionality?

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

Background from Subcommittee:

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 as 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 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.

Additional information requested by subcommittee:

1. Since this material is available organically, does it need to remain on the National List?
2. Are there barriers to obtaining organic carnauba wax in the needed form or quantity?

Colors - Beet juice extract color, 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)
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

Background from Subcommittee:

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 on the agricultural lists – 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.

Discussion:
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 powder 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.

Additional information or questions requested by Subcommittee:

1. Why types of organic products are currently using each color listed, and are powdered or liquid forms used?
2. Going color by color, have you been able to source organic forms of each color - if not, what has been the barrier?
3. Manufactures of colors: What colors can be readily produced organically today? For those that cannot, what are the barriers?
4. On a color by color basis, are both powdered and liquid forms of each color available organically if both forms are needed by processors?
5. Which colors are not available in sufficient organic quality or quantity and should be relisted?

Glycerin

Reference: 205.606 - produced by hydrolysis of fats and oils.

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

Background from Subcommittee:

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 a 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 non-agricultural form of glycerin. 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.

Discussion:
In 2012 the NOSB received a petition to remove Glycerin from §205.605(b) and 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 rule making on the NOSB recommendation, moving Glycerin form 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)"

Additional information or questions requested by Subcommittee:

1. What are the barriers to sourcing organic glycerin?

2. Glycerin is often labeled as 99% pure. What is the 1%? Are ancillary substances present in glycerin? If so, what are they?

Inulin-oligofructose enriched

Reference: 205.606 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

Background from Subcommittee:

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

Manufacture:
IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin, however, 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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Is inulin-oligofructose, enriched still in use in certified organic products, and if so what types of products?
2. Are alternative organic forms available?
3. Is organic inulin + conventional FOS (already listed at §205.606) an acceptable alternative in product formulations? If not, why?

Kelp

Reference: 205.606(m) Kelp—for use only as a thickener and dietary supplement.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB recommendation; 10/2010 NOSB sunset recommendation; 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

Background from Subcommittee:

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:
Allowed in *Canadian General Standards Board Organic Production Systems* under aquatic plants and aquatic plant products, Table 4.2.
European Union Annex IX 1.1.3 Algae, including seaweed, permitted in non-organic foodstuffs preparation.
Japanese Agricultural Standard (JAS) for Organic Plants-Dried Algae, including the powdered form.

Ancillary Substances:
N/A

Environmental Issues and Human Health Impacts:
Kelp is a renewable resource. It is also a keystone species, and there are concerns over responsible harvesting 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 Subcommittee would like more information on the impact of harvesting on kelp populations. There are also concerns over contamination of kelp from ocean radiation.
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.

Additional information or questions requested by Subcommittee:

1. Are there organic supplies of kelp available? If so, is there enough organic supply available to meet commercial demand?
2. How is the use of organic kelp in livestock production different from uses for human consumption?
3. Are there sufficient 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 needs of kelp as a thickener and dietary supplement?

Orange shellac

Reference: 205.606(r) Orange shellac-unbleached (CAS # 9000-59-3).
Technical Report: 2002 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 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

Background from Subcommittee:
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 is it 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 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 give high gloss. Zein is a protein of the prolamine group occurring in maize and used in fruit 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 various factors, including shine, permeability, cost, etc.

Additional information or questions requested by Subcommittee:

1. Please provide any information on ancillary substances that may be part of organic shellac formulations used in organic products.
2. Is this product still needed in the processing of organic products?
3. What are the barriers to producing this agricultural product as organic?

Starches: cornstarch

Reference: 205.606(v) Starches.
(1) Cornstarch (native).
(2) Sweet potato starch - for bean thread production only.
Technical Report: 1995 TAP - Cornstarch
Petition(s): N/A – Cornstarch; 2007 Petition - Sweet Potato Starch
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset 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

Background from Subcommittee:

Use:
From the 2017 review: "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."

Manufacture:
As described in Wikipedia, 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 13 suppliers of "cornstarch", including 12 in the United States. Cornstarch is listed under §205.606, so non-organic material can be used only when organic cornstarch is not available. The Handling Subcommittee requests public comment on the need to list cornstarch under §205.606.

Additional information or questions requested by Subcommittee:

The Handling Subcommittee requests public comment addressing the following questions:

1. Are there adequate organic sources of all types of cornstarch for food processing and production so this material can be removed from §205.606?
2. If not, please identify which types of cornstarch are not available organically and describe their use and the impact of removal from §205.606?
3. If any types of essential cornstarch are not available organically, please describe barriers to producing this material and any steps to promote organically sourced product.
4. Is there a risk of cornstarch derived from GMO corn contaminating materials used for producing organic products?

Starches: sweet potato

Reference: 205.606(v) Starches.

(1) Cornstarch (native).

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

Technical Report: 1995 TAP - Cornstarch

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

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset review Sweet potato starch; 10/2015 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

Background from Subcommittee:

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 requests 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.

Additional information or questions requested by Subcommittee:

1. Please provide more detail on the manufacturing steps to produce sweet potato starch.
2. What organic products is this material being used in?
3. Are there adequate sources of organic sweet potato starch to meet existing market demands?
4. What are the barriers to obtaining organic sweet potato starch and how can these barriers be overcome?

Turkish bay leaves

Reference: 205.606(x) Turkish bay leaves.
Technical Report: N/A
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 recommendation; 10/2010 NOSB sunset recommendation; 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

Background from Subcommittee:

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."

Additional information or questions requested by Subcommittee:

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for Turkish bay leaves in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.

2. Has the industry made progress in its efforts to locate organic sources of whole and ground Turkish bay leaves? What specific efforts have been made and what degree of success has the industry had?

3. Are there other ingredients with suitable flavor profiles that could be used in place of Turkish bay leaves, given adequate transition time for ingredient inventory and label depletion?

4. In what organic products is non-organic Turkish bay leaves currently used, and what are the specific reasons for its necessity in these products?

Whey protein concentrate

Reference: 205.606(z) Whey protein concentrate.
Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 05/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 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

Background from Subcommittee:

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. 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.

Discussion:
During the last review, the NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, (5) use in the industry. 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.

Additional information or questions requested by Subcommittee:

1. Are there any forms of whey protein concentrate that are not available organically beyond what has been found in the NOP Organic Integrity Database?

2. If yes, what are the barriers to producing that whey protein concentrate or other whey products in an organic form, since it appears there are many manufacturers of raw liquid whey from both cow and goat suppliers and numerous manufacturers are currently certified and capable of making a variety of organic whey products?

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Discussion Document
Fenbendazole

Summary of Petition:

A petition requesting a revision to the annotation for fenbendazole to expand the use to poultry was submitted to the NOSB in July 2019. The petition requests an annotation to 7 CFR §205.603(23)(i) to include laying hens and replacement chickens intended to become laying hens.

Background of Current Listing:

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

> *(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 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.*

The NOP issued a final rule with an effective date of January 28, 2019, with the following language:

> *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. AMS has reviewed and agrees with the NOSB recommendation that the annotation for fenbendazole be amended to clarify its use in organic livestock production.*
>
> *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:

Add this definition to 205.2

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.

To date, the NOP has taken no action on this NOSB recommendation.

Summary of Review:

The Livestock Subcommittee reviewed the petition seeking a revision to the annotation of fenbendazole to expand the use of fenbendazole to include use in laying hens and replacement chickens intended to become laying hens. The Subcommittee requested a technical report (TR) after the Fall 2019 NOSB meeting. The TR is currently in development and is expected back in the summer of 2020.

With the shifting demand for eggs from hens with humane certifications of Free Range or Pasture Raised production models requiring 2.0-108.9 square feet per bird of outdoor access, many laying hen flocks are seeing large internal parasite infestations. When birds are out grazing, they are scratching and digging in the dirt for worms and in return picking up intestinal parasites. Intestinal parasites can cause issues such as lower feed absorption, increased mortality, parasite transmission into the egg, and disease transmission to the hens.

Currently poultry producers use a diatomaceous earth product to help control intestinal worms. There are several concerns with this product including amount needed to be ingested in relation to daily feed intake (non-balanced diets), worker and animal health hazards (respiratory concerns) and many producers feel that diatomaceous earth does not control severe parasite infestations.

If fenbendazole is added to the National List for laying hens and replacement chickens, it would only be allowed for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Producers and certifiers would need to work together to define what an emergency is for each producer. The Subcommittee discussed several potential instances such as if internal parasites are seen during routine posting or autopsy sessions of flocks or parasites are observed

in manure droppings. The Subcommittee felt strongly that fenbendazole should only be used in emergency situations and not on a routine basis.

Even though the current listing for fenbendazole for cattle, sheep, goats, and other dairy species lists withdrawal times, the Subcommittee is not suggesting a withdrawal time for the use of fenbendazole on poultry. During the review of fenbendazole's use as an approved animal drug the FDA did not require a withdrawal time on the label for poultry as compared to other animals. "The data in study #S12173-00-DWF-MET-PO show that total residues of fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs."[1]

Use of the Substance:

- 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 (replacement layers age 0-17 weeks of age) or before outdoor access is given to birds to ensure birds have no internal parasites before starting eggs 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 of time when birds have access to the soil and come into contact with many internal parasites. Organic producers will need to utilize preventative management practices defined in their Organic System Plan as a first line of defense for internal parasites, and if those preventative practices fail an emergency treatment of fenbendazole may be required to control internal parasites.

Mode of Action:
Fenbendazole binds to β-tubulin, inhibiting assembly of microtubules, resulting in cell and parasite death. 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)

Questions:

1. Is fenbendazole needed by organic poultry producers? If so, why?
2. Do currently allowed alternatives work to control internal parasites? At what level of effectiveness?
3. What would be some of the "emergency" events that would trigger use of this product? And how would producers determine those events?
4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

[1] https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/3083

Sunset 2022
Meeting 1 - Request for Public Comment
Livestock Substances §§ 205.603 & 205.604
April 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
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2020 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2020 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 3, 2020 as explained in the meeting notice published in the Federal Register.

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

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

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

For Comments That Support Substances under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

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

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

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

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 3, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 1 - Request for Public Comment
Livestock Substances §§ 205.603 & 205.604
April 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

Background from Subcommittee:

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.

Additional information or questions requested by Subcommittee:

1. Is butorphanol considered the preferred choice for its use at this time, or are there other options?
2. Are there nonsynthetic materials that would serve the same purpose as Butorphanol?

Flunixin

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

Background from Subcommittee:

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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Is flunixin, listed in §205.603(a), still deemed necessary for organic livestock production?
2. Are there other non-synthetic materials that would serve the same purposes as flunixin?

Magnesium hydroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(15) 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

Background from Subcommittee:

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.

Discussion:
Based on prior Subcommittee review and public comments, the NOSB found magnesium hydroxide compliant with OFPA criteria, and did not recommend removal from the National List.

Additional information or questions requested by Subcommittee:
None

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(21) 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

Background from Subcommittee:

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 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."

Additional information or questions requested by Subcommittee:

1. Are organic approaches to dealing with bloat (e.g., use of oils) sufficient to address this healthcare issue or is poloxalene an essential tool for organic livestock production?
2. Is poloxalene consistent with the OFPA criteria and the organic regulations?

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(2) 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

Background from Subcommittee:

Use:
Formic acid has been registered by the EPA as a pesticide since 1999 to control varroa and tracheal mites in honeybee. It is formulated into a pad that is placed in the hive and as the formic acid volatilizes the vapors kill the mites attached to bees, inside bees and in some cases in uncapped and capped brood cells. The mites die of asphyxiation, and they fall of the bees after exposure to the formic acid fumes. The lifespan and behavior of the honeybees are not negatively affected by the treatment. Mite mortality from formic acid treatment can be as high as 95%. Formic acid is present in nature in the stings and bites of many insects including ants and bees, and found in some nectars and fruits of plants including coffee and nettles. The natural form of formic acid is not available in sufficient quantities for commercial use. Its other uses include processing latex sap into rubber, or can be used to remove limescale as well as other uses in the textile industry as well as an antibacterial agent and preservative in livestock feed. Formic acid is an alternative to synthetic pyrethroids and organophosphates that have been used to kill mites. Label use requirements require no honey supers can be used on the hive during the 21-day treatment period. Honey supers may be placed on the hive after the 21-day treatment period and the formic acid gel pack has been removed. The honey in these supers cannot be extracted for harvest sooner than two weeks after placing on the hive. Formic acid can be used after honey supers have been removed from the hive at the end of the honey collecting season.

Manufacture:
Formic acid is produced through the hydrolysis of methyl formate, which also produces methanol. The methanol and carbon monoxide are combined with a strong base such as sodium methoxide, in the liquid phase and at elevated pressure to produce methyl formate. The methyl formate is then hydrolyzed to produce formic acid. Formic acid is also produced as byproduct in the manufacture of other chemicals, such as acetic acid, but this production is insufficient to meet demand, and so the first method is used as well to meet market demand.

International Acceptance:
Allowed by Canadian Organic Standards with a 30-day withdrawal time between use and addition of honey supers on the hive, as well as for organic silage preservation. The European Economic Community Council Regulation Organic Standards allows formic acid to be used to control varroa mite in honeybee hives as well as for silage preservation. The FDA considers formic acid "generally recognized as safe" GRAS (21CFR 186.1316). It is permitted to be used in the feed and drinking water of nonorganic livestock, as well as a flavoring agent in human consumed beverages and foods at permitted concentrations (21 CFR 573.480).

Ancillary substances:
Mite-Away Quick Strip lists the product as containing 46.7% formic acid and 53.3% inert ingredients. The only other information that was available, was that the formic acid is impregnated into a gel encased in a plastic wrap.

Environmental Issues:
Honeybees can produce minute levels of formic acid and it is found naturally in honey. Since formic acid is used only within the hive, no residues of formic acid are found outside the hive and no negative effects on the environment have been found when used according to package instructions. Plants can be killed when exposed to high concentrations of formic acid. Human health can be negatively affected through oral ingestion or inhalation, and it is highly irritating to the respiratory tract, eyes and mucous membranes of the mouth and throat. Chronic skin contact may cause sensitization dermatitis. The label requires the use of personal protection equipment including coveralls, long sleeve shirt, long pants, socks and shoes, acid resistant gloves and protective eyewear. A respirator is required only if working with the formic acid product indoors. Beekeepers typically wear protective equipment around their hives to prevent stings, even when not applying formic acid.

Discussion:
The introduction of the non-native varroa mites and tracheal mites to North American honeybees in the 1980s has been devastating to both domestic and feral honeybees. While hygienic behavior can be encouraged through breeding, and bees then do what they can to clean themselves and remove the mites, this breeding activity is insufficient to control these destructive parasites. Use of screened bottom boards where mites drop off bees and cannot crawl back into the hive, drone trap frames where mites tend to congregate and then removal before the drone brood hatches, and various types of essential oils including thymol can all be used to lessen mite populations, but these strategies are insufficient to control the mites to acceptable levels. Major losses of honeybee colonies are attributed to these two parasites. Oxalic acid was recently recommended by the NOSB to be added to the National List as another control for formic acid, and can be used in package bees (formic acid cannot) as well as in rotation with formic acid to prevent mite resistance. There is concern that a product that addresses organic apiculture production should not be on the National List since there are no NOP apiculture standards.

Additional information or questions requested by Subcommittee:
1. Are there natural sources of formic acid that are commercially available to beekeepers for use in their hives?
2. Are there other natural products that are effective in controlling varroa and tracheal mites in honeybees, that would make formic acid no longer necessary in organic production?
3. When formic acid is used in the hive as a miticide, would there be higher than the natural levels of formic acid in the propolis, royal jelly, or beeswax?

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 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

Background from Subcommittee:

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

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

International:
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.

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.

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, herbicide and fungicide 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.**

Additional information or questions requested by Subcommittee:

1. How can the Safer Choice Program be used to evaluate inerts? How can the Board help facilitate this in moving forward?
2. If the NOSB and NOP use the Safer Choice Program, would *all* inerts reviewed and approved by Safer Choice be allowed? Would only certain criteria established by Safer Choice or those criteria established by an MOU with the NOP be allowed?
3. How should the NOSB establish review criteria based on the Safer Choice Program while also ensuring it is consistent with OFPA criteria and the regulation?
4. If Safer Choice is not the ideal path forward, or a formal relationship with EPA cannot be established, how should the Board proceed with addressing inerts?
5. Should the Board focus on inerts of greatest toxicity? If so, how should the Board identify and prioritize these for review?

Excipients

Reference: §205.603(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application
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 Date: 3/15/2022

Background from Subcommittee:

Use:
There are more than 8,000 food, drug, and cosmetic excipients available to conventional production; however, excipients currently appear in the USDA National Organic Program (NOP) regulations at §205.603 only 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; or 3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application. In 2009, the National Organic Standards Board (NOSB) recommended a fourth criterion for their allowance: “Approved by APHIS” for vaccines.

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."

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.

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.

Discussion:
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.

Additional information or questions requested by Subcommittee:

1. Are excipients listed in §205.603(f) still deemed necessary for organic livestock production?
2. How are excipients currently being reviewed in livestock health products by the certifiers?
3. Since the previous TR and NOSB Subcommittee reviews, has there been any further research completed to document environmental or health issues that would justify removing excipients used in organic production?
4. Are there any specific excipients that cause more concern to the public than others? If so, how should the review of those excipients be addressed separately?

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

Background from Subcommittee:

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, 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 Livestock 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 Livestock Subcommittee and the full NOSB voted to not remove strychnine from §205.604, non-synthetic substances prohibited for use in organic crop production.

Additional information or questions requested by Subcommittee:
None

USDA National Organic Standards Board
Research Priorities Discussion Document
Spring 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 products.
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. NOSB October 2019 proposals and discussion documents Page 121 of 230
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 Discussion Document
2020 Research Priorities
February 9, 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 and have updated those priorities based on written and oral public comment received leading up to and since that meeting. The topics listed below are the 2020 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:

Livestock

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; and (3) assessment of management practices for improving existing organic poultry welfare under different conditions. 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, 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, or other alternative treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures 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 to 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

[1] Policy Memo 15-1

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 (*new in 2020*)
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:

- 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 (*new in 2020*)

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 can 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 various nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, and subsequent planting time of the cash crops. This topic asks researchers to examine farm fertility needs using cover crops as the primary form of nutrient delivery.

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 (*new in 2020*)
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 (*new in 2020*)
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 (*new in 2020*)
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 (*new in 2020*)

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 (New in 2020)
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.

2. 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 accept the 2020 research priorities discussion document
Motion by: Dan Seitz
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Dave Mortensen, Materials Subcommittee Chair, to transmit to NOSB February 11, 2020