National Organic Standards Board Meeting
Intercontinental Saint Paul Waterfront Hotel, Saint Paul, MN
October 24-26, 2018

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USDA National Organic Standards Board
Research Priorities, 2018

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. The topics listed below are the 2018 priorities.

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 biobased mulch film.
2. Organic no-till practices for diverse climates, crops, and soil types.
3. Plant disease management, including alternatives to antibiotics for fire blight in fruits, alternatives to copper, and research into disease-resistant varieties and biopesticides.
4. Mitigation measures for pesticide residues in compost, including identification of problematic feedstock.
5. Strategies for the prevention, management, and control of invasive insects.
6. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
7. Examination of the factors influencing access to organically produced foods.
8. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.
9. Side-by-side trials of organic synthetic materials, natural materials, and cultural methods, with a request for collaboration with the IR4 project.

Coexistence - 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. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
4. Testing for fraud by developing and implementing new technologies and practices.

Food Handling and Processing

1. Comparison of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.
3. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

National Organic Standards Board
Materials Subcommittee Proposal
2018 Research Priorities
July 24, 2018

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 propose the priorities at the Fall Board meeting and reflect both written and oral public comments received by the Board. The topics listed below are the 2018 priorities.

BACKGROUND

Research needs are prioritized along the following criteria: 1) persistent and chronic, 2) challenging, 3) controversial, 4) nebulous, 5) lacking in primary research, and 6) relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List[1].

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: 2018 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 that 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 full 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

[1] The National List of Allowed and Prohibited Substances identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies a limited number of non-organic substances that may be used in or on processed organic products. The NOSB advises the National Organic Program (NOP) on which substances should be allowed or prohibited.

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 20 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 Biobased Mulch Film

This type of mulch film was recently approved by the NOSB but did not include a specific percentage of biobased components it must contain. In 2015, NOP issued a Policy Memo[2] that states that certifiers and material organizations should review biodegradable biobased mulch film products to verify that all of the polymer feedstocks are biobased. This requirement makes biobased mulches unavailable to organic producers, due to the petroleum-based polymers 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 would be useful to develop more clarity on mulch films and possibly develop an additional annotation to address any concerns:

- How rapidly do these mulches fully decompose, and does the percentage of the polymers in the mulch film affect the decomposition rate? Are there metabolites of these mulches that do not fully decompose?
- Are there different cropping systems, climate, soil types, or other factors that affect the decomposition rate?
- What type of 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?
- Does the use of these synthetic polymers over time affect the balance of soil biology?
- Is there any cumulative effect if this mulch film is used 3-5 years or more in the same location?
- Are the testing regimens available adequate to meet the decomposition standards in our definition and to validate the non-GMO status of source materials?
- Even though petroleum-based polymers may be developed so they are consumed completely by the microbiological life in the soil, is the balance of various nutrients and/or biological life different from the decomposition of biologically-based materials? Is there any comparison between decomposing petroleum-based polymers and the effects that petroleum based fertilizers and other inputs have on soil biological life in nonorganic agricultural systems?

2. Organic No-Till

Organic no-till, using a terminated cover crop for in-place mulching, 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. There can also be some challenges from organic no-till using a cover crop, such as occasional insect infestation associated with the cover crop.

Even though this killed-in-place mulch practice has been used for more than a decade, widespread adoption has not occurred. 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.
- Which mulch crops, systems, and timing of practices provide specific weed management benefits to support crop growth and yield?

[2] Policy Memo 15-1

- Research on various techniques that would provide a variety of options for diverse cropping systems including but not limited to: strip tillage within a killed mulch, mowing or other organically approved techniques versus rolling to terminate the cover crop, and living mulches in standing crops.
- Development of systems that allow for either continuous no-till organic crops or for multiple years of organic no-till in the crop rotation.
- How does the lessened soil disturbance of this system contribute to pest, weed, and disease management?
- What specific insect 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?
- How can the use of this system be managed to improve water infiltration and retention in annual and perennial cropping systems.
- What are the biodiversity benefits to these living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Does this system 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?

Finally, many organic farmers successfully employ tillage with continual attention to building soil biological life. This is accomplished through minimal tillage and cultivation strategies, use of cover crops and compost, longer-term crop rotations that often include a fallow period, and other strategies. It should be recognized that it is difficult for many organic growers to adopt a complete no-till system, depending upon the crops grown and climate. As evidenced by the very healthy soil on many organic farms, even when tillage is engaged, much of the tillage damage can be mitigated. Additional research examining how farmers are protecting soil biology in both no-till and tilled systems is needed.

3. Disease Management

a) Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight

Prior to October 2014, oxytetracycline and streptomycin were allowed for the control of fire blight in apple and pear trees only. Since 2014, neither substance may be used in any organic practice. Organic apple and pear growers must now find suitable alternatives to control the deadly fire blight disease. Since apples and pears are grown throughout the United States in many regions, these alternatives must work in a variety of climates and management systems. The following research issues are important to investigate: location; planting density; choice of varieties of cultivar and rootstock; soil improvement practices; pruning practices and general sanitation; groundcovers or intercrops; pollinator management; dormant copper sprays; bloom thinning/lime sulfur; early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment; surveys for fire blight activity; and other cultural and preventative techniques.

b) Alternatives to Copper for Disease and Algae Control

Copper has been used for more than a century to control serious diseases in crops such as late blight in tomatoes and fire blight in pears. Because the copper products degrade to elemental copper, continued use over time can cause copper to accumulate in soil. If used improperly or to excess, copper can be toxic to aquatic life and wildlife.

Alternative materials are not yet available to address the many diseases and crops on which copper is used. 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.

c) General

There is a need for research into plant disease management practices and alternative materials, particularly for the humid areas of the country, that decrease reliance on copper or other substances that might have a negative impact on the soil and health of farmworkers. Genera of pathogens include, but are not limited to: *Alternaria, Erwinia, Pseudomonas, Xanthomonas, Cercospora, Colletotrichum, Cladosporium, powdery mildew, downy mildew, Phytophthora, Pythium, Mycosphaerella, Phomopsis, Taphrina, Elsinoe, Gnomonia, Fusicladium, Nectria, Phyllosticta, Diplocarpon, Albugo, Guignardia, Botrytis, Exobasidium, Entomosporium, Exobasidium, Pestalotia, Phoma, Cristulariella*, and *Monilinia*. For example, mildew on spinach in the West Coast is a serious problem, on that often leads to over planting by 10-20% to mitigate loss to disease.

Citrus greening, caused by the bacterium *Candidatus liberibacter*, and spread by a disease-infected Asian citrus psyllid, is an emerging problem. Promising avenues of research include disease-resistant varieties, predators and parasites and how they interact with approved materials, nutrition (calcium, boron, and nitrogen have been identified), and botanical oils.

A large body of research has shown that plant diseases caused by bacteria and fungi can often be prevented by the application of a non-pathogenic microorganism before infection occurs. Although much basic research has been done to identify microbial biological control agents, there is still a need for commercial development, field testing, and adoption by growers. Biological controls have been researched for late blight of potato and tomato (*Phytophthora infestans*), several diseases caused by *Botrytis cinerea*, and powdery mildew (several species) controlled by mites, fungi, and bacteria.

Biological materials are often more expensive than conventional pesticides, and they need be applied before disease is apparent. In the past, there was little market for biological controls because the organic acreage was limited. Now that organic acreage has increased, the market for alternative plant disease controls has also increased which can spur commercialization of natural methods of disease control. The availability of biological controls for plant diseases can also make it more feasible for conventional farmers to transition to organic, thus benefitting organic consumers.

4. Mitigation Measures for Residues in Compost

Residues of pesticides in compost material are a problem that requires research, according to the Organic Materials Research Institute or OMRI. Because of the importance of compost to organic management systems, research is needed on types of mitigation measure that are efficacious, identification of problematic feedstock (e.g. cotton-based materials and yard waste), types of corrective action, and if thresholds for allowable residues are established, testing guidelines are required. This is more important than ever with events of 2016 regarding contamination in compost.

5. Management and Control of Invasive Insects

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 that 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.

6. Nutrition in Organic Crops *(new in 2018)*

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.

7. Increasing Access to Organic Foods *(new in 2018)*

What factors influence access to organically produced foods? Individual-based studies are What factors influence access to organically produced foods needed to assess the constraints to access 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.

Note: The following two topics-- new in 2018-- were brought to the NOSB's attention by numerous stakeholder commenters during the public input process.

8. Organic Transition Barriers *(new in 2018)*

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.

9. Side-by-Side Organic Input Trials *(new in 2018)*

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.

Handling

1. Chlorine Materials and Alternatives

The three 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. New 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 quantity and use in wash tanks, including information about amount of time of exposure. Would this be 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. Celery Powder

Celery Powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (note: products must still be labeled “uncured”). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

3. 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.

<u>Materials/GMO</u>

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. 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.

4. **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.

Subcommittee Vote:

Motion to adopt the proposal on 2018 NOSB Research Priorities
Motion by: Emily Oakley
Seconded by: Tom Chapman
Yes: 5   No: 0   Abstain: 0   Recuse: 0   Absent: 2

Approved by Harriet Behar, Materials Subcommittee Chair, to transmit to NOSB on July 25, 2018

National Organic Standards Board
Materials Subcommittee Proposal
Genetic Integrity Transparency of Seed Grown on Organic Land
August 14, 2018

I INTRODUCTION

The USDA National Organic Program (NOP) regulations do not allow the use of "excluded methods" in certified organic production. The term "excluded methods" in the USDA organic regulations refers to organisms including seed, bacteria, insects, animals and vaccines that have been produced through genetic engineering. According to the most recent U.S. production information, at least 94% of soybean, 92% of corn, 94% of cotton, 75% of Hawaiian papaya, 98% of sugar beets and 90% of canola are genetically engineered. By contrast, less than 1% of crops grown in Europe are genetically modified, and that production is limited to a handful of countries in southern Europe. Nursery stock such as vegetables and fruit can also be genetically engineered (for example, the GE non-browning apple), as well as fish and pigs. A range of engineered traits exist; however, so-called "input traits" that make crops resistant to herbicides and plant incorporated protectants (for example Bt corn) account for the overwhelming majority of genetically modified crops under cultivation. As molecular genetic methods become more sophisticated, disease resistance, drought tolerance and other traits are expected to be packaged in with the input traits, a process referred to as "gene stacking."

II BACKGROUND

The National Organic Standards Board (NOSB), in separate recommendations in 2016 and 2017, defined terms used when describing gene altering technologies, and identified which technologies are to be considered excluded methods. These definitions are as follows:

Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position cited above)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)

Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)

Non-GMO – The term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding involves natural plant reproductive processes (*e.g.,* pollination) but relies on phenotypic selection, field-based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection. Furthermore, classical plant breeding does not bypass the plant's reproductive process.

In addition, the following criteria are used when determining if a technology should be excluded from organic production.

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements to the genome are refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.

2. The ability of a variety to reproduce in a species-specific manner has to be maintained, and genetic use restriction technologies are refrained from (e.g. Terminator technology).

3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.

4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes) are refrained from.

This list of excluded methods is continually being worked upon, but at the time of the writing of this proposal, the following technologies were recommended by the NOSB to be considered excluded methods:

- Sequence-specific nucleases (SSNs)
- Meganucleases Zinc finger nuclease (ZFN)
- Mutagenesis via Oligonucleotides
- CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes
- TALENs (Transcription activator-like effector nucleases)
- Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System

- RNA-dependent DNA methylation (RdDM)
- Silencing via RNAi pathway RNAi pesticides
- Reverse Breeding
- Genome Elimination
- FasTrack
- Fast flowering
- Creating new DNA sequences
- Synthetic chromosomes
- Engineered biological functions and systems
- Somatic nuclear transfer
- Plastid transformation
- Cisgenesis
- Intragenesis
- Agro-infiltration

Currently, in the U.S., testing is not required to verify if seeds planted on organically certified farms were produced using an excluded method. Organic farmers plant both organic seed and non-organic seed (when the organic seed is not commercially available in the form, variety or quantity they require). Some, but not all, certification agencies perform GE testing on finished product or seed, as part of their residue sampling program.

Farmers are required to provide documentation that the seed they use is not produced through excluded methods. If it is organic seed no documentation is required, since the seed supplier would have gone through their own organic inspection to verify excluded methods were not used in the production of that seed. For non-organic seed, a non-GE affidavit is required if the crop is one that has a genetically engineered equivalent in the marketplace. Affidavits typically state the seed was not produced through excluded methods, but they do not state if there is any contamination of the seed with genetic material from these prohibited excluded methods. Under the organic regulation, the presence of genetically engineered material within an organism is not considered noncompliant. Only the *intentional* use of a product produced by an excluded method would prevent that seed (or another organism) from being certified as organic. Non-GE affidavits have been accepted as proof by their organic certifiers that the seed is acceptable in organic systems.

It is known that seed at risk for genetic contamination, such as corn, has been found to have various levels of contamination. Some, but not all, seed suppliers test their seed lots to determine the presence of GE traits, and/or the level of contamination. Some, but not all, companies test, and they make this information available to their customers upon request or it may be publicly available in their catalogs or advertisements.

The organic marketplace, on the other hand, has developed a fairly robust testing protocol for both human and livestock feeds. Depending on the market being served, various tolerance levels of genetic contamination must be met in order to sell into that market. In most cases, the amount of GE contamination found in seed will be the baseline contamination level, and when the farmer grows this seed into a crop, that level will not be lower than the seed's contamination level. To meet organic market demand, and to provide farmers with what they need to make informed decisions when choosing seeds, transparency of GE contamination levels has become a necessity.

The NOSB put forth discussion documents on this subject in 2013, 2014, 2015, 2016 and 2017. Public comment has clearly shown this to be an important issue for organic farmers, processors, and consumers. In developing this proposal, the Materials' Subcommittee has considered the many written and oral public comments and has attempted to address these issues in a pragmatic way, employing systems that many seed suppliers and buyers are already using.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

NOP standards adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibit the use of excluded methods in the production and handling of organic products certified to national organic standards. The terminology used for Genetically Engineered or GMOs in the NOP Regulation, "excluded methods," is specified under section 205.2 (Terms Defined) as:

> ***Excluded methods***. *A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.*

At its October 2016 meeting, the NOSB passed a recommendation to update and clarify the definition of Excluded Methods. The definitions and criteria are described in the previous section.

Detection and Testing Requirements: Under the NOP residue testing requirements, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods. This requirement is specified in Subpart G (Administrative) of the regulations:

§205.670 Inspection and testing of agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

NOP Policy: The NOP issued a Policy Memo on April 15, 2011 (Policy Memo 11-13) on GMOs. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard, and the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

IV DISCUSSION and PUBLIC COMMENT

As noted above, this issue has been discussed by the NOSB and the public every year since 2013. The creation of a task force determining the extent of GE contamination of seed for all types of crops at risk of contamination has been requested by all sectors of the organic industry, including seed breeders, farmers, consumers and advocacy groups. To date, the NOP continues to consider this request.

In 2015, an invited panel of seed breeders presented testimony at the NOSB meeting, detailing the extent of seed contamination they have experienced. Statistical data of GE contamination of corn seed, and the significant negative economic impact this has had on their businesses was clearly described. They discussed how organic seed breeders take on the expense of GE testing, whereas nonorganic seed suppliers who sell to organic farmers, typically do not. This extra testing expense, as well as the destruction of seed lots with unacceptable levels of contamination, drives up the price of organic seed. These higher costs place the organic seed suppliers at a competitive disadvantage with nonorganic seed suppliers who are not transparent with their customers concerning possible GE contamination of their seed. As stated above, most nonorganic seed dealers state they did not use excluded methods in the production of their seed, but do not take the extra step to determine if there is presence of GE contamination.

Since there is an allowance for the use of non-organic seed when organic seed of an equivalent variety in the quality and quantity desired is not available, the risk of GE contamination of organic crops is increased. If a farmer starts out with GE contaminated seed, many of their defensive management tactics are ineffective in producing a GE free crop. The contaminated seed they plant will cross fertilize other cultivars of that crop on their farm and could result in compounding the contamination problem.

The issue of maintaining the genetic integrity of organic and non-organic seed, and planting stock grown on organic land and sold in the organic marketplace is complex. The marketplace demands some assurance quantifying the presence of GE in seed and crops, and has responded by instituting testing at various levels of the supply chain. Non-GMO labeling such as the Non-GMO Project does not guarantee 100% GMO free products, but has a 0.9% tolerance level allowed in foods for human consumption and a 5% allowance of GMO contamination in livestock feeds whose final product would then be labeled as non-GMO. The Non-GMO Project currently has a tolerance of 0.25% for seed.

Many organic farmers sell into markets that will test their at-risk crops for GE contamination, where entire grain loads are rejected if their level of GE contamination exceeds a specific tolerance level. Without transparency detailing GE contamination of seed, a farmer could spend the growing season using expensive organically approved inputs, expending the extra labor and time tending to their crops using organic methods, and end up with a crop that is rejected due to seed GE contamination. This crop would then typically be sold on the nonorganic market, even though it did not lose its organic certification. These economic losses are significant, and are occurring in crops where the U.S. needs to increase domestic organic production to reduce dependence on organic imports.

Several discussion documents and subsequent public comments addressed the issue of tolerance levels, testing and sampling protocols. Most seed suppliers and producers did not favor tolerance levels, due to concerns that this approach would narrow the availability of needed crop traits, and the overall crop choice. Concern was also raised that strict tolerance levels could result in the unintended consequence of causing damage to the growth and integrity of organic agriculture, as well as negatively impacting organic growers and seed breeders. However, all commenters felt contamination of organic seed and crops by excluded methods negatively affects the integrity of organic foods. Testing and sampling protocols are now widespread in the seed industry, with models that have clear statistical accuracy both in sampling procedures and testing.

V PROPOSAL DISCUSSION

It is important to move forward on these issues to provide certainty and clarity in the marketplace for those who grow seeds and those who buy and plant them. Transparency about GE contamination provides the confidence to those entering organic production, and can help increase the acreage of domestic organic crops. The NOSB Materials Subcommittee feels the proposal described below addresses numerous aspects of this complex subject.

Based on discussions with seed suppliers and testing laboratories, the requirements in this proposal mirror what is currently being done in the marketplace, and should not add significant cost for those already doing testing for GE contamination. Currently, there are in-house tests that cost less than a polymerase chain reaction (PCR) test and have statistical accuracy down to 0.9%. . These detection limits would be acceptable, but only when they meet the proposal's requirements, as noted below. The seed seller can make a choice to describe their seed as having at least a 0.9% level of purity, even though their seed may actually have been found to have a lower level if they had performed the more expensive PCR test. By not requiring specific types of tests or laboratories, this proposal allows for future improvement and innovation in testing for GE contamination, while at the same time requiring rigor and consistency.

The levels of purity chosen represent the various levels of GE contamination currently tested for in the marketplace on seed and finished crops. This transparency will allow farmers to decide which level of purity they are most comfortable choosing, in order to meet specific market demands for their final crop. Since field corn is the mostly widely tested crop for GE contamination, the Subcommittee suggests starting with this crop, and after a period of implementation, expand this to requirement to other at-risk crops.

The NOP can choose to maintain the information provided by certifiers detailing the levels of purity from GE contamination, and the location the seed was grown. Alternatively, the NOP can seek to contract this work out to an organic certification agency or a materials review organization. The NOP or an outside entity can develop a system by which certifiers will transmit this information, to enable certifiers to setup their internal systems to track and provide this information to the NOP. It is anticipated this information will be sent once per year to whatever entity is tracking the information. Since the information for this database does not contain the seed supplier, nor farmer name, privacy is preserved while providing the organic industry with important information to aid in development of benchmark low to no-detectable amounts of GE contamination in seed used on organic land.

The Materials Subcommittee believes this proposal is practical and would be feasible to implement within one or two years of the NOSB passage of a recommendation. There is sufficient existing testing infrastructure, the sampling protocols are clear and achievable, and the organic community could implement this rapidly since much of the procedures are already being done by organic seed suppliers. The main roadblock to implementation would be for nonorganic seed suppliers to begin this testing. Since the cost of organic seed already includes the fees paid for testing and would be required under this proposal, the extra cost added to nonorganic seed only serves to level the playing field between organic and nonorganic seed. Farmers would need to do the testing themselves if they choose to plant non-organic seed, however. They could also choose to purchase seed from suppliers that value the patronage of their organic customers and would maintain the transparency needed to establish the level of purity from excluded method contamination.

The initial focus of this proposal requires the sampling, testing, and documentation describing the level of purity from GE contamination of field corn seed, including the state/province/country of origin. Field corn seed was chosen since it is a high-risk crop, and is already widely tested in the marketplace. This proposal is intended to be a starting point, to learn how best to provide information to producers and track the contamination risk, while expending a limited amount of resources. It is anticipated that in the future similar, species specific protocols would be instituted for additional types of seeds at risk of GE contamination.

VI. PROPOSAL

1. A system of sampling, testing and transparency of findings of GE contamination on all field corn seed planted on organic land is required. Once this has been implemented for one or two years, other at-risk crops could be added.
2. We request the NOP develop an "Instruction to Certifiers" based upon this recommendation and place this in the NOP Program Manual.
3. All field corn seed lots planted on organic land, both organic and nonorganic seed, and whether sold or used to feed on-farm livestock, shall be tracked in the farm Organic System Plan (OSP) with information detailing the state/province and country of origin of the seed, as well as the level of purity from GE contamination. In addition, certified organic field corn seed suppliers must track these items in their OSPs. If nonorganic field corn seed is planted, the organic farmer is mandated to obtain the level of purity information, determined through approved protocols, and document this in their OSP. The organic farmer would need to have this test performed before planting each lot of nonorganic seed they purchase. This information can be supplied in the submitted OSP at the beginning of the crop year, or at the annual inspection.
4. Seed suppliers or farmers have the option of five levels of purity, determined through approved sampling and testing protocols.
   The detectable levels of purity from GE contamination for organic field corn seed are:
    a. 0.1% or less
    b. 0.25% or less
    c. 0.9% or less
    d. 5% or less
    e. Over 5%
5. Documentation that the testing and sampling met these requirements must be provided to buyers of the seed.

6. The level of purity must be included on the seed tag, or for bulk shipments, on the invoice or other sales document.
7. Testing must include all known GE traits available in that crop species.
8. Outside labs used for this testing must be accredited to ISO 17025.
9. The testing technology must be capable of providing accuracy within a 20% relative standard deviation of the target concentration of GE contamination.
10. If in-house testing is done, the equipment must be validated to have the accuracy required to declare the specific targeted level of purity from GE contamination. Additionally, personnel using the in-house equipment must have training and demonstrate proficiency on an annual basis, through the quantitative analysis of a blind sample.
11. Sampling protocols must be recognized as having at least a 90% statistical rate of accuracy for confidence in the quantification of GE presence. Sampling protocols, such as those performed by various state “crop improvement” agencies, would meet this requirement. Information on various state and international agencies that subscribe to these protocols and can explain these protocols can be found here. https://www.aosca.org/seed-certifying-agencies/

    An example of the seed sampling protocol, from the California Crop Improvement Association is here. http://ccia.ucdavis.edu/files/178676.pdf
12. Sampling must include a demonstrated method of achieving a homogeneous blend representative of the finished seed lot derived from the cleaned and ready-for-sale seed.
13. Sampling must be documented to illustrate the sample was sufficiently intact for valid PCR quantitative analysis.
14. Each lot of seed must be sampled and tested.
15. The certifier will keep track of this information and send this information to a central database, without the farmer or seed supplier information. This information would help the organic community gain a better understanding of the levels of seed purity from GE contamination used on organic land, as well as regional differences in seed production.
16. This GE purity testing and information transparency is required of all organic field corn seed suppliers and must be documented in the annual organic seed handler OSP. The organic field corn farmer would document the information from their organic field corn seed supplier in their OSP as well.
17. Organic farmers should retain samples of each lot of seed they planted for at least one year after their crop grown from this seed has been sold.

VI Subcommittee vote

Motion to approve the proposal on “Genetic integrity transparency of seed grown on organic land”.
Motion by: Dan Seitz
Seconded by: Harriet Behar
Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair to transmit to NOSB, August 20, 2018

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Method Determinations October 2018
August 14, 2018

Introduction and background

At the November 18, 2016 in-person NOSB meeting, the NOSB recommended that the National Organic Program (NOP) develop a formal guidance document for the determination and listing of excluded methods. This 2016 recommendation, entitled "Excluded Methods Terminology," clarified the excluded methods definitions and criteria in response to increasing diversity in the types of genetic manipulations performed on seed, livestock and other biologically-based resources used in agriculture. Genetic engineering is a rapidly expanding field in science. The NOSB recognizes the need to continually add methods to the list for review and to determine if the methods are or are not acceptable in organic agriculture. In addition to the 2016 recommendation, a discussion document provided a list of technologies needing further review to determine if they should be classified as excluded methods or not. At the Fall 2017 NOSB in-person meeting, the NOSB passed a recommendation to add three technologies as excluded methods to the NOP guidance document.

Goals of this proposal/document

This proposal for the October 2018 NOSB meeting addresses three additional methods listed as "To Be Determined" in the November 2016 discussion document. Using the NOSB's proposed improved definitions of excluded methods, the NOSB Materials Subcommittee identified one technology as an excluded method in organic agriculture and another technology as a method that should not be excluded in organic agriculture.

Public comment at numerous NOSB meetings over the years continues to stress the view that technologies used to manipulate the genetic code in a manner that is outside traditional plant and animal breeding should remain prohibited in organic production. Among all of the organic stakeholders, there is a strong belief that genetic engineering is a threat to the integrity of the organic label. Both organic producers and consumers reject the inclusion of genetic engineering in organic production. This document represents the continuing work of the NOSB to clarify which methods, in the expanding field of genetic engineering, can be used under the USDA organic seal.

Definitions

The NOSB previously recommended the use of the following definitions to determine whether or not a method should be/is excluded.

Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)

Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)

Non-GMO – The term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding relies on phenotypic selection, field-based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

Criteria

Below are the criteria listed in the previous NOSB recommendations to determine if methods should be excluded:

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.
2. The ability of a variety to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are refrained from (e.g. Terminator technology).
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes are refrained from).

The NOSB has voted and determined these to be excluded methods.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	• Sequence-specific nucleases (SSNs) • Meganucleases Zinc finger nuclease (ZFN) • Mutagenesis via Oligonucleotides • CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes • TALENs (Transcription activator-like effector nucleases) • Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are currently difficult to determine through testing.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid Transformation		YES	1, 3, 4	

Cisgenesis		YES	1, 3, 4	Even though the genetic manipulation may be within the same species; this method of gene insertion can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.
Intragenesis		YES	1, 3, 4	Even though the genetic manipulation may be within the same species; this method of gene rearrangement can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.
Agro-infiltration		YES	1, 3, 4	*In vitro* nucleic acids are introduced to plant leaves to be infiltrated into them. The resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.

The following genetic engineering methods were found by the NOSB NOT to be excluded methods.

Method and synonyms	**Types**	**Excluded Methods**	**Criteria Applied**	**Notes**
Marker Assisted Selection		NO		
Transduction		NO		

Discussion

The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda to determine if new technologies do or do not meet our current definitions. We may also need to incorporate additional criteria into our current definitions to evaluate new and unique technologies.

We are aware that specific laboratory tests are not currently available to detect the use of several new excluded genetic modification technologies in organisms. However, we still believe that the technology should be listed as an excluded method, when appropriate, and anticipate the development of tests or other methods that can detect the presence of these technologies. The Materials Subcommittee may put forward another discussion document in the future to aid the NOP in determining how to enforce this prohibition when there is no means to detect an excluded method was used in production.

Public comment received has been positive regarding the listing of all proposed excluded and non-excluded methods listed above. At the November 2017 meeting, when three new items were added to the excluded methods list, there were numerous comments requesting a clear description of the methods used in these excluded technologies. The three items added were cisgenesis, intragenesis, and agro-infiltration. Basic descriptions of these technologies are described below.

- Cisgenesis—the intact DNA of a plant is directly modified through gene transfer, and the integrity of the nuclear genome is disturbed. The introduced gene is from the same taxonomic family. Cisgenesis is a form of genetic engineering where genes are artificially transferred from the same species, or between closely related organisms. Unpredictable outcomes can occur through gene transfer, random or otherwise, even within the same species, through the introduction of intended or unintended change to genetic sequences and unintended insertions of novel bacteria, viruses or DNA to the host.
- Intragenesis—the intact DNA of a plant is directly modified through gene transfer, and the integrity of the nuclear genome is disturbed. The introduced gene or multiple genes are from the same taxonomic family, and the gene sequence may be rearranged. The same inherent risks of cisgenesis caused by the unpredictable outcomes of gene modification technology, are also risks associated with intragenesis.
- Agro-infiltration—in vitro nucleic acids, usually via a bacterial transporter, are introduced to plant leaves by direct injection or by vacuum infiltration into the plant. This method manipulates the genetic code within the nucleus of the organism. The goal is to produce a desired protein not present in the plant. The bacteria can make a hole in the cell wall, move into the nucleus of the plant and integrate into the plants' chromosomes. Stable integration into the plant's cell structure is not guaranteed. Agro-infiltration can also be used to silence specific genetic traits, although exact knowledge of how this is working at a genetic level is not currently known.

Proposal

Two items were considered for this proposal. One item was determined to be an excluded method depending on the method used to cause the change to the organism. The other method was determined to not be an excluded method.

Transposons, when produced from chemicals, ultraviolet radiation or other synthetic methods, are to be added to the list of excluded methods.

- **Transposons** are jumping genes that occur in nature and are responsible for mutations. Transposon activity can be modified to increase mutation rates. This can be done by chemicals or by physical stress like drought or heat. Changes or mismatches to the individual nucleotides occurs, altering the cell's genetic identity and genome size. When the transposon cleaves from its original location to another location, there is also a change to the genetic makeup at the site where it no longer resides.

- IFOAM's 2018 position paper on Techniques in Organic Systems considers transposons caused by physical stress to be compatible with organic systems.
- The NOSB livestock subcommittee discussed transposons in an August 2014 Memorandum to the NOP on Livestock Vaccines Made with Excluded Methods. Transposons were described as follows in that document.

  Transposons, also called transposable elements, are naturally occurring, double stranded DNA sequences with a defined structure. Each end of the transposon includes inverted repeats. In prokaryotes, the internal structure includes at least one gene for transposase and may contain many more depending upon the type of transposon. Genes for antibiotic resistance, one example of the types of transposon genes, occur both naturally and sometimes as a marker in lab modified transposons. When the transposase gene is expressed, the protein binds to the inverted repeats of the transposon, cleaves the genomic DNA and excises the transposon. Transposase can then cleave the genomic DNA at another spot and recombine the transposon into a new position in the genome.

The method below has been determined to be an excluded method based upon the criteria listed above.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons		YES - when produced by any means other than physical stress	1, 3, 4	Can be naturally occurring due to drought, heat or other means of physical stress, are not an excluded method. Transposons produced through chemical, artificial ultra violet radiation or other synthetic stress or interaction is considered to be an excluded method.

The following technology was found to not be an excluded method.

- **Embryo rescue in plants**—a technique that recovers plants from sexual crosses in which the majority of the embryos cannot survive *in-vivo* or may have gone dormant. The method helps to overcome embryo unviability, due to inherent weakness, immaturity or hybrids that degenerate. This method can combine desirable traits of complementary parents, such as in the development of seedless fruits. This method aids in shortening the breeding cycle. Embryos are placed in a controlled sucrose culture, for specific times and under controlled temperatures and light, to aid in the successful recovery of viable plants. The IFOAM position paper "Compatibility of Breeding Techniques in Organic Systems states, "In order to improve frequency of progeny of wide crosses, the embryo is transferred to artificial media. The embryo is derived from natural fusion of an egg and pollen cell. However, in wide crosses, the endosperm is often not well developed to feed the embryo. This method was used to produce triticale (Triticum aestivum x Secale cerale)." IFOAM also states this is compatible with organic systems.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Embryo rescue in plants		No		IFOAM's 2018 position paper on Techniques in Organic Systems considers this technique compatible with organic systems.

The following methods will continue to be researched.

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Protoplast Fusion		*TBD*		There are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are discussed and developed, these technologies cannot yet
Cell Fusion within Plant Family		*TBD*		Subject of an NOP memo in2013. The crops subcommittee will continue to explore the issue of detection and testing.
TILLING	Eco-TILLING	*TBD*		Stands for "Targeted Induced Local Lesions In Genomes." It is a type of mutagenesis combined with a new screening procedure.
Doubled Haploid Technology (DHT)		*TBD*		There are several ways to make double haploids, and some do not involve genetic engineering while some do. It is difficult or impossible to detect DHT with tests.
Induced Mutagenesis		*TBD*		This is a very broad term and needs to be classified based on what induces the mutations, such as chemicals, radiation, or other stresses.
Embryo transfer in animals	Embryo rescue in animals	*TBD*		FiBL distinguishes embryo rescue in plants from animals. A technique used in animal breeding, FiBL involves inducing superovulation of the donor with gonadotropins (glycoprotein polypeptide hormones), artificial insemination, recovery of embryos, isolation and storage of embryos, and transfer of embryos into an animal, which results in a pregnancy and hopefully a birth of a live animal at maturity. More research is needed to clarify if use of hormones is essential to this technique.

Future Work on this Topic

The Materials Subcommittee will discuss embryo transfer in animals, study the various methods of induced mutagenesis, and will review the NOP February 2013 policy memorandum on cell fusion techniques used in seed production. We will continue to review new technologies as they are introduced to the marketplace, such as GAANTRY (Gene Assembly in Agrobacterium by Nucleic acid Transfer using Recombinase Technology*),* as additions to our list of methods for discussion and classification.

Subcommittee Proposal:

The NOSB recommends the NOP add the following to the table of excluded or not excluded methods in the NOP excluded methods guidance.

1. "Transposons, when produced from chemicals, artificial ultraviolet radiation or other synthetic methods," is to be added to the table listing excluded methods.
2. "Embryo rescue in plants" should be listed "not an excluded method".

Subcommittee Vote:

Motion to accept the proposal on excluded methods as stated above
Motion by: Harriet Behar
Second: Dan Seitz
Yes: 4 No: 0 Absent: 3 Abstain: 0 Recuse: 0

Approved by Harriet Behar, Materials Subcommittee Chair, to transmit to NOSB August 21, 2018

National Organic Standards Board
Materials Subcommittee Discussion Document
Marine Materials in Organic Crop Production
June 12, 2018

SUMMARY:

This discussion document explores the issue of environmental impact of harvesting marine vegetation[1] for organic crop production inputs through a proposed requirement that aquatic plants under §205.601 (j)(1) and other nonsynthetic uses of marine vegetation be certified organic to the wild crop standard §205.207. Guidance is needed to elaborate how the wild crop standard is applied in a marine environment and how certifiers and producers can meet the condition that harvesting "will not be destructive to the environment".

INTRODUCTION:

Seaweeds have been commonly used throughout human history. They comprise a seemingly unlimited renewable resource; however, they are subject to the usual depletion through unintended over-harvesting and pollution. The laws that control harvesting, establish conservation zones, and seek to ensure sustainable seaweed harvest worldwide are highly variable, typically poorly articulated, and not easy to enforce. Some seaweed species grow back very quickly following harvest, while others take many years. Because of high demand, harvesting does not necessarily protect biomass and rarely involves ecosystem management. Little is understood about the multi-trophic impact of seaweed harvesting or cultivation.

There are nine separate listings for marine materials on the National List; however, only one is the subject of this discussion document: §205.601 (j)(1) Aquatic Plant Extracts. Aquatic Plant Extracts incorporating *Ascophyllum nodosum*, *Sargassum* spp., and *Laminaria* spp. are used as fertilizers for organic farming (TR lines 514-16). Marine materials are also used in nonsynthetic form as soil conditioners.

Approximately 50,000 metric tons of wet seaweed is harvested annually, yielding 10,000 metric tons of seaweed meal (TR lines 238-39). The Food and Agriculture Organization's 2004 Report, "The State of World Fisheries and Aquaculture" noted:

> In 1991, it was estimated that about 10,000 tonnes of wet seaweed were used annually to make 1,000 tonnes of seaweed extracts with a value of US$5 million. However, since that time the market has probably doubled as the usefulness of these products has become more widely recognized and organic farming has increased in popularity[2].

As this report is fourteen years old and the organic industry larger, the current figures is surely considerably higher. The high fiber content of the seaweed acts as a soil conditioner and assists moisture retention, while the mineral content is a useful fertilizer and source of trace elements (TR lines 241-42). An area of growth in seaweed fertilizers is in the production of liquid seaweed extracts that can be produced in concentrated form for dilution by the user. Seaweed fertilizers can be applied directly onto plants or watered in around the root areas. Organic farming provides a market for liquid

[1] This Discussion Document looks only at marine vegetation and does not address freshwater vegetation or fish.
[2] Food and Agriculture Organization (FAO). 2014. The State of World Fisheries and Aquaculture. FAO of the United Nations. Rome, Italy. 154 pp.

seaweed fertilizers as a result of wider recognition of the usefulness of the products and their effectiveness in growing of vegetables and some fruits (FAO 2004) (TR lines 247-51).

BACKGROUND:

During the 2015 sunset review of almost 200 materials, the NOSB and public comment noted concern that in the years since these materials were added to the National List, global harvesting has increased, overharvesting of many marine macro-algae has occurred, and the potential for contamination and destruction of marine ecosystems has accelerated.

In order to more fully examine marine materials in organic production, a Technical Report (TR) was obtained in 2016. The NOSB submitted brief information on each of the nine materials on the National List and posed seven questions regarding nomenclature, overharvesting, selective harvesting, contamination, certified organic wild crafting, cultivation, and CO2 sequestration.

Based on the issues raised in the TR, a Discussion Document was posted in Fall 2016, and the following three questions were posed:

1. Should the naming conventions of the marine plant/algae listings on the National List be consolidated and/or clarified to avoid redundancies and duplication, using Latin binomials?
2. Should annotations be written to clarify specific uses or harvesting guidelines for any of the marine algae listings, such as "no machine harvesting of *Ascophyllum*" and "Not harvested from a conservation area identified by State, Federal, or International bodies"?
3. Is there a need for further NOP Guidance on marine plants/algae?

Considerable public comment, both written and oral, was provided for the Fall 2016 NOSB meeting and was extensive and substantive in nature.

In the Spring of 2017, the Handling Subcommittee brought forth a proposal recommending that the marine algae materials be annotated with Latin binomials where possible, or by Class, and that the NOP develop Guidance to clarify the term "kelp" as used in organic production and wild harvesting. An identical proposal was brought forth in the Crops Subcommittee with a motion to amend the listing for Aquatic Plant Extracts to read (proposed changes are underlined):

> Aquatic plant extracts (other than hydrolyzed) derived from brown seaweeds, class *Phaeophyceae*. –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction.

Upon receipt of public comments stating that the annotations needed further justification and support and that stakeholders required more time to reflect upon the potential impacts of the proposals, both the Handling and Crop proposals were sent back to subcommittee for additional work. For the Fall 2017 meeting, the Handling Subcommittee reissued their proposal in the form of a discussion document to solicit additional input.

With respect to the Crops proposal to annotate §205.601 (j)(1) Aquatic Plant Extracts, public comment revealed that there are a number of aquatic plant products containing more than the brown class of seaweed. OMRI conducted a search of OMRI-listed crop input products that contain aquatic plant extracts and found:

"Of the 75 OMRI Listed products that contain aquatic plants as an ingredients:

· 48 contain **brown** algae (*Ascophyllum Nodosum, Sargassum, Durvillaea Potatorum, Egregia menziesii, Laminaria spp., Pelagophycus sp.* and/or Macrocystis *integrifolia)*

· 5 contain **red** (*Gelidium* sp.) and/or **green (***Ulva sp.)*
· 22 products do not have information about seaweed species".

Additionally, Table 5 of the 2016 TR lists the following species used for agricultural production and their country of origin:

- **Chlorophyta (Green)-** *Dictyosphaeria cavernosa* Kenya; *Enteromorpha spp.* Portugal; *Ulva spp.* Italy, Portugal
- **Rhodophyta (Red)-** *Ahnfeltia plicata* Chile*; Gracilaria spp.* Portugal; *Gracilaria chilensis* New Zealand; *Halymenia venusta* Kenya; *Laurencia papillosa* Kenya, Philippines; *Lithothamnion corallioides* France, Ireland, UK; *Phymatolithon calcareum* France, Ireland, UK
- **Phaeophyta (Brown)-** *Ascophyllum nodosum* France, Canada, China, Iceland, US; *Ecklonia maxima* South Africa; *Fucus spp.* France; *Fucus gardneri* Canada; *Hydroclathrus clathratus* Philippines; *Laminaria schinzii* South Africa; *Macrocystis pyrifera* Australia; *Nereocystis luetkaena* Alaska, Canada; *Sargassum spp.* Brazil, Vietman; *Turbinaria spp.* Vietnam

Given that there are aquatic plant input products using green, red, and brown algae, the Crops Subcommittee determined to re-examine its approach to this issue.

While the Spring 2017 proposal focused on nomenclature, questions over the environmental impact of marine material harvesting for organic production are of concern. The TR explores the issue of "sustainable harvesting", but a lack of an agreed-upon means of defining, measuring, and enforcing such practices makes the term problematic. Consequently, this Discussion Document instead looks at ways of addressing the environmental impact of harvesting marine materials for organic crop production. It poses the idea of requiring that all marine materials used in crop input products be certified organic. As most of these materials would be certified to the wild crop standard, we explore the issue of better defining, measuring, and enforcing the requirement under §205.207 (b) that wild harvesting "will not be destructive to the environment".

Note: Much of the research, text, and goals of this Discussion Document are the effort of former NOSB member, Dr. Jean Richardson, and were completed prior to the end of her term in January 2017. Thank you to Dr. Richardson for spearheading this within the NOSB and for providing a framework from which to continue the important work on this topic.

RELEVANT AREAS OF THE RULE, NOP GUIDANCE, NOP POLICY MEMO, and OMRI:

§205.601 Synthetic substances allowed for use in organic crop production
In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided that, use of such substances does not contribute to contamination of crops, soil, or water...
(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction.

§205.207 Wild-crop harvesting practice standard.
(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance as set forth in §205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§205.200 General.
Production practices … must maintain or improve the natural resources of the operation, including soil and water quality.

NOP 5022, effective July 22, 2011, Guidance: Wild Crop Harvesting provides details to clarify §205.207, including:

> Section 205.200 states that production practices must maintain or improve the natural resources of an operation under organic certification. This applies to all types of organic certification, including wild crops. Unmanaged, untrained and uninformed harvesting of wild products from a wild habitat without maintaining or improving the natural resources can disqualify the wild products from organic certification.

Additionally, the Guidance states:

4. A description of the proposed ecosystem management and harvesting practices, the impact of their proposed harvesting on the long-term viability of the wild species and on the area's ecosystem, and information on any equipment planned for use or being used to harvest and manage the wild-crop and ecosystem.
    a. This should include a description of the monitoring system that will be used to ensure that the crop is harvested in a sustainable manner that does not damage the environment, including soil and water quality.
5. A list of any rare, threatened, or endangered terrestrial or aquatic plants or animals that occur in the harvest area.
    a. The presence of rare, threatened, or endangered species in a wild harvest area does not automatically disqualify an operation from organic certification, but any potential or actual impacts need to be described and addressed.
    b. If there are potential or actual negative impacts resulting from the wild crop management and harvesting, actions that address and correct these impacts need to be described, implemented, and monitored.
6. The procedures employed that prevent contamination from adjoining land use or other point or non-point sources contamination.
7. The training provided and the procedures employed to ensure that all collectors harvest crops in accordance with the OSP and in a manner that does not damage the environment.

NOP 5020, effective 1/15/16, Guidance: Natural Resources and Biodiversity Conservation clarifies organic regulations at 7 CFR 205.200 that states, "to maintain or improve the natural resources of the operation….".

NOP Policy Memo 12-1, Production and Certification of Aquatic Plants, issued September 12, 2012 provides further clarification as follows:

> This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List of Allowed and Prohibited Substances at 7 Code of Federal Regulations (CFR) 205.601-205.602, as the basis for the production and certification of cultured and wild crop harvested aquatic plants.

While current USDA organic regulations specifically exclude aquatic animals from organic certification, no such exclusion exists for aquatic plants. Further, some parts of the USDA organic regulations specifically address aquatic plant production. For example, some aquatic plants, such as kelps and seaweeds, are listed in 7 CFR 205.606 of the USDA organic regulations, allowing their use in non-organic form when certified organic forms are not commercially available. Producers and certifiers are required to comply with the USDA organic regulations when producing or certifying cultured and wild crop harvested aquatic plants.

The use of ground and surface waters, ponds, streams, or other waterways for aquatic plant production may be regulated by Federal, State, or local authorities. Aquatic plant producers should consult with Federal, State, and local authorities to ensure compliance with all applicable laws, in addition to the USDA organic regulations, regarding the use of synthetic substances and other materials in ponds and waterways. Also, under 7 CFR 205.200, aquatic plant producers must ensure, and certifying agents must verify, that production practices maintain or improve the natural resources of the operation, including soil and water quality.

OMRI definition of Kelp in Crop Production:
The dried marine algae of the botanical divisions of Rhodophyta (red algae), Phaeophyta (brown algae), and Chlorophyta (green algae) (AAPFCO).

PREVIOUS PUBLIC COMMENT AND TECHNICAL REPORT:

Following the receipt of the 2016 limited scope TR, the NOSB presented questions to the public in a November 2016 Discussion Document. Thousands of pages of public comment and peer-reviewed scientific research articles were received in Fall 2016, providing the NOSB with a substantive body of documented research from a number of perspectives which helped form this Discussion Document.

Public comment included concerns for the following:

- Conservation of wild marine algae species, and marine ecosystems.
- Lack of clarity as to which species are allowed on the National list and confusion over names used.
- Overharvesting of some species in some geographic areas.
- Need for clarification of which species are used, and from which geographic areas.
- Desire to encourage organic cultivation and wild harvesting of marine materials.
- Need for clarification of which species can or are being cultivated.
- Clarification of wild harvesting techniques.
- Feasibility of harvesting by individual species selection as opposed to multi-species harvesting by littoral or marine zone
- Extraction methods.
- Sequestration of metals or other contaminants in some wild and cultivated algal species.

Of the seven questions posed in the limited scope TR in 2016, three are most relevant to this discussion document:

<u>1. Overharvesting:</u> The nine listings include thousands of species of algae from many different geographic locations, the marine intertidal zone, deeper ocean areas, and wild harvested beds. Which species, genera, classes are being overharvested? Which geographic regions indicate overharvesting

impact? What is the trend in harvesting marine algae? What is the present status and trends in harvesting and overharvesting of Ascophyllum nodosum?

Public comment received from producers of seaweed materials provided statements that overharvesting is not an issue, or if it was that there are regulations in place to control harvesting. By contrast, other public comment by marine biologists and the international research community indicates that overharvesting and harvesting in such a manner that ecosystem structures are destroyed is relatively widespread and inadequately monitored or regulated.

The TR provides examples of the following seaweeds being overharvested: Irish Moss (*Chondrus crispus*), Rockweed (*Ascophyllum nodosum*) and giant Kelp (*Macrocustis pyrifera*) (TR lines 523-24).

> "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 lines 528-35)
>
> 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)

It must also be noted that ocean warming and other environmental factors probably contribute to depletion of these species (see also: Halat et al. 2015[3], Kay et al. 2016[4], and TR lines 579-83). Overharvesting impacts not only the specific plant species or genus but all the associated plant and animal species which form the marine ecosystem in a given location (see also: Keats et al. 1987[5], Kelly 2005[6], and TR lines 597-611).

Seaweeds, particularly those that form canopy structures, such as rockweed, are bioengineers and contribute to a highly productive habitat. Their presence helps to reduce the physical stresses of the intertidal habitat. Some of their key ecological functions include nutrient cycling and maintaining water quality. Seaweeds provide a habitat and food source for numerous invertebrates and fish, grazers and feeders, and maintain water quality. They also provide a physical barrier against waves, protecting the shore and inhabiting species. As such, certain species that are slow to regenerate from moderate harvesting or have substantial benthic repercussions from their removal, may not be compatible with

[3]Halat L, Galway ME, Gitto S, Garbary D. 2015. Epidermal shedding in *Ascophyllum nodosum* (*Phaeophycea*): seasonality, productivity and relationship to harvesting. Phycology. 54(6):599-608.
[4] Kay LM, Schmidt AL, Wilson KL, Lotze HK. 2016. Interactive effects of increasing temperature and nutrient loading on the habitat-forming rockweed Ascophyllum nodosum. Aquatic Botany. 133:70-78.
[5] Keats DW, Steele DH, South GR. 1987. The role of fleshy macroalgae in the ecology of juvenile cod (Gadus morhua) in inshore waters off eastern Newfoundland. Journal of Zoology. 65:49-53.
[6] Kelly E (editor). 2005. The role of Kelp in marine environment. Irish Wildlife Manuals No. 17, National Parks and Wildlife Service. Dept. Environment, Heritage, and Local Govt. Dublin.

organic principles.[7]

For example, maerl harvesting off the northeast Atlantic has long-term repercussions. "Maerl beds represent a non-renewable resource as extraction and disruption far out-strips their slow rate of accumulation"[8]. The authors of a review of branch growth rates noted, "although rapid on a geological time-scale these accumulation rates are far too low for the maerl to be regarded as a sustainable resource for extraction for agricultural and industrial use"[9]. A study of the same region concluded that maerl dredging was a major threat to the habitat and that there is more to be gained from protecting rather than exploiting these habitats[10].

Some species have relatively rapid growth rates and reproductive techniques that allow for replenishment with intentional harvesting rates. Seaweed harvesting must ensure the proper stem length is left attached to the underlying substrate. Reproduction will then occur from this stem, promoting a second generation of seaweed growth from both the intact stem and the recruitment of new plants. The species replenishment rate and frequency of harvest are, therefore, critical factors impacting future seaweed generations and the marine habitat. Failing to take species and harvest rate into account can result in seaweed plots that are quickly exploited and, over time, lead to long-lasting damage to the benthic and trophic communities. Frequent harvests may also have impacts on the heterogeneity of age classes within a seaweed population. This means the population will eventually only consist of young seaweed that are not only smaller than older seaweeds, but may then be harvested before their full life cycle is completed. This could have recruitment and reproductive impacts on future generations in terms of sustainability.[11]

In the case of rockweed, even studies that indicate environmental resilience to commercial harvesting note that though extraction may, in some cases, represent a low percentage of annual biomass production, but "the lack of knowledge of energy pathways prevents us from concluding that this is a low level of ecological impact"[12]. Some research has shown that fallow periods are necessary for sustainable harvesting. Fallow periods also prevent the encroachment of faster growing species. The

[7] Maine Department of Marine Resources. 2014. Fishery Management Plan for Rockweed (Ascophyllum Nodosum). Maine Department of Marine Resources & Rockweed Plan Development Team. 51 pp.; Werner A, Kraan S. 2004. Review of the potential mechanization of kelp harvesting in Ireland. Marine Environment and Health Series 17; McCook LJ, Chapman ARO. 1991. Community succession following massive ice scour on an exposed rocky shore: effects of Fucus canopy algae and of mussels during late succession. Journal of Experimental Marine Biology and Ecology. 154:137-169; Lamote M, Johnson LE. 2008. Temporal and spatial variation in the early recruitment of fucoid algae: the role of microhabitats and temporal scales. Marine Ecology Progress Series. 368:93-102; Watt CA, Scrosati RA. 2013. Bioengineer effects on understory species richness, diversity, and composition change along an environmental stress gradient: Experimental and mensurative evidence. Estuarine, Coastal and Shelf Science. 123:10-18; McCook LJ, Chapman ARO. 1997. Patterns and variations in natural succession following massive ice-scour of a rocky intertidal seashore. Journal of Experimental Marine Biology and Ecology. 214:121-147.

[8] Barbera C, Bordehore C, Borg JA, et al. 2003. Conservation and management of northeast Atlantic and Mediterranean maerl beds. Aquatic Conservation: Marine and Freshwater Ecosystems. 13:S65-S76.
[9] Bosence D, Wilson J. 2003. Maelr growth, carbonate production rates, and accumulation rates in the northeast Atlantic. Aquatic Conservation: Marine and Freshwater Ecosystems. 13:S21-S31.
[10] Hall-Spencer JM, Grall J, Moore PG, Atkinson RJA. 2003. Bivalve Fishing and maerl-bed conservation in France and the UK—retrospect and prospect. Aquatic Conservation: Marine and Freshwater Ecosystems. 13:S33-S41.
[11] Jenkins SR, Norton T, Hawkins SJ. 2004. Long term effects of Ascophyllum nodosum canopy removal on mid shore community structure. Journal of the Marine Biological Association of the UK. 84(02):327-329.

[12] Sharp GJ, Pringle JD. 1990. Ecological impact of marine plant harvesting in the northwest Atlantic: a review. Hydrobiologia. 204/205:17-24.

undisturbed seaweed population can therefore sustain other dependent populations for longer periods of time, establishing the trophic benefits of a stable ecosystem. Additionally, fallow periods allow seaweed to gain biomass overtime. Many species reach peak size after two or three years[13].

2. Selective harvesting: There are about 6,500 species of red algae (Rhodophyta) such as Chondrus species, Palmiria, Delessaria; about 2,000 species of brown algae (Phaeophyta) such as Laminaria species, Ascophyllum species, Sacharina, Fucus, Sargassum muticum; and about 1,500 green algae (Chlorophyta) such as Dunaliella, of which many are not marine. How many species of each class are being wild harvested? Can one species be harvested without impacting other species in the same location?

The TR indicates that there is limited research on algal species harvested for economic purposes. An additional literature search shows some work has been done on multi-tropic consequences of kelp harvest on the coast of Norway, indicating negative impacts of kelp harvesting on fish abundance and diminishment of coastal seabird foraging efficiency (Lorentsen et al, 2010[14]). Lorentsen points out that kelp fisheries are currently managed in order to maximize net harvest of kelp biomass, and the underlying effects on the ecosystem are partly ignored.

A Literature review did not turn up any scientific research comparing certified organic kelp harvesting with non-certified wild harvesting.

There is peer-reviewed research on the habitat impact of seaweed on common eider ducks (such as Blinn et al. 2008[15]), fish impact in Nova Scotia (such as Black 1991[16]), and impact of mechanical harvesting on Ascophyllum (such as Ang 1993[17], Ang 1996[18], and Arzel 1998[19]). There is considerable research on Ascophyllum harvesting impacts, including findings in the 2016 TR. "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 (Ingolfsson 2010) (TR lines 892-96).

3. Cultivation: Which species are being cultivated, and in which geographic locations? What are the environmental issues associated with farming marine algae?

Not all marine algal species are easily or economically cultivated. For example, *Ascophyllum nodosum* (Rockweed), a species widely harvested and overharvested for aquatic plant extracts and alginic acid, is

[13] Maine Department of Marine Resources. 2014, *supra* note 6; Werner A, Kraan S. 2004, *supra* note 6; Wippelhauser GS. 1996. Ecology and Management of Maine's Eelgrass, Rockweeds, and Kelps. Maine Natural Areas Program, Department of Conservation. Maine.
[14] Lorentsen SH, Sjotun K, Gremillet D. 2010. Multi-tropic consequences of kelp harvest. Biological Conservation. 143:2054-2062.
[15] Blinn BM, Diamond AW, Hamilton DJ. 2008. Factors affecting selection of brood-rearing habitat by common eiders (Somateria mollissima) in the Bay of Fundy, New Brunswick, Canada. Waterbirds. 31:520-529.
[16] Black R, Miller RJ. 1991. Use of intertidal zone by fish in Nova Scotia. Environmental Biology of Fishes. 31:109-121.
[17] Ang PO, Sharp GJ, Semple RE. 1993. Change in the population's structure of Ascophyllum nodosum due to mechanical harvesting. Hydrobiologia. 260/261:321-326.
[18] Ang PO, Sharp GJ, Semple RE. 1996. Comparison of the structure of populations of Ascophyllum nodosu, (Fucales, Phaeophyta) with different harvest histories. Hydrobiologoa 326/237 179-184.
[19] Arzel P. Les luminaires sure les cotes bretonnes. Evolotion de l'exploitation et de la flottille de peche, actuel et perspectives. Editions IFREMER BP 70-29280. Plouzane, France. 139 pp.

a brown seaweed which is not economic to cultivate. By contrast, Laminaria saccharina is easy to cultivate. The TR provides considerable detail on seaweed farming of many species worldwide.

As with terrestrial agriculture, focusing on the production of any few select species could lead to monoculture plots of those species. While this makes harvesting species of interest easier, these plots are then susceptible to diseases and may limit the resources available to other organisms in the ecosystem. Additionally, some native seaweed beds are wiped out to make room for the more profitable species. Various studies have elaborated on the detrimental effects of invasive seaweed cultivation. Without competition or predators, invasive seaweeds can colonize on thriving corals eventually causing death. There is also the potential for epiphyte outbreaks or species diversity declines.[20]

DISCUSSION:

This discussion document proposes a new way of looking at the sourcing of materials for organic production. Currently, there is inconsistency in the review and use of inputs for organic production. Synthetic materials are closely evaluated through the material petition and sunset review processes while natural materials allowed under the regulations receive relatively little scrutiny. Nonsynthetic inputs deserve equal assessment for their impact on the environment, including contamination during manufacture or extraction and adverse impacts on biodiversity. While it could be said that organic areas of use of marine materials are of least concern in terms of the quantity of the overall harvest, it does not prevent the organic community from examining the impact the industry is having on marine ecosystems. It is similar in many respects to the requirement that organic livestock be fed organic feed, as in the case of NOP 5027 Guidance: The Use of Kelp in Organic Livestock Feed that clarifies that marine materials used as a livestock feed must be certified organic to the wild crop standard.

The use of seaweed as a fertilizer presents a comparatively unique situation in organic certification: materials are largely harvested from wild native ecosystems as inputs for organic crop production products—both synthetic (aquatic plant extracts) and natural (soil conditioners). The review above illustrates the importance of addressing the effects of seaweed harvesting on wild native ecosystems, both in terms of cultivated and wild seaweed.

In the absence of a universal standard for “sustainable harvest” within marine environments, and given the goal of limiting ecological harm from seaweed harvesting, this discussion document explores a means of addressing the environmental impact of harvesting seaweed for use in organic crop production through existing organic certification tools. In addition to addressing environmental impact, requiring organic certification to the wild crop standard would also help mitigate potential contamination issues which are also dealt with in terrestrial farming systems, particularly in relation to drift. Delineated no-cut buffer zones could also serve as conservation areas.

Nevertheless, the wild crop standard is quite general in its language when it requires that “a wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be

[20] Cottier-Cook EJ et al. 2016. Safeguarding the future of the global seaweed aquaculture industry. United Nations University (INWEH) and Scottish Association for Marine Science Policy Brief. ISBN 978-92-808-6080-1. 12pp.; Werner & Kraan, 2004, *supra* note 5; Zemke-White WL, Smith JE. 2006. Environmental Impacts of Eucheuma spp. Farming. In: Critchley AT, Ohno M, Largo DB, editors. World Seaweed Resources. Degussa, Amsterdam; Lindeberg MR, Lindstrom SC. 2010. Field guide to seaweeds of Alaska. University of Alaska Fairbanks, Alaska: Sea Grant College Program; Aquenal Pty Ltd. 2008. National Control Plan for Japanese Seaweed or Wakame Undaria Pinnatifia. Rep. Australian Government.

destructive to the environment and will sustain the growth and production of the wild crop." This standard encompasses both terrestrial and aquatic systems of production and therefore includes a broad range of crops, from herbs to mushrooms to kelp, for example. NOP 5022 Guidance: Wild Crop Harvesting addresses some of this; however, there remains much in the wild crop standard that is subjective in interpretation. Each certifying agency is left to develop its own guidelines for enforcing these standards.

Some certifiers who currently certify both wild harvested and cultivated seaweed to the wild crop standard have expressed a strong desire for more explicit standards for marine ecosystems, stating that it is challenging to try to adopt terrestrial criteria to an aquatic system. Further NOP guidance on applying both the wild crop standard, NOP 5022 Guidance: Wild Crop Harvesting, and NOP 5020 Guidance: Natural Resources and Biodiversity Conservation could help elucidate questions of avoiding prohibited substances, prohibitions of harvesting in conservations areas, safeguarding biodiversity conservation, and evaluating long-term harvest impacts, among other concerns. Organic wild crop harvesting should aim at not changing the natural environment. While this may be difficult to predict and will vary significantly by location and species, it is important for maintaining the complicated interactions that take place within the local ecosystem. Clear demarcations of harvesting areas, ecosystem health assessments, detailed species identifications and population figures, and exposure to potential contaminants would be base appraisals. Some specific evaluation questions could include:

- How does structural change from harvest benefit/detract from habitat?
- How does architecture of the harvested species affect associated species?
- How much loss/change is too much?
- Assess the long-term effects of harvesting on a large spatial scale.
- What is the difference between the commercial harvest rate and natural mortality in a given year in different areas of the harvest zone?
- Will cumulative effects of successive harvest restructure habitat and/or ecosystems?[21]

The topic of marine materials is vast and complicated, and the proposed recommendations below are a first step in approaching the issue. Future work to safeguard against negative environmental impact might include specifying which species, geographic regions, and/or methods of harvest are allowed or prohibited. Currently, there are no plans to prohibit the harvest of any specific species, as that would require a case-by-case review with sufficient data that is beyond the preview of this present effort.

RECOMMENDED PROPOSAL:

1) This discussion document suggests an annotation to §205.601 (j)(1) requiring (proposed changes are underlined and in red):

§205.601 Synthetic substances allowed for use in organic crop production

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided that, use of such substances does not contribute to contamination of crops, soil, or water...

(j) As plant or soil amendments.

> (1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction. <u>Must be made with certified organic aquatic plants, including, but not restricted to, algae.</u>

[21] Maine Department of Marine Resouces. 2014, *supra* note 6.

2) An additional listing is proposed at §205.602 prohibiting seaweeds unless organically produced to address seaweeds used in non-synthetic products and therefore not covered by the annotation under Aquatic Plant Extracts. This prohibition, unless certified organic, would help safeguard that seaweeds harvested for and used in organic crop production do not harm the environment (proposed changes are underlined and in red):

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
The following nonsynthetic substances may not be used in organic crop production:
(e) Marine algae (seaweeds)--unless organically produced.

3) Recommendation that the NOP develop Guidance on applying §205.207 "Wild-crop harvesting practice standard" to the production and harvesting of marine algae. Guidance is needed to clarify how marine algae can "be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop". In particular, "will not be destructive to the environment" involves a wide range of impacts on the marine ecosystem, while "will sustain the growth and production of the wild crop" refers to the ability to sustain production of biomass of the crop.

CONCLUSION:

As one public commenter succinctly stated: "A central tenet of organic food production is the conservation of biodiversity and natural resources. As such, it is imperative that materials allowed for use in organic food and farming be sourced and/or manufactured in a manner that does not contribute to ecological damage via resource depletion, species endangerment or extinction, pollution, or significant habitat alteration."

Each marine material grows in a complex and not fully understood ecological context subject to internal and external stressors and never in homeostasis. In order to fully review a material against the required OFPA criteria, each marine material must be assessed in the context of where it is growing with an understanding of verifiable assurances against environmental harm. The harvest of marine materials for organic production must be based on the maintenance of the biodiversity of natural aquatic ecosystems and the continuing health of the surrounding aquatic and terrestrial ecosystems in a period of rapid commercial expansion of both wild and cultivated seaweeds and limited international regulation.

DISCUSSION QUESTIONS:

We are seeking comments from the public on the following questions:

1. Please discuss the feasibility of requiring all seaweed harvested for use in organic crop production to be certified to the wild crop standards.
2. For certifiers currently certifying marine materials to the wild crop standard, please describe how you verify that biodiversity is conserved and how wildlife are maintained in the harvest areas.
3. Could species be comprehensively listed on aquatic plant extract product ingredients?
4. Would the establishment of a working group be useful in providing additional guidance on wild cropped and farmed marine algae and to clarify the definition and measurement of "not destructive to the environment" stipulated in the wild-crop harvesting practice standard §205.207 (b)?

5. Is there a potential to replace marine materials with freshwater materials for crop production inputs? Many of these freshwater materials are invasive species and are already removed as part of restoration efforts.

Vote in Subcommittee

Motion to accept the marine materials in organic crop production discussion document
Motion by: Emily Oakley
Seconded by: Lisa de Lima
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair, to transmit to NOSB, June 12, 2018

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee Proposal
Developing Criteria for Risk-based Accreditation Oversight
August 17, 2018

I. INTRODUCTION

In early 2018, the National Organic Program (NOP) requested the NOSB provide input on the factors that contribute to an accredited certifier having a higher risk of fraud, either within its organization or the operations it certifies. This proposal seeks to establish criteria for assessing risk factors when engaging in the oversight of USDA-accredited certifiers. Oversight includes on-site and desk audit activities of the certifier in the primary and satellite offices, as well as on-site audits of inspection procedures.

II. BACKGROUND

The NOSB has received a wealth of input from stakeholders, as the organic community and the NOP respond to concerns and findings of fraudulent organic imports. We have expanded the scope to include fraud anywhere in the supply chain, be it in domestic or international markets. This input, in the form of public comments in advance of and during NOSB meetings and across two expert panels at the Fall 2017 and Spring 2018 NOSB meetings, has informed NOSB recommendations and discussion documents, as well as the NOP's oversight and enforcement of the organic market abroad and here in the U.S.

NOSB efforts have included a proposal addressing tightening the exclusion of certain operations in the supply chain, a discussion document on import oversight soliciting input on over 75 questions, and a proposal on the qualifications and training of inspectors. NOP initiatives have included development of a web-based interactive training on conducting investigations, an interim instruction on organic imports for certifiers, in-person trainings with certifiers, a working session webinar with certifiers to exchange best practices and barriers for reporting acreage to the Organic Integrity Database, and a webinar focused on receiving further feedback from stakeholders on the Program's forthcoming enforcement rulemaking.

III. RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

Organic Foods Production Act of 1990, as amended, Sec. 2115 [7 U.S.C. 6514] Accreditation Program, and Sec. 2116 [7 U.S.C. 6515] Requirements of Certifying Agents

7 CFR Part 205 Subpart F—Accreditation of Certifying Agents

NOP 2005 Accreditation Assessment Checklist

Organic Oversight and Enforcement: Summary of Activities and Overview Action Plan, May 2018

IV. DISCUSSION

The following factors identify potential for risk and suggest a starting point from which the NOP can develop a guide for determining risk, as well as activities to address them. This is an unranked list and is not exhaustive, but a starting point from which to build. Additionally, the NOP may already include these factors as part of its audit activities. To be clear, presence of these criteria does not suggest fraud is present but is an indicator of its potential to occur. In addition to taking these criteria into account, we encourage the NOP to consider the frequency and intensity of audits when these or other risk factors are present and schedule sufficient time to address them.

Factors that contribute to a certifier's risk and activities to address them:

1. Operates in an area or region known to have or have had fraudulent activity
    a. Prior to an audit, review findings/adverse actions for the region in which the operation is based or undertakes certification activities
    b. Focus on certifications and transactions of the fraudulent product
    c. Work closely with other accreditation bodies operating in the region where fraud has been found
2. Certifies a high number of operations exporting to/importing from foreign markets
    a. Review procedures for issuing export documents and include in exporting operations audits
    b. Review procedures for evaluating import documents and organic integrity
    c. Ensure operators have appropriate organic system plans that cover brokering activities in more detail
    d. Ensure inspection and review staff have detailed checklists to verify all documentation and activities are within organic certification requirements
3. Maintains one or more satellite offices
    a. Where a satellite office is functioning as a quasi-independent branch of the certifier, accreditation audits should include a complete review of the key activities, practices, and procedures
    b. Verification that practices and procedures closely reflect the primary office
    c. When variances found, separate accreditation should be required
4. Certifies operations from which a significant portion of revenue is derived from a small percentage of operations
    a. Include specific high value operations in audit activities in addition to randomly chosen operations
    b. Include witness audit of inspection activities along with evaluation of certification review activities
5. Employs or contracts with inspectors and/or reviewers new to certification and the organic sector
    a. Review the certifier's Annual Report Checklist to identify staff with less experience
    b. Focus on the training practices of the certifier to ensure these staff received comprehensive training
6. Works predominantly with contract inspectors for which they have minimal management or oversight
    a. Review witness audits of inspectors to determine adequate oversight
    b. Review training plans to determine adequacy of continuing education requirements
    c. Include operations in witness audits to which a contracted inspector is or has been assigned
7. Certifies high-risk commodities
    a. Include a comprehensive supply chain audit of the high risk commodity
    b. Include a cross check of all certifiers involved in the production and handling of the high risk commodity
8. Reports incomplete or minimum required data to the Organic Integrity Database (e.g., updates certified operation list with commodities grown/handled but does not report acreage or volume)

    a. Review certifier data systems to determine data gaps
    b. Require timeline for implementation to address gaps
9. Residue sampling results show lower than average/no positive results of certified operations
    a. Include in audit a review of residue results
    b. Review procedure for sampling and include in inspection witness audit
10. Fewer or lower than average noncompliances or adverse actions issued
    a. Include audit review of the procedure for issuing noncompliances
    b. Review inspection report findings to assess accuracy/thoroughness of inspection process
11. Has received a past Notice of Suspension or Revocation of relevant accreditation from USDA or other accreditation body
    a. Include a comprehensive review of the certifier's systems that focuses on the noncompliances that led to suspension or revocation
    b. Focus unannounced inspections on certifier
12. Has received a noncompliance that points to a breakdown in the control system
    a. Evaluate steps taken to address the root cause of the system breakdown
    b. Review objective evidence demonstrating the system is sound
    c. Reference and update as necessary NOP Instruction 2608 Responding to Noncompliances
13. Certifier provides certification to employees, contractors, or members of its advisory bodies or management boards
    a. Include these operations in audit activities in addition to randomly chosen operations
    b. Include witness audit of inspection activities along with evaluation of certification review activities

V. Request for Public Comment

The NOSB requests comments from certifiers and the organic community that further expand on areas of risk not included in the above list.

Subcommittee vote
Motion to approve this proposal on Developing Criteria for Risk-based Accreditation Oversight
Motion by: Scott Rice
Seconded by: Ashley Swaffar
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board

Compliance Accreditation and Certification Subcommittee Proposal
Training and Oversight of Inspector and Certification Review Personnel
August 17, 2018

I. INTRODUCTION & BACKGROUND

In Spring 2018, the CACS brought forward a proposal entitled Inspector Qualifications and Training which recommended the establishment of mandatory qualifications, ideal levels of experience or background, and compulsory continuing education. The goal of this proposal was to further strengthen the skills and abilities of the inspector pool and bolster the certification system on the whole. The proposal passed with broad support of the Board and organic stakeholders, both of whom clearly expressed interest in being involved in the establishment of such qualifications, as well as expanding the scope to include certification review staff.

As the Program moves forward with the Board's recommendation, it has requested specific areas of training that could be incorporated into the USDA's Learning Management System (LMS), an online platform for remote learning. This proposal summarizes public comments regarding improvement of inspection skills, identifies specific areas that could be included in the LMS, and provides further approaches for strengthening inspector and review staff.

II. RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

205.501(a) General requirements for accreditation.
(a) A private or governmental entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

NOP Memo to Accredited Certifying Agents: *Criteria and Qualifications for Organic Inspectors*, April 2012

NOP 2027, *Instruction: Personnel Performance Evaluations*, March, 2017

CACS Proposal: *Personnel Performance Evaluations of Inspectors*, April 2017

Accredited Certifiers Association Guidance on Organic Inspector Qualifications, February 2018

[CACS Discussion Document: Import Oversight, February 2018]

[CACS Proposal: Inspector Qualifications and Training, May 2018]

III. DISCUSSION

Many commenters noted the essential and critical work on-site inspectors and office certification review staff perform, especially in the complicated area of import oversight. There are specific skills needed to address the challenges of tracking diverse organic products through both domestic and international supply chains as the products move through numerous physical handlers as well as brokers and others who do not take physical possession of the products. International, U.S. federal, state and local regulations contribute to the risk to organic integrity through phytosanitary and other requirements. NOP accreditation auditors should have the skills, background and expertise needed as described in the NOP 2500 Auditor Criteria, to provide certification oversight and to continually improve their knowledge along with inspectors and certification personnel.

Based upon public comment regarding the Import Oversight discussion document, as well as the Inspector Qualifications and Training Proposal passed at the Spring 2018 meeting, the NOSB received practical solutions for improvement to our pool of inspectors and certification review staff. Some of these comments follow under the relevant topic area:

Accounting Skills

- Improve skills and background for performing in/out mass balance audits, and include a clear description in the inspector report on what was reviewed and discovered on-site
- Improve performance of rigorous trace backs from received product through the entire chain to original source
- Increase command of basic accounting skills and understanding of tracking of financial records through a variety of accounting systems
- Inform clients that the organic inspection could include more detailed review of financial records, including bank statements, deposits, etc.

Technical and Interpersonal Skills

- Increase awareness and skill in reviewing organic certificates and other documentation to identify areas of weakness where fraud could occur
- Improve communication, including interview and listening skills
- Improve skills in how to diffuse negative situations

Organic System Plan

- Add a specific section where the operator provides a sample audit in their OSP, with sample documents and how they interact with each other, to aid the on-site inspector when they are tracking a sale with this "roadmap"

Inspector Training and Oversight

- Trainings should be rigorous and include testing
- Continuing education should be required
- Mandatory minimum qualifications
- Some commenters proposed a system of licensing or accrediting inspectors, however there was no consensus around this idea

- Specialized trainings by type of operation
- Inspectors should be categorized by scope and skills to aid certifiers in choosing qualified inspectors for each entity
- Improve and expand inspector mentoring for beginning inspectors, peer mentoring for experienced inspectors
- Encourage team inspections
- Create more robust systems for client and reviewer/inspector feedback to identify areas of weakness and strength
- Increased understanding of import protocols and requirements

In order to meet these challenges, the NOSB recommends a variety of approaches:

1. The current system of training inspectors on the organic regulations through the International Organic Inspectors Association (IOIA), the Accredited Certifiers Association (ACA), and individual certifiers should be improved and become more standardized. This would improve professionalism and confidence in our system. Accreditation of training programs through a third party such as ISO should be a long-term goal. A cost/benefit analysis of this accreditation should be completed. The NOP could fund a task force to develop a baseline curriculum and attendee testing protocols, using templates from other sectors of the food industry.
2. The USDA should provide organic inspectors and certification review personnel access to the Learning Management System. The following areas, available through LMS, would be most appropriate to the organic industry: investigative skills, auditing, organic regulations, and other items as needed.
3. The USDA could facilitate the development of a practical and comprehensive apprenticeship/mentor/peer mentor program, to enhance the skills of all levels of organic inspectors and review staff. This could include one-on-one in-person mentorships, long distance communication and learning through conference calls or webinars, and on-line courses with testing.
4. A standardized system of tracking inspector skills, background and knowledge should be developed, to aid certifiers in choosing appropriate inspectors for specific jobs. This could also encourage inspectors to improve their resumes with continued education, such as taking an accounting course at a local technical college. This would then be added to their list of skills. This information should be publicly available.
5. A standardized system of inspector and reviewer feedback should be developed for use by organic certification agencies, to provide consistency and confidence in how inspectors are chosen between various certifiers.
6. This process of inspector oversight and training subject areas should be continually improved and updated by the NOSB and NOP, to address issues as they arise.

V Subcommittee vote

Motion to adopt this proposal as guidance to the NOP: “Inspector and Certification Review Personnel Training and Oversight”.
Motion by: Harriet Behar
Seconded by: Rick Greenwood
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Scott Rice, Subcommittee Chair to transmit to NOSB, August 17, 2018

Sunset 2020 Meeting 2 - Review
Livestock Substances §205.603
October 2018

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 in 2022. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments

Written public comments will be accepted through October 4, 2018 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

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

Alcohols (i) Ethanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(1) Alcohols. (i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
Technical Report: 1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use

The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products.

Manufacture

Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations.

International Equivalency

Several international organizations provide guidance on the application of synthetic ethanol in organic crop and livestock production as well as the processing of organic foods. Among these are international regulatory agencies (EU, Canada and Japan) and independent organic guidelines and standards organizations (Codex and IFOAM).

European Economic Community Council (EU) – Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils.

Canada – Canadian organic production standards permit the use of ethanol for a number of agricultural applications.

Japan – Ethanol may be used in the processing, cleaning, storage, packaging and other post-harvest processes when physical or methods using naturally derived substances are insufficient.

Codex Alimentarius – Ethanol is allowed when mechanical, physical and biological methods are inadequate for pest control.

IFOAM – Synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available.

Environmental/Health Issues

Aside from accidental spills, the risk of environmental contamination from released ethanol is minimal. The release of strong acids and bases used in the production of ethanol due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments. However, no incidents involving the release of these chemical feedstocks from ethanol production facilities have been reported. Further, lesser amounts of ethanol are constantly released to the environment from animal wastes, plants, insects, forest fires, and microbes without causing environmental impairment (HSDB, 2012). It is therefore unlikely that large-scale spills and associated environmental contamination will occur under the allowed use of ethanol as a sanitizer and disinfectant in organic livestock production.

Questions

1. Is ethanol still a commonly used substance in livestock?
2. Would you be able to meet the need for non-synthetic/non-GMO and/or organic ethanol if the demand for it were created by eliminating the listing for synthetic ethanol?

Public Comments

Public comments support ethanol remaining on the National List for antiseptic purposes because it is integral for preventing infection and the spread of pathogens while cleaning wounds. However, one commenter suggested the NOSB investigate the availability of non-synthetic ethanol from non-GMO fermentation organisms and feedstock, as well as the availability of organic ethanol.

Subcommittee vote

Motion to remove ethanol based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Jessie Buie
Seconded by Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Alcohols (ii) Isopropanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (1) Alcohols. (ii) Isopropanol-disinfectant only.
Technical Report: 1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use

Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage. Agricultural uses of isopropanol include the disinfection of production tools and surfaces and topical antisepsis during medical treatments. Livestock producers may use alcohol (i.e., isopropanol and/or ethanol) solutions for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and during medical treatments as a topical disinfectant (Jacob, 2013; Dvorak, 2008).

Manufacture

Chemical synthetic procedures are used in the commercial production of isopropanol that is used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011).

International Equivalency

A small number of international organizations provide guidance on the application of synthetic isopropanol in organic crop and livestock production as well as the processing of organic foods. Among these are the Canadian General Standards Board and the International Federation of Organic Agriculture Movements (IFOAM).

Canada – Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.

IFOAM – Isopropanol is an approved synthetic equipment cleaner and equipment disinfectant. Isopropanol is also an allowed synthetic substance for pest and disease control and disinfection in livestock housing.

Environmental/Health Issues

Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely. Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses. According to US EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410

1995).

Questions

1. Is isopropanol still essential?
2. Would you be able to meet the need for non-synthetic/non-GMO and/or organic ethanol if the demand for it were created by eliminating the listing for synthetic isopropanol?

Public comments support isopropanol remaining on the National list for disinfectant use in livestock.

Subcommittee vote

Motion to remove isopropanol based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Jessie Buie
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Aspirin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (2) Aspirin-approved for health care use to reduce inflammation.
Technical Report: 1995 TAP; 2017 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Manufacturing Process
The most prevalent method of synthesizing aspirin is via an esterification. Salicylic acid is treated with acetic anhydride, an acid derivative, causing a quantitative chemical reaction that turns salicylic acid's hydroxyl group into an ester group (R-OH → R-OCOCH3; Figure 2). This process yields aspirin and acetic acid, which are considered byproducts of this reaction. Small amounts of sulfuric acid (and occasionally phosphoric acid) are almost always used as a catalyst.

The chemical feedstocks for synthesizing aspirin are also manufactured through a chemical process. Salicylic acid is produced commercially via the Kolbe-Schmitt process. Here, phenol and sodium hydroxide react to make sodium phenoxide. The phenoxide comes into contact with CO2 to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from aqueous solution to give a technical grade 99.5% salicylic acid product. For a pharmaceutical grade product, salicylic acid is further purified by sublimation.

The commercial process for acetic anhydride was developed by Wacker Chemie in 1922 and uses a chemical reaction between acetic acid and ethenone at a low temperature and pressure.

Specific Uses of the Substance
Aspirin (i.e., acetylsalicylic acid) is a nonsteroidal anti-inflammatory drug (NSAID) used for temporary relief of minor aches and pains due to headache, muscular aches, minor arthritis pain, toothache, backache, the common cold, and premenstrual and menstrual cramps. It is also used for temporarily reducing fever, the prevention of cardiovascular events, and the treatment of rheumatologic disorders.

Approved Legal Uses of the Substance
Aspirin is considered a pain reliever and fever reducer in the over-the counter, tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use by the U.S. Food and Drug Administration (FDA) (53 Federal Register 46204, Nov. 16, 1988 and 21 CFR 343). Aspirin is included under 21 CFR 343.12 and 343.13 for the prevention of cardiovascular events and the treatment of rheumatologic disorders.

Aspirin is also listed at 7 CFR 205.603 as a synthetic substance allowed for the use in organic livestock production and is approved for health care use to reduce inflammation.
Its half life is short in cattle and it is not as beneficial in reducing pain as Flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency. Additionally, Flunixin must be administered under written orders of a licensed veterinarian and it has a restriction annotation for a withdrawal time.
A second pain medication approved for pain relief in organic livestock is Butorphanol (7 CFR 205.603(a)(5) and 21 CFR 522.246). Butorphanol is a synthetic opioid partial agonist analgesic; however, it also must be administered under a veterinarian's written orders, and it too is restricted by annotation to a withdrawal time.

Action of the Substance
Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effect. Depending on where in the body these prostaglandins are produced, they may trigger pain, inflammation, fever, or blood clotting. Following absorption, aspirin is hydrolyzed to salicylic acid, which is the active metabolite for its major clinical effects. Aspirin also inhibits platelet aggregation by irreversibly inhibiting prostaglandin cyclooxygenase.

Public Comments:
During the Spring 2018 NOSB meeting the Livestock Subcommittee received several comments in favor of relisting aspirin and no comments against relisting aspirin. Some of the comments in favor of relisting included:

- This product is important to the humane treatment of organic animals and is commonly used to reduce inflammation.
- It is the only real-time responsive form for inflammation and fever management available. There are other products that are available but do not offer the same type of timely response to ensure animal health and wellbeing. This is also a proven remedy and is critical in organic livestock production.

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of aspirin.

Subcommittee vote
Motion to remove aspirin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Ashley Swaffar
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Biologics—Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (4) Biologics—Vaccines.
Technical Report: 2011 TR (Vaccines from Excluded Methods); 2014 TR (Aquaculture)
Petition(s): 2012 Petition (Aquaculture)

Past NOSB Actions: 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation on Vaccines at §205.105; 10/2010 NOSB sunset recommendation; 10/2014 recommendation on Vaccines from Excluded Methods; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290 Sunset renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review
In addition to the allowance of this category of synthetic materials on the National List (NL), there are other areas that address 'biologics—vaccines" in the USDA organic regulations.
§205.200 Terms defined:
Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.
§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:
(e) Excluded methods, except for vaccines: *Provided,* That, the vaccines are approved in accordance with §205.600(a)

The Organic Food Production Act (OFPA) specifically allows vaccines to be used in the absence of illness, while prohibiting all other medications from this use.

Vaccines are produced through a variety of methods that use natural pathogens grown in a culture (yeast, bacteria or cell), separation and purification of the vaccine, and addition of other materials that may enhance the efficacy of the vaccine. These methods will result in a live, modified live, or killed vaccine.

Vaccination against bacterial or viral infections is a cost effective and efficient method or lessening animal suffering and disease. A vaccine contains, or produces in the vaccinated individual, an antigen that stimulates an immune response and enables protection from the disease and/or future infection.

Public comment
There was universal agreement among producers, certifiers and organic advocacy groups that vaccines are an important health maintenance tool on the organic livestock farm, with agreement to relist with no other annotation.
At the same time, there were numerous comments stating the implementation of §205.105 (e) is inconsistent between certification agencies, with some certifiers asking producers to determine if the vaccine they wish to use is genetically modified, and others not asking this of their producers. Some ask for the information, but allow all vaccines to be used, others prohibit the use of GMO vaccines. There

was agreement, especially among certifiers and organic advocacy groups that the current wording in the regulation is leading to inconsistencies in certification and confusion among producers and certifiers on this material.

Discussion

The Livestock Subcommittee is aware of the inconsistencies as described in public comment around the use of GMO vaccines. The Subcommittee also recognizes the great importance vaccines play in the prevention of livestock disease, and that the presence of Biologics-Vaccines on the National List is not the area in the regulation that is causing the confusion and inconsistency in the use of GMO vaccines. The Subcommittee has reviewed this material and judged it to meet the OFPA criteria for placement on the NL.

When an organic livestock producer loses one or more of their animals, there is more than just that animal's production capability lost, even though that is significant. Many times, there have been many years, even decades of breeding and genetic selection resulting in that specific animal. When that animal is lost to the farm, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer's toolbox to protect the investments that producers have in individual animals as well as their herds or flocks.

Subcommittee vote

Motion to remove biologics, vaccines from §205.603(a)(4) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A
Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(8) Electrolytes—without antibiotics.
Technical Report: 1995 TAP; 2015 TR
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Electrolytes are considered animal drugs by the FDA, and in USDA organic production they may only be used when preventative practices are inadequate to prevent illness, and may not be given in absence of illness. Electrolytes are used to restore ionic balance, treating a variety of metabolic conditions such as hypocalcemia, scours, milk fever, dehydration, mastitis, ketosis, acidosis and more. Electrolyte balance is essential to maintain normal physiology and health of livestock. When there is an imbalance of cations such as sodium, potassium, calcium or magnesium, either too low or high, the health and life of the animal is at risk. Stages of life, environmental stresses, stages of production such as birthing an animal, are all conditions that can throw the electrolyte balance off and would necessitate the use of this material to restore health and well-being to the animal.

Electrolytes are produced through industrial processes, fermentation, or may be mined. The major component of electrolyte formulations are salts and would have a variety of carriers or other ingredients (i.e., excipients) that enhance their properties, such as dextrose, citric acid, glucose, glycine, and more. The 2015 Technical Report (TR) has a detailed description of the various manufacturing processes.

Public Comment

In response to the questions of essentiality of this material in organic livestock production, and if there were any natural alternatives that could replace it, there was universal agreement among all commenters to retain this material on the National List, with no changes to the annotation. Organic certification agencies noted they certify many organic producers who use this material to maintain healthy livestock, both mammals and poultry. Environmental and consumer groups also supported this material as well as companies that market organic livestock products.

Discussion

This subcommittee believes this material satisfies the OFPA evaluation criteria. This material is used regularly and found to be essential by a large number of organic livestock producers. There were no negative public comments noted for this material.

Subcommittee Vote

Motion to remove electrolytes from §205.603(a)(8) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: Harriet Behar
Seconded by: Dan Seitz
Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Glycerin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**.** (11) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
Technical Report: 2010 TAP (Livestock)
Petition(s): N/A
Past NOSB Actions: 1999 NOSB recommendation; 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Glycerin falls under OFPA section 6517(c)(1)(B)(i) that describes livestock medicines. Glycerin is a by-product of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats & oils (either animal or vegetable): heat, steam, and pressure "split" the glycerin from the oil. The glycerin is concentrated in multistage evaporators and refined. Purification is achieved through either an ion exchange process or a distillation system, but it can also be produced synthetically from propylene. If only heat, steam or pressure is used to split the ester bonds to liberate free glycerol from fat (i.e. triglycerides), then this is a hydrolysis reaction catalyzed by physical forces and is compatible with organic criteria. However, if glycerol is formed by the chemical reaction of sodium hydroxide, then glycerol is produced by a chemically catalyzed hydrolysis reaction and may be considered synthetic.

Glycerin has over 1,000 uses; however, its use in organic is limited to an ingredient in teat dips (§205.603(a)(11)). As an ingredient in teat dips it prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990).

Glycerin is widely used as a carrier for other medications because it does not have detrimental chemical interactions with other substances, staying inert without changing the properties of whatever substance in which it is used. Furthermore, it acts as an emollient, reducing moisture evaporation of the skin. Glycerin mist can act as an inhalation irritant. It is easily digested with the same metabolism as carbohydrates.

Natural alternatives include castor oil and vegetable oils. There are some management tools for controlling mastitis, which include wiping debris from the teats, massaging the teat to loosen debris and stimulate milk letdown, wiping off the teat dip using individual cloths or paper towels, and applying the milking unit without air admission. None of the management tools seem to be effective alone.

The Livestock Subcommittee asked the following questions for the Spring 2018 meeting: (1) If there are non-food agricultural sources of glycerin available, should synthetic glycerin be removed from §205.603(a); and (2) How are certifiers tracking that the glycerin used as a teat dip is being produced through the hydrolysis of fats or oils?

The public comments were supportive of continued listing of glycerin as a livestock tip dip, and there were no responses to the questions.

Subcommittee vote
Motion to remove glycerin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A
Motion by: Sue Baird
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (19) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
Technical Report: 2003 TAP (Handling)
Petition(s): N/A
Past NOSB Actions: 10/1999 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Phosphoric acid, (H_3PO_4), has many uses. As a cleaner, it is generally used to remove rust and mineral deposits found on metal equipment such as boilers and steam producing equipment. In dairy operations, it is used to remove calcium and phosphate salt deposits from processing equipment.

Phosphoric acid is a hazardous substance. The exact dangers of it depend on the concentration strength of the solution, with higher concentrations presenting greater hazards. Phosphoric acid, at 85 wt. %, is considered a corrosive chemical solution that can cause, through skin exposure and inhalation, severe skin burns, permanent eye damage, sore throat, shortness of breath, and even death—among other things.

Additional information requested by Subcommittee

1. Is the substance essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment
Written comments were submitted prior to the spring 2018 NOSB meeting by three organizations and one organic dairy farmer. All commenters support relisting the substance, as phosphoric acid is considered essential for the purposes for which it is allowed. One organization stated that because phosphoric acid is highly corrosive, it would be worthwhile to see whether EPA's Safer Choice program offered any potential alternatives. Another organization recommended that an annotation be added that clarifies when a rinse or purge is, or is not, required.

The subcommittee recommends continued listing of the substance because it satisfies OFPA criteria.

Subcommittee vote
Motion to remove phosphoric acid from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Daniel Seitz
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Lime, hydrated

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Specific Uses of the Substance
Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parasiticide (7 CFR 205.603(b)(5)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes. Composition of hydrated or "slaked" lime consists primarily of calcium hydroxide [Ca(OH)2] and magnesium hydroxide [Mg(OH)2] at 50 - 95% and 0 - 50% of the substance, respectively. High purity forms of the substance contain greater than 90% calcium hydroxide.

Approved Legal Uses of the Substance
The USDA organic regulations currently permits the use of hydrated lime (calcium carbonate) for plant disease control in crop production (7 CFR §205.601(i)(4)) and external pest control in livestock production (7 CFR §205.603(b)(5)).

Discussion
The Livestock Subcommittee discussed the use of hydrated lime in both livestock and crop production, specifically, the relationship between crop use and livestock use and whether approval for use in one category affected the other. The following questions were posed to stakeholders:

1. Is the substance essential for organic livestock production and is it regularly used?

2. Since the material was last reviewed, have additional commercially available natural alternatives emerged?

Public comment
The majority of public comment supported relisting. Many commenters suggested that hydrated lime was essential for organic production in that it prevents the spread of pests among herds. A few commenters said that there are no alternatives to hydrated lime. The Subcommittee requests public comment on revising the annotation for hydrated lime.

Additional information requested from stakeholders
Is hydrated lime a useful tool for deodorizing animal waste?

Subcommittee vote
Motion to remove hydrated lime based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A
Motion by: A-dae Romero-Briones
Seconded by: Jessie Buie
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Mineral oil

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(6) Mineral oil—for topical use and as a lubricant.
Technical Report: 2002 TAP; 2015 TR
Petition(s): 2002 Petition
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Approved Legal Uses of the substance
The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding the use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites. Conventional operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. This medical practice is not currently approved in organic production, although a proposed rule by the National Organic Program (83 FR 2498, March 19, 2018) would allow for this use, if finalized

Discussion
In Subcommittee discussion, there was some concern about the manufacturing process and there was also brief discussion about the frequency of use in the organic community. A few members reiterated the importance of mineral oil to organic livestock farmers. The Subcommittee seeks input on the following questions:

1. Is mineral oil an essential material?
2. Are organic farmers using mineral oil as a lubricant?

Public comment
The majority of commenters considered mineral oil essential for organic agriculture and suggested re-listing. Most commenters indicated that they use mineral oil as a spray, and use it minimally (as little as one cup per animal) to control flies and mites. One commenter suggested de-listing mineral oil citing alternative substances to control pests

Subcommittee vote
Motion to remove mineral oil based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A
Motion by: A-dae Romero-Briones
Seconded by: Sue Baird
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Sucrose octanoate esters

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.
Technical Report: 2005 TR
Petition(s): 2004 petition; 05/2004 petition amendment; 09/2004 petition amendment
Past NOSB Actions: 08/2005 NOSB 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. SOEs, marketed as biopesticides, are intended to mimic the pest control properties of *Nicotiana gossei* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant. The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids. EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops; for sciarid fly control in mushroom-growing media; and for varroa mite control on honeybees.
The listing at §205.603(b) specifically addresses the petitioned use for livestock (i.e., honey bees) as a control of varroa mites.

Effect on the Environment
SOEs are an effective adult miticide and also control other pests. SOEs are not harmful to fish, hazardous to bees, or phytotoxic. When applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOE is expected.
SOEs biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so there is minimal potential for exposure to insects, fish, and other nontarget wildlife. A limited number of experiments have shown SOEs do not affect a range of predators and parasitoids that are killed by insecticidal soaps. Impacts on soil fauna have not been established.
Effect on Human Health:
SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified. An ocular risk exists but is unlikely if the product is used according to label.
Status:
The previous TR and/or NOSB recommendations do not provide sufficient information to evaluate SOEs relative to OFPA criteria for livestock production, specifically for varroa mite control on bees.

Public Comments
There were no substantive comments from beekeepers during the Spring 2018 public comment period on the continued listing of SOEs at §205.603(b); nevertheless there were comments from other livestock producers who stated that they were aware that SOEs are an important tool for beekeepers in controlling varroa mites in honey bees.
A public health advocacy organization commented that in view of the restrictive use of SOEs, and the difficulty that beekeepers are experiencing in maintaining the health of honey bee colonies, they supported keeping SOEs on the National List.

Additional information requested by Subcommittee

1. The TR does not address the toxicity of SOEs to non-targeted organisms, including predators, parasitoids, soil fauna, and aquatic organisms when exposed by spraying SOEs. Should there be further information requested about the toxicity of SOE to non-target organisms?
2. Is this product still being used, or are there other synthetic products that are more effective? If used, do we need to keep it available to be rotated with other products?

Subcommittee vote

Motion to remove sucrose octanoate esters (SOEs) from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Sue Baird
Seconded by: Jessie Buie
Yes: 2 No: 4 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Discussion Document
Oxalic Acid Dihydrate
August 21, 2018

Summary of Petition for Oxalic Acid Dihydrate:

A petition for oxalic acid was received in October 2017 for addition to the National List at §205.603 as a treatment of varroa mites in organic beehives. This material has not been petitioned for inclusion on the National List in the past. Oxalic acid is currently labeled and approved by the EPA for use in beehives (Registration #91266-1). A 2010 National Organic Standards Board proposal for Organic Apiculture recommended this material be approved with no restrictions for control of varroa mites in honeybee hives. Currently there are two materials on the National List that are used as pesticides in honeybee hives. As topical treatment, external parasiticide or local anesthetic as applicable: §205.603 (b)(2) Formic Acid and (b)(8) Sucrose Octanoate Esters (in accordance with approved labeling). A petition was received in December 2016 for thymol, a material that is also used for varroa mite control in honeybee hives, but this petition requested synthetic thymol be considered only for use in organic livestock footbaths. As with all materials on the National List, materials can only be used as annotated. Thymol for use in livestock foot baths is still under review by the National Organic Program. A request for a technical review (TR) was given to the National Organic Program in December 2017. At the date of the writing of this petition discussion document, the oxalic acid TR had not yet been received by the Livestock Subcommittee.

Oxalic acid dihydrate is presented as an alternative treatment to formic acid for varroa mites. This material can be used in rotation with, or instead of formic acid. Like formic acid, oxalic acid is present naturally in honey. Current research indicates that the amount of oxalic acid typically applied to the honeybee hive is not toxic to the bees, but is sufficient to kill varroa mites. The petition correctly states this material is listed for use in organic honeybee hives under the Canadian Organic Standards.

Since it is an acid, it is considered very hazardous in cases of skin contact, eye contact, ingestion or inhalation. Handling instructions include use of protective equipment, such as long sleeves and pants, chemical resistant gloves, goggles and a respirator. This material has also been sold as the active ingredient for bleaching wood.

Oxalic acid can be applied to a hive in two ways: In a sugar syrup to be trickled between frames, and as a vapor treatment. There are numerous types of equipment, both home-made and commercially available, that provide the beekeeper the means of heating the oxalic acid and filling the hive with this vapor. In addition, oxalic acid is used to treat packaged bees before they are shipped to customers. Packaged bees with infestations of varroa mites has been a problem for beekeepers and the use of a sugar/oxalic acid syrup spray is one method to address this issue.

Questions:

1. Is this material needed by organic beekeepers, and why?
2. There are alternatives to this material on the National List for control of varroa mites in honeybee hives. In addition, nonsynthetic materials such as essential oils and management techniques such as brood comb trapping are used for mite control. Why are the other materials/methods insufficient for varroa mite control in organic production?

3. This material is categorized as very hazardous by the EPA. Explain how accessible and practical the necessary protective equipment is for the operator. If you have experience with this material, describe your handling equipment and protocols.

Subcommittee vote

Motion to accept the oxalic acid dihydrate petitioned material discussion document
Motion by: Harriet Behar
Seconded by: Sue Baird
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB, August 24, 2018

Sunset 2020 Meeting 2 - Review
Handling Substances §205.605, §205.606
October 2018

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments
Written public comments will be accepted through October 4, 2018 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Note: With the exception of tragacanth and gellan gum, the materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

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)).''

Reference: 7 CFR §205.605(a) Nonsynthetics allowed:
Calcium carbonate
Flavors
Gellan Gum
Oxygen
Potassium chloride

Reference: 7 CFR §205.605(b) Synthetics allowed:
Alginates
Calcium hydroxide
Ethylene
Glycerides: mono and di
Magnesium stearate
Phosphoric acid
Potassium carbonate
Sulfur dioxide
Xanthan gum

Reference: 7 CFR §205.606
Fructooligosaccharides
Gums: Arabic, Carob bean, Guar, Locust bean
Lecithin - de-oiled
Tragacanth gum

Calcium carbonate

Reference: 205.605(a) Nonsynthetics allowed: Calcium carbonate.

Technical Report: 1995 TAP; 2018 TR
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Use
Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and nutritional fortification additive. The FDA allows the use of calcium carbonate as a binding agent in meat and poultry pieces. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List. Calcium carbonate has been used as a coloring agent. However, in historic organic food processing, both within the United States and internationally, calcium carbonate is not allowed for coloration purposes.
Public comments widely supported the relisting of this material, noting its essentiality to organic production in the absence of viable alternatives. Commenters detailed uses including in soy cheese, yogurts and beverages as a source of calcium, as much as 15% of the RDA. Comments also pointed to its use as a stabilizer.
Manufacture
Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. It is a mined mineral of at least 98% purity that is ground and screened.

International Equivalency
Canada - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015
- Allowed, prohibited for use as a coloring agent

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
- Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products
- Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production

Japan Agricultural Standard (JAS) for Organic Production
- Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance

International Federation of Organic Agriculture Movements (IFOAM)

- Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handing aids

Environmental/Health Issues
The mining and processing of calcium carbonate can have negative environmental impacts, which may include impacts on above and below ground water systems. Mining may have impacts on biological diversity as the mining may draw down the water table and impact surface water features that play host to a variety of species.

Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will avoid these issues. There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee has determined that calcium carbonate continues to be essential to organic production.

Subcommittee vote
Motion to remove calcium carbonate from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Flavors

Reference: 205.605(a) Nonsynthetics allowed: Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Technical Report: 2005 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use

Natural flavors are compound substances derived from natural sources including plants, herbs, spices, botanicals and other substances. They are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product.[1] The significant function of natural flavors must be flavor rather than nutrition. The FDA defines Natural Flavors in 21 CFR 101.22 as:

> The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in 172.510 of this chapter.

Manufacture

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

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

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

International

Natural/Non-synthetic flavors are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex Standards.

[1] http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf
[2] http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf
[3] http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf

Ancillary Substances

Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: "must not be produced using synthetic solvents and carrier systems or any artificial preservative." Flavoring constituents are considered proprietary by flavoring companies and are not normally disclosed.

Discussion

During the Fall 2010 NOSB meeting, the NOSB completed its sunset review of flavors for re-listing and stated:

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

On January 21, 2011, the NOP issued a Policy Memorandum on Use of Natural Flavors that stated, in part:

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

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

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

At the Fall 2015 NOSB meeting, the NOSB recommended revising the annotation for flavors to read as follows:

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

At the Fall 2015 NOSB meeting, substantial comment was received from industry, trade associations, and Accredited Certifying Agents (ACAs) supporting the continued listing of natural flavors as well as the adoption of the flavor petition.

On January 17, 2018, the NOP published a proposed rule (83 FR 2498) to adopt the Fall 2015 recommendation and change the annotation for flavors at § 205.605(a) to:

> Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Public comment was received from several interest groups and industry that encouraged the adoption of the 2015 NOSB proposal to change the annotation for natural flavors. There was also support from interest groups for furthering the requirements for organic flavor usage. Some commenters specified that that the flavoring constituents in the flavor, as well as the carrier system, need to be organic. Other comments objected to the fact that flavors were a categorical listing. Several businesses and trade associations commented on use and essentiality. In one of the surveys by one of the associations, manufacturers rated flavors as a 9 or 10 on a scale of 1 to 10 of essentiality; 10 being the most essential. Certifiers also reported a wide usage of flavors amongst their clients. One retailer asked about further restriction of flavors when their use is to replace the natural source of the food's advertised flavor, stating that natural flavors should not be allowed to be used as the only defining source of a food's advertised flavor. This is addressed and regulated by the FDA, particularly under 21 CFR 101.22 and 21 CFR 102.5 that define characterizing flavors based on the label, including words and pictures, advertisement or consumer expectations. If the characterizing flavors are not present without the use of a natural flavor ingredient, then the product would need to be labeled as naturally or artificially flavored on the front panel even when natural flavors were used depending on formulation.

The NOSB received no new information to support removing flavors from the National List. To the contrary, the NOSB received significant public comment in support of the relisting of natural flavors.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports the relisting of flavors.

Subcommittee vote

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

Gellan gum

Reference: 205.605(a) Nonsynthetics allowed: Gellan gum (CAS # 71010-52-1)—high-acyl form only.

Technical Report: 2006 TAP; 2018 TR

Petition(s): 2004 Gellan gum

Past NOSB Actions: 2007 Formal Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 6/22/2020

Subcommittee Review

Material Use

Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution (2006 TR 32-34, Petition pg. 10). Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR 182-187, 2006 TR 37-41, Petition pg. 2). Typical use of gellan gum is at <0.5% of a finished product formula (Petition pg. 2). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life, and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR 16-19, 66-70, 2018 TR 648-660). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR 662-670). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR 54-55). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g. potassium, calcium, magnesium); these deacylated forms are not approved on 205.605(a) (2006 TR 109-112). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR 107-117).

International Equivalency

The material is FDA approved as a direct food additive in accordance with 21 CFR 172.665; it is also approved in many countries worldwide in food and non-food items. Gellan gum is listed by the World

Health Organization Joint Expert Committee for Food Additives (Petition pg. 5).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of gellan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Gellan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Gellan gum is allowed for use as compliant with Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Gellan gum is neither listed as allowed, nor as prohibited (2018 TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Gellan gum is not listed as allowed, nor prohibited (2018 TR 538-541).

East African Organic Product Standard

Gellan gum is neither listed as allowed or prohibited (2018 TR 543-541).

Ancillary Substances

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

The two available technical reports (TRs) did not list any notable human health or environmental concerns regarding the use of gellan gum.

During the 2018 spring public comment period, a number of manufacturers wrote in support of the material, with multiple manufacturers stating that they are using gellan gum as a carrageenan replacement due to customer concerns. Examples of specific products that use gellan gum include plant-based creamers and beverages, dairy beverages, and yogurt.

A couple different organizations requested that the Confidential Business Information (CBI) from the original petition be disclosed and requested the material be delisted until that happens. One retailer commented that organic consumers want to avoid products with stabilizers and emulsifiers, including gellan gum, and was opposed to its re-listing.

Additional information requested by Subcommittee

None

Subcommittee vote
Motion to remove gellan gum from §205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Oxygen

Reference: 205.605(a) Nonsynthetics allowed: Oxygen—oil-free grades.

Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Use
Oxygen is used in modified atmosphere packaging, the processing of olives, and by wineries, breweries, and manufacturers of carbonated beverages.

Manufacture

Oxygen is separated from air cryogenically; super cold temperature liquefaction of air and fractional distillation.

International

The use of oxygen is permitted in organic standards in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances

None.

Additional information requested by Subcommittee
None

Public comment prior to the spring 2018 NOSB meeting was mostly in favor of relisting. One organization commented that oxygen should be removed from the National List if necessity wasn't documented. According to public comment it is used by wineries, breweries, and manufacturers of carbonated beverages. One certifier reported that it is listed on 14 Organic System Plans (OSPs). One winery commented they use it for micro-oxygenation, a process where oxygen is added to red wine at a controlled rate and flow to stabilize color, improve astringency, and aromatic components of the final wine. Micro-oxygenation also allows wines to be released to consumers at a younger age which in turn reduces the amount of sulfur dioxide that needs to be added during the wine making process.
No negative impacts on health or the environment were brought to the subcommittee's attention.

Subcommittee vote
Motion to remove oxygen from§205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Potassium chloride

Reference: 205.605(a) Nonsynthetics allowed: Potassium chloride.
Technical Report: 1995 TAP; 2015 TR Nutrient Vitamins and Minerals
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Specific Uses

According to the Food & Drug Administration FDA), potassium chloride is generally recognized as safe (GRAS). Affirmed uses of potassium chloride in foods are as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. Like salt, potassium chloride provides a salty flavor and can also often play other functional roles (e.g. microbial management, protein modification, flavor enhancement) that impact the taste, texture, and shelf life of food products. Potassium chloride is generally used for two main purposes in food products. The first is to provide potassium enrichment to foods. The second is as a salt replacement to reduce the sodium content in foods.

Discussion

During Subcommittee review, one Board member stated that potassium chloride is primarily used in infant and baby products.

The following questions were posed to stakeholders:

1. Is the substance essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

The public comment was unanimous in support of re-listing potassium chloride. Several commenters focused on potassium chloride as a key ingredient in low-sodium products. Another commenter stated that potassium chloride is essential in the fortification of infant and baby formula.

Subcommittee vote

Motion to remove potassium chloride from§205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: N/A

Motion by: A-dae Romero-Briones
Seconded by: Steve Ela
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Alginates

Reference: 205.605(b) Synthetics allowed: Alginates.
Technical Report: 1995 TAP; 2015 TR

Petition(s): 1995 Alginates

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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use
Alginates are useful as gelling, thickening and stabilizing agents in a wide variety of organic products, including drinks, ice cream, puddings, cookies, meat, and pasta dishes. They are particularly useful in that they do not need heat to be activated. They can be used to gel cold products and do not melt if the product is heated. They can be used in coatings to help preserve moisture content, protect flavor and enhance shelf life. They can also be used to generate spheres with a thin membrane and liquid center that provide texture and flavor "pops" in certain foods. While not technically a preservative in themselves, they can be used as carriers for preservatives and may inhibit food deterioration due to moisture loss.

Despite their widespread use in a variety of foods, alginates have several limitations. They have limited solubility at low pH values, and high calcium content foods can interfere with their activity.

Alginates have been accepted for use in organic foods since the National Organic Program rule was published in 2000. They have been recommended for relisting in each of three sunset reviews. A 2015 technical report detailed the production of, use of, and alternatives to alginates. Information from that technical report was used for the following summation.

Manufacture
Alginates are normally extracted from the cell walls of seaweed, specifically, brown algae. While they can also be generated by bacterial fermentation, the fermentation process is not currently economically viable. To isolate alginate from seaweed, several isolation steps involving extraction, acid additions, purifications, and base additions are required. The final result is either alginic acid or the salt form, alginates. Alkali extraction renders alginates as synthetic.

International (drawn from the 2015 TR)
Canada - certain alginates are permitted under the Canada Organic Regime due to their appearance in the section titled "Non-organic Ingredients Classified as Food Additives, of the Organic Production Systems Permitted Substances List." In this section, alginates (alginic acid, sodium alginate and

potassium alginate) are included in Table 6.3 (Canadian General Standards Board 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - certain alginates are permitted. Only potassium (402) and sodium (401) alginates are listed as allowed food additives in Table 3.1 as an ingredient of nonagricultural origin in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (Codex Alimentarius Commission 2014).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 **-** alginates (E401-E405) are permitted because they are included in the list of allowed food additives for use as thickeners and stabilizers (E400-E499). Alginates are classified as nonagricultural in the EU Organic Regulations (The Council of the European Union 2008). Sodium alginate (E 401) is listed as an approved food additive for use in certain unprocessed fruit and vegetables in an amendment to Annex II of the Commission Regulation (EC) No 969/2014 (The Council of the European Union 2014).

Japan Agricultural Standard (JAS) for Organic Production **- c**ertain alginates are permitted. The JAS for Organic Processed Foods identifies sodium alginate as an allowed food additive limited to use only in processed foods of plant origin, INS number 401 (The Japanese Organic Standard 2005).

International Federation of Organic Agriculture Movements (IFOAM) **- c**ertain alginates are permitted. Sodium and potassium alginate are recognized by IFOAM as approved additives for use in organic processed products without annotation (IFOAM 2014) (Appendix 4: Table 1).

Ancillary Substances
No ancillary substances (e.g. stabilizers, 352 preservatives or anti-caking agents) were listed on publically available specification sheets (2015 TR).

Discussion
Alginates are Generally Recognized As Safe (GRAS) when used with good manufacturing practices. Alginates are not absorbed by the human body, making them useful as a low-calorie ingredient. While human health effects are generally recognized as minimal, there is evidence that alginates in foods may reduce iron absorption.

The production of alginates generally involves the harvesting of wild seaweed. Increased harvesting of seaweeds leads to questions about the sustainability. Seaweed populations are potentially impacted by overharvesting, the effects of increased ocean water temperatures, and pollution. Attempts at farming seaweed have not been economically successful, thus the sustainability of current wild harvesting is crucial to future alginate production.

While there are a number of alternative thickeners and gelling agents available to organic handlers, the property of alginates to make gels without the use of heat distinguishes them from many other products.

Additional information requested by the Handling Subcommittee
Are there any organic alternatives to alginates that have become available for use since the 2015 technical report was written?

Of the comments received during the Spring 2018 public comment period, most manufacturers and users of alginates noted that the unique properties of alginates were critical to the formulations of their products. Many commenters supported the relisting of alginates on the National List.

Other commenters noted that alginates are synthetic derivatives of brown seaweeds. Thus, issues of sustainable harvesting of seaweeds, disturbances of marine ecology through their harvesting, and bioaccumulation of contaminants such as heavy metals and radioactivity should be accounted for in the review of this material. Several of these commenters asked that the use of alginates require the seaweeds to be organically produced, either through cultivation or by following the wild harvesting rules.

Finally, several commenters noted that they believed the NOSB should review each ingredient derived from brown seaweeds separately. The National List should list each of these substances separately, together with the species name the substance is derived from, and not lump these ingredients under the more general category of "alginates".

Subcommittee vote
Motion to remove alginates from §205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Calcium hydroxide

Reference: 205.605(b) Synthetics allowed: Calcium hydroxide.
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Specific Uses and approved legal uses of the Substance

Calcium hydroxide is used as a component of aluminum free baking powder, to clarify sugar for molasses, and as a conditioner for corn tortillas. It is known as "slaked lime" or "hydrated lime." Calcium hydroxide is lime that is calcined in a kiln to obtain carbon dioxide and quick lime. The quicklime is mixed with water to produce calcium hydroxide. Calcium hydroxide is used as a pH buffer and as the alkaline substance in aluminum-free baking powder. It is also used to fortify foods with calcium, clarify sugar cane or beet juice, for making hominy and masa, and as a firming agent. It is also used in the production of organic corn starch and to remove impurities from solutions.

Discussion

The subcommittee requested the following information from stakeholders:

1. Is calcium hydroxide essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

The majority of commenters supported relisting. However, one commenter suggested that the NOSB clarify which uses of calcium hydroxide are permitted, specifically if calcium hydroxide can be used as a firming agent. Additional commenters stated that they use calcium hydroxide in infant formula.

Subcommittee vote

Motion to remove calcium hydroxide from §205.605(b) from the National List based on the following criteria in the Organic Food Productions Act (OFPA) and/or 7 CFR 205.506(b) if applicable: N/A
Motion by: A-dae Romero Briones
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Ethylene

Reference: 205.605(b) Synthetics allowed: Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.

Technical Report: 1995 TAP; 1999 TAP - Processing

Petition(s): 1995 N/A, 2008 Ethylene (for use with pears)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote (add tropical fruit and citrus); 11/2005 sunset recommendation; 11/2008 recommendation for pears; 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Ethylene is currently listed at §205.605(b) as a material allowed for postharvest ripening of tropical fruit and degreening of citrus. Ethylene ($CH_2{=}CH_2$) is a colorless gas at room temperature. It is produced naturally in small amounts by some plants and functions as a ripening agent. The commercially used form, which is synthetic, is chemically identical to the naturally occurring form. The synthetic form is produced from hydrocarbon feedstocks, such as natural gas liquids or crude oil, and may also be derived from liquid ethanol.

Use of ethylene naturally produced by fruits has not been commercialized. Amounts produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires. It is used in the post-harvest ripening of tropical fruit and the de-greening of citrus.

International

Canada: Allowed for post-harvest ripening of tropical fruit and degreening of citrus.
Japan: Limited to use for after-ripening banana and kiwifruits.
IFOAM: De-greening of citrus and ripening
EU: Degreening bananas, kiwis and kakis; Degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus.
CODEX: Degreening of citrus for fruit fly prevention. As sprouting inhibitor for potatoes and onions.

Ethylene is potentially flammable and also an asphyxiate if high concentrations displace oxygen, but based on previous reviews, significant impacts on human health and the environment are likely minimal.

Public comment about ethylene gas (EG) was very limited and reflects two opposing views. Some consumer groups considered EG to be an unnecessary synthetic growth regulator (ripening agent) and contrary to organic principals, while wholesale and grocer organizations considered it essential for tropical fruits and allowing organic fruit production that is important to the organic produce sector.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting of ethylene.

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

Glycerides (mono and di)

Reference: 205.605(b) Synthetics allowed: Glycerides (mono and di)—for use only in drum drying of food.

Technical Report: 1995 TAP; 2015 TR

Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use
Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life (TR 2015 82-83). However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals (TR 2015 91-92). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (TR 2015 105-106).

Manufacture
Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides.

When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources (TR 2015 56-59). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut or palm oil (TR 2015 59-60), and their main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils. (TR 2015 56-62).

International

Glycerides are permitted in organic standards in Canada, with the annotations: From organic sources if commercially available. For use in drum drying of products.

They do not appear in the following organic standards: CODEX, EU, IFOAM or Japan.

Ancillary Substances

None.

According to the 2015 technical report (TR), alternative ways to dry foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Drum drying is said to be preferred for potato flakes. Freeze drying has been suggested as an acceptable alternative to drum drying.

Evaluation question #13 in the 2015 TR suggested a few potential agricultural alternatives. One is a commercial product, made of organic rice bran extract, which is marketed as an emulsifier and drum release agent. Trials by the manufacturer concluded that rice bran extract had the highest capacity for oil-in-water binding. However, the hydrophilic –lipophilic balance of rice bran extract is narrower than that of mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of the mix to which it is added.

Organic soy lecithin and gum arabic (both currently on the National List) were also raised as possible alternative substances to glycerides, although the use of gum arabic in drum dried food is not widely reported. The TR also considered the use of lecithin as an alternative but stated that as compared to mono and diglycerides it provides much less emulsion stability, much less starch interaction, and more fat modification.

The TR concluded that in general, each emulsifier (and its form) is selected based on specification of the food and the processing application (TR 2015 522-547).

Additional information requested by Subcommittee

1. The TR lists possible alternatives to drum drying, such as spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Have any of these alternatives been tried? And if so, what were the results?
2. Has rice bran extract, soy lecithin, or gum arabic been tried as an alternative to glycerides (mono and di) in drum drying? What were the results?

Subcommittee vote

Motion to remove mono- and diglycerides from §205.605(b) from the National List based on the following criteria in the Organic Food Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Magnesium stearate

Reference: 205.605(b) Synthetics allowed: Magnesium stearate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".

Technical Report: 1995 TAP; 2018 TR
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 renewa notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Magnesium stearate (CAS # 557-04-0) is used as an anti-caking agent in salt. It is a flow agent, food processing machine lubricant, and may be an incidental additive. The most common use of magnesium stearate is as a binding agent in dietary supplements. Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" and is prohibited in agricultural products labeled "organic."

Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils, magnesium stearate is produced by adding an aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

The Canadian General Standards Board (CGSB) includes nonsynthetic sources (and synthetic sources provided that nonsynthetic sources are not commercially available) of magnesium stearate as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients. The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999).

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). Magnesium stearate must meet the specifications outlined in the Food Chemicals Codex (21 CFR 184. 1440(b)) and can be used in food with no limitation other than current good manufacturing practice. There was no information provided indicating any significant human health impacts and historically there have not been comments recommending removal of this material from the National List.

In the past, the NOSB Subcommittee has requested public comment on availability of alternatives and any information on possible negative human health impacts. Public comment has been very limited. One certifier commented that two of their members use magnesium stearate to manufacture pharmaceutical and dietary products. The Council for Food Additives supported relisting. Others raised concerns about the use of pesticides/genetic engineering in the non-organic production of oils used for its manufacture and the availability of organic or sustainable alternatives. Magnesium stearate is allowed only in agricultural products labeled "made with organic." Some of those same commenters said they were not opposed to the relisting since the material is only used in "made-with products" and, hence, does not threaten organic integrity.

This proposal to remove magnesium stearate will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting magnesium stearate.

Subcommittee vote

Motion to remove magnesium stearate from §205.605(b) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: N/A
Motion by: Asa Bradman
Seconded by: Tom Chapman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Phosphoric acid

Reference: 205.605(b) Synthetics allowed: Phosphoric acid—cleaning of food-contact surfaces and equipment only
Technical Report: 2003 TAP
Petition(s):N/A
Past NOSB Actions: 10/1999 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Specific Uses of the Substance

Phosphoric acid is used in cleaning procedures to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining on stainless steel, lime and scale from heat exchangers and in Clean-In-Place cleaning operations, especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

Discussion

The Handling Subcommittee reviewed phosphoric acid as part of a larger discussion about "sanitizers" and whether phosphoric acid has safer alternatives. The discussions were inconclusive.
The following information was requested from stakeholders:

1) Is the substance essential for organic food production?
2) Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

The majority of stakeholders supported the relisting of phosphoric acid; however, there were numerous comments that suggested the Board find ways to explore safer alternatives to phosphoric acid. One commenter in particular focused attention on the environmental damage to water resources because of the continuous build of phosphoric acid when washed down drains. Many commenters focused on phosphoric acid as part of a food safety plan for organic operations since many other sanitizers cannot be used in contact with food like phosphoric acid. Other commenters mentioned that some phosphoric acid alternatives have already been removed from the list so phosphoric acid is even more important to food safety planning. The majority of commenters agreed that a safer alternative needs to be explored, but is not readily available at this time.

Subcommittee vote

Motion to remove phosphoric acid from §205.605(b) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b): N/A
Motion by: A-dae Romero-Briones
Seconded by: Scott Rice
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Potassium carbonate

Reference: 205.605(b) Synthetics allowed: Potassium carbonate.
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 03/21/17 (82 FR 14420)
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Use

Potassium carbonate has many uses. It is commonly used in the Dutch alkali process for processing cocoa and chocolate to reduce acidity. It is also used as a pH control, leavening agent, a boiler water additive, a tenderizer for tripe, in soap production, soft drinks, and confections. Also, it is used as a buffering agent in making wine and mead to reduce acidity.

The original technical advisory panel (TAP) notes that it be used only when sodium carbonate is not appropriate. However, it can be used to replace sodium carbonate when a lower sodium content is desired.

Public comments demonstrated a continued need for this material. One manufacturer noted its use as a sodium reduction agent and that removal from the list would result in a rise in sodium levels in their product by 18%. Other commenters noted use in a protein bar and as a nutritional supplement.

Manufacture:

Potassium carbonate is a strongly alkaline white salt, a major component of the mined salt potash, which is made by passing carbon dioxide through a solution of potassium hydroxide. It is a caustic material with chlorine gas, a bi-product at manufacture, collected to avoid environmental pollution and human health impacts.

International Equivalency:

Canada - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Appears on Table 6.3 - Ingredients classified as food additives

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items
- 05.0 Confectionery
- 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category
- 07.007.2 Fine Bakery wares (sweet, salty, savoury) and mixes; not permitted in food of animal origin
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3
- Drying of grape raisins

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

- Appears in Annex VII, Section A - Food additives including carriers
- Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production, drying of grapes

Japan Agricultural Standard (JAS) for Organic Production

- Appears in Table 1, Food additives, Limited to be used for drying processed fruit products, or used for grain processed foods, sugar, processed beans products, noodles, bread or confectionary.

International Federation of Organic Agriculture Movements (IFOAM)

- Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handling aids

This proposal to remove will be considered by the NOSB at its public meeting. Potassium carbonate continues to be essential to organic production, and the Handling Subcommittee supports relisting.

Subcommittee vote

Motion to remove potassium carbonate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A.

Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Sulfur dioxide

Reference: 205.605(b) Synthetics allowed: Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.

Technical Report: 1995 TAP; 2011 TR
Petition(s): 1995 N/A; 2010 Sulfur Dioxide
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 12/2011 annotation change; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Sulfur dioxide is primarily used to prevent spoilage and oxidation in wine. It may also be used to preserve meats, fruits and other products; however, there are limitations to its use. These limitations include foods used as a source for Vitamin B1, raw fruits and vegetables, foods consumed in large quantities, or meats. The current National List annotation limits the use of sulfur dioxide to wine labeled "made with organic grapes" and further limits the sulfite concentration to not exceed 100 ppm.

Sulfur dioxide has undergone three sunset reviews and has been relisted each time. A technical report (TR) was done in 2011 and forms the bases of the comments summarized below:

In wines, sulfur dioxide is commonly referred to as 'sulfite' or 'sulfites'. The sulfur dioxide inhibits microbial growth and prevents oxidation. Sulfur dioxide is often added to grapes to be fermented in very specific doses. Cultivated yeasts added to enhance fermentation of wines have been selected to be more tolerant of sulfur dioxide than wild yeasts. Enough sulfur dioxide is added to deter growth of the wild yeasts or bacteria present in the grape juice, while not exceeding a level that will deter the growth of the desired, added, yeasts to the juice. This process helps to prevent the formation of "off" flavors and helps to preserve the "freshness" flavor in white wines. While sulfur dioxide occurs naturally in wines, the level is too low to have pragmatic effect. Wines without added sulfur dioxide generally must be kept in perfect storage conditions and have a shortened shelf life of around six months. This is often very difficult to achieve, and the addition of sulfur dioxide has become accepted for meeting consumer expectations of wine quality.

Manufacture

Sulfur dioxide can be produced commercially from several sources including elemental sulfur, ores of sulfide containing minerals, gypsum and anhydrite, and waste materials or flue gasses that contain sulfur. Most commonly, sulfur dioxide is generated by simply burning sulfur in devices that control air flow and that can capture the sulfur dioxide as it is generated.

International (drawn from the 2011 TR)

Canada – Canadian standards permit the use of sulfurous acid as preservative only in alcoholic beverages labeled as organic but do allow those beverages to be made from grapes or other fruits, unlike the United States which limits its use to wine made from grapes. Furthermore, the Canadian standards allow the alcohol to be labeled as "organic" and set a range of allowable sulfite concentrations that depend on the residual sugar content of the beverage.

The European Economic Community (EEC) allows sulfur dioxide at a maximum of 50 mg/L after fermentation in fruit wines, cider, perry or mead that do not have added sugar. They allow sulfur dioxide at a maximum of 100 mg/L after fermentation for cider and perry that have sugar added. All these beverages may be labeled as organic.

The CODEX Alimentarius Commission permits the use of sulfur dioxide for making cider, perry, mead, and wines made from grapes or other fruits.

Ancillary substances

The 2011 TR makes no mention of ancillary substances associated with sulfur dioxide.

Discussion

Sulfur dioxide is considered to be Generally Recognized As Safe (GRAS) by the Food and Drug Administration when used in accordance with good manufacturing practices, except it is not to be used in meats, food recognized as a source of vitamin B1, on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented as fresh (21 CFR 182.3862). It is recognized to be used in organic products internationally, although various restrictions are placed on its use, either in limitations of concentration or on the products it may be used in.

Sulfur dioxide may cause health effects in sensitive individuals. These effects range from allergic reactions in individuals born without the enzyme sulfite oxidase, asthma attacks, which vary depending on individual sensitivity, hives and swelling, to anaphylaxis. There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in on the National List.

The current annotation allows the use of sulfur dioxide only in wine made from organic grapes. The increasing interest in ciders, wines not made from grapes, and other fermented beverages has led to inquiries about possible use in these products; however, a petition to the NOSB would be required to change the current annotation. While alternatives to sulfur dioxide for winemaking have been investigated, the TR notes that there are not organic alternatives that are satisfactory to prevent spoilage and oxidation in wine.

Public comments received during the Spring, 2018, public comment period noted the essentiality of sulfur dioxide for winemaking. Wine producers used sulfur dioxide to prevent oxidation and spoilage of wines. No alternatives have been identified, and commenters noted that they would not be able to produce quality white wines and that red wines would have a limited shelf life without the use of this material.

A number of commenters noted that in the United States, wines that use sulfur dioxide can only be labelled “made with organic grapes,” whereas in many parts of the world wines may be labelled as “organic” when this material is used. Thus, the United States is more restrictive than most countries. Several commenters noted that if the material were removed, there would be a considerable loss of market share and quality for wines made with organic grapes.

Subcommittee vote

Motion to remove sulfur dioxide based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Eric Schwartz
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Xanthan gum

Reference: 205.605(b) Synthetics allowed: Xanthan gum.

Technical Report: 1995 TAP; 2016 TR; 2018 TR

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 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review

Material Use

Xanthan gum is used in numerous foods products as a hydrocolloid (i.e. substances that disperse water, giving a thickening or gelling effect) including but not limited to: baked goods, beverages, dairy products, dressings, nutritional supplements, frozen foods, etc. (TR 758-759, 135-137). Xanthan gum is commercially available to consumers for use in gluten-free baking and other recipes. The gum is used in small percentages of the finished products, usually at <0.5% by weight (TR 145-146). Xanthan gum is used along with other gums to achieve the desired viscosities and product structures for firmness, water binding, flavor delivery, etc. (TR 229-236); it is particularly effective in frozen and chilled products where it can impart thickness, freeze-thaw protection, and stability during processing and shelf-life (TR 251-256). Common synergistic gums used along with xanthan gum are locust bean gums, guar gums, carrageenan gums (TR 229-236).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture

Xanthan gum is a high-molecular weight polysaccharide produced though natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried and milled (TR 36-38, 90-97).   The gum is water soluble, stable at numerous pH, salt and temperature ranges (including frozen temperatures) (TR 120-124). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 50-55). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (TR 48-50). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 Gums TR 424-432).

International Equivalency

FDA has approved the use of xanthan gum as a food additive since 1969 without restrictions on quantity in finished applications (TR 162-163, 637-638); it must be isolated by isopropyl alcohol precipitation and made into a sodium, potassium, or calcium salt (TR 164-166). It is approved by FDA at 21 CFR 172.695 but is not GRAS; although three FDA notices for GRAS allow isolation of xanthan gum by ethanol and pyruvate, and in combination with konjac glucomannan and sodium alginate (TR 651-659).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of xanthan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 Gums TR 491-496).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Xanthan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 Gums TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Xanthan gum is allowed for use as compliant with General Standard for Food Additives Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 Gums TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Xanthan gum is allowed in processed foods of animal origin limited to dairy or confectionary (2018 Gums TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Xanthan gum is allowed with no limitations on use (2018 Gums TR 538-541).

East African Organic Product Standard

Xanthan gums is allowed in fats, fruits and vegetable products, and cakes and biscuits.

Ancillary Substances

According to the 2016 TR (258-263), ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. Through a search of publically available specification sheets a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®.

Xanthan gum has been used for decades globally in the food system and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 637-742). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR 933, 963-976). In 2011 there was a recall of a xanthan gum product that was being fed to premature babies. The recall was due to the lack of destruction of potentially harmful bacteria that may lead to necrotizing enterocolitis; no conclusions were made regarding the safety of xanthan gum thickeners for premature baby formulas (TR 678-711).

There was no mention in the TR of specific environmental issues regarding the production of xanthan gum.

During the Spring 2018 public comment period, a number of organizations, certifiers, and manufacturers expressed support for the material, with one larger certifier stating that of all the gums xanthan is the most commonly found in organic system plans. One manufacturer stated that other organic gums didn't have the same functionality in their organic baked goods. One retailer commented that organic consumers want to avoid products with stabilizers and emulsifiers, including xanthan gum, and was opposed to its re-listing.

Additional information requested by Subcommittee: None

Subcommittee vote

Motion to remove xanthan gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Fructooligosaccharides

Reference: 205.606(e) Fructooligosaccharides (CAS # 308066-66-2).
Technical Report: 2006 TAP; 2015 TR
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

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

Manufacture:
There are two common commercial methods to produce FOS:

- **Inulin derived.** Inulin, a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), Agave, and other plants. Chicory inulin is extracted from the source material via water extraction; the resulting inulin undergoes a partial enzymatic hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger*. The hydrolysis breaks long chain inulin into the shorter chain FOS.
- **Sucrose derived.** Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas*. The *A. japonicus* cells must be immobilized for production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicus* culture suspended in calcium alginate, an immobilizer. *A. japonicus* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfer fructose molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicus* is generally inefficient. Higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

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

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

International:
FOS is not specifically listed in the Codex, EU, Japanese organic standards or Canadian standards. However non-organic agricultural products are not listed in these standards.
Discussion: During the 2015 sunset review, the NOSB received limited feedback from users of this substance. However, the comments that were received supported the continued listing for usage in the baking industry and no sources of organic FOS were identified. During the current sunset review the NOSB posed questions about the development and general availability of organic FOS. No comments were received on this question. The NOSB also inquired about the difference between inulin- and sucrose-derived FOS, but no new information was presented about its manufacture that wasn't known to the NOSB in 2015 when it concurred with previous NOSB determinations that this substance was agricultural. Lastly

the NOSB asked about the functional necessity of FOS, and while detailed information was not provided, several manufacturers (some via trade associations) spoke about its essential usage as a prebiotic, particularly in baby and infant foods and in kombucha beverages.
This product is currently used in organic processed products, and no new material information was received to justify removing this substance from the national list.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting of FOS.

Subcommittee vote
Motion to remove fructooligosaccharides (FOS) from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Tom Chapman
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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

Reference: 205.606(g) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Material Use
Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR 78-103). These gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (TAP pg. 8, 2018 TR 443). These gums are used in various food applications due to their ability to modify viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR 182-187). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR 189-192).
Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:
Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder. (2018 TR 566-573)
Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR 594-595)
Guar gum is formed form the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR 584-586).

International Equivalency:
Gum arabic, locust/carob bean gum and guar gum are all listed by the FDA as Generally Recognized as Safe (GRAS) (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of Gum Arabic, locust/carob bean gum, and guar gum as long as they are derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Gum Arabic (414), locust/carob bean gum (410), and guar gum (412) are allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008
Gum Arabic, locust/carob bean gum, and guar gum are allowed for use in processed organic foods as a food additive in the preparation of foodstuffs of plant 508 or animal origin with no specific limitations (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Arabian gum (INS 414) is limited to dairy products, edible fat, and oil and confectionary products (2018 TR 527).
Carob bean gum/locust bean gum (INS 410) is limited to dairy and processed meats. (2018 TR 529)
Guar gum (INS 412) can be used in processed foods of animal origin limited to dairy, canned meat or egg products. (2018 TR 531)

International Federation of Organic Agriculture Movements (IFOAM)
IFOAM allows locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415). There are no restrictions on how any of these items can be used (IFOAM, 2014). (2018 TR 539-541)

East African Organic Product Standard
Locust bean gum, guar gums are allowed with no restrictions. Arabic gum is allowed for milk products, fat products, confectionary, sweets and eggs (2018 TR 544-550).

Ancillary Substances:
According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) Panel on Food Additives and Nutrient Sources evaluated five gums in 2017 including arabic, guar, and locust. The panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population. The panel also concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children and recommended that additional data be generated.
Public comment prior to the Spring 2018 NOSB meeting included manufacturers and associations in support of these gums on the National List. One manufacturer noted that they source organic guar and locust bean gum but are in favor of retaining them on the list as they don't know if the organic supply is adequate. During the public comment webinar one manufacturer said they were able to source organic gum arabic this year but that in previous years supply has been inconsistent, and that the supply chain is variable due to the geography of where the gum is coming from. One organization thought that the Board should investigate whether there is gum arabic that could be certified as wild-crafted organic and also look at the availability of organic carob/locust bean gum. A couple of organizations requested that the gums be listed individually so that organic supply could be taken into account for those that are produced organically.

Additional information requested by Subcommittee
Are organic versions of gum arabic, locust/carob bean gum, and guar gum commercially available?

Subcommittee vote
Motion to remove gum arabic, locust bean gum, carob bean gum, and guar gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Lecithin—de-oiled

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

Technical Report: 1995 TAP; 2009 TR
Petition(s): Lecithin, bleached (remove 2008)
Past NOSB Actions: 04/1995 NOSB minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606); 10/2015 sunset recommendation
Recent Regulatory Background: Annotation change effective 03/15/2012 (77 FR 8089); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Lecithin has a wide range of food applications, including emulsification, release properties, wetting, dispersing, and texturization. The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat. In release applications, lecithin modifies the cooking surface to allow products to be more easily removed. As an instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products. In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation. Lecithin improves water absorption in baked goods and dough, increasing volume and shelf life, and improving uniformity of the products. It is also used as a packaging aid and directly on processing equipment as a lubricant. In addition, lecithin is used in pharmaceuticals (as dietary supplements, emulsifying agent for intravenous injections, and dispersant for vitamins); in cosmetics (as emulsifier and emollient in hair and make-up preparations, creams, and oils); and in animal feeds (as a nutritional ingredient, emulsifier, and wetting aid in calf milk replacers, pet foods, and many other types of feeds required high fat and oil contents). Bleached lecithin is used in applications where a lighter color is deemed important. Unbleached fluid lecithin has a dark brown color which does not permit high use levels in white or very light colored products; however, in some formulations, brown fluid lecithin can be used effectively at low concentrations (Scocca, 1976). Dry lecithin is used in commercial applications of food systems where liquid lecithin is more difficult to handle, and the powdered or granular lecithin is more easily incorporated.

Approved Legal Uses of the Substance

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Most commercial lecithin is made from crude soy oil extracted from soy flakes. The crude soy oil is then treated with water or steam to precipitate the lecithin as gums. These wet gums are centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become a bleached lecithin.

International (acceptance/non-acceptance) by other International certification agencies

The Joint FAO/WHO Expert Committee on Food Additives— Lecithin (INS1: 322) functional uses as antioxidant and emulsifier agent. Acceptable daily intake is not limited.

Canadian Organic Standards— Lecithin bleached form is allowed when unbleached form is not suitable from organic sources only. Lecithin is listed in the table of “Food Additives” of the “Non-organic Ingredients” section under permitted substances lists for processing and sanitation

The EU Organic Regulation No 2092/91- The use of lecithin as (1) a fungicide, listed in the section

“Substances of crop or animal origin”, for plant protections; and (2) a food additive, listed in the subsection “Food additives, including carriers” of the section “INGREDIENTS OF NON-AGRICULTURAL ORIGIN”, for preparation of foodstuffs composed essentially of one or more ingredients of plant and/or animal origin.

The Codex Guidelines for Organically Produced Foods - Lecithin used for pest and disease control need recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin (such as dairy products and analogues, fats and oils, fat emulsions, emulsified sauces, and infant formulae and follow-on formula).

Discussion

The NOSB reviewed the points in favor of renewing the substance as well as those in favor of removal from the list. Those in favor of renewing pointed out that there is insufficient supply in an organic form, specifically from raw materials other than soy. Those in favor of removal argued the product was available in an organic form internationally and was closer to becoming available in other organic forms.

The following question was posed to stakeholders: Are there organic forms of lecithin in de-oiled form?

Public Comment:

The majority of public comment supported relisting with the exception of one commenter, who suggested de-listing based on hazards associated with the production of lecithin and current availability of organic lecithin. Another commenter said while they support re-listing, de-listing the lecithin would give more incentive to processors to create organic forms. Again, public commenters emphasized that organic lecithin is not available except from soy products.

This proposal to remove lecithin-de-oiled will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting lecithin de-oiled.

Subcommittee vote

Motion to remove lecithin, de-oiled from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: A-dae Romero Briones
Seconded by: Eric Schwartz
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Tragacanth gum

Reference: 205.606(q) Tragacanth gum (CAS #-9000-65-1).

Technical Report: 2018 TR

Original Petition: 2007 Tragacanth Gum

Past NOSB Actions: 2008 Final Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 06/22/2020

Subcommittee Review

Material Use

Tragacanth gum is a polysaccharide that forms gels and can be used as a thickener and emulsifier. This material is effective at low pH and at many temperatures; its stability at low pH is noted as one of its distinguishing characteristics and is commonly used in high acid products like salad dressings (2018 TR 218-225, 337). The percentage in final formulations is usually low, below 1% of a total formula (2018 TR 338).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species during July to September (2018 TR 576-581). Once collected it is dried and ground into powder and may, or may not, undergo a mitigation step to reduce the microbial load of the powder (2018 TR 578-581).

International Equivalency

Tragacanth gum is listed as Generally Recognized as Safe (GRAS) by the FDA at 21 CFR 184.1351 (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of tragacanth gum as long as it's derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Tragacanth gum (412) is allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Tragacanth gum is listed with no limitations (2018 TR 535).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows tragacanth gum (INS 413) with no restrictions on how any of this item can be used (IFOAM, 2014) (2018 TR 539-541).

East African Organic Product Standard

Tragacanth gum is allowed with no restrictions (2018 TR 547).

Ancillary Substances

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Subcommittee Review

No environmental or health concerns were noted in the manufacture or use of tragacanth gum. The 2018 technical report (TR) for gums summarized the results from the 2017 European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food, and for tragacanth gum the panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population.

The NOSB Subcommittee noted in 2008 that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited. During the last sunset review in 2014, the Handling Subcommittee was unable to find evidence that tragacanth was available in organic form and received testimony from a certifier and a producer who used non-organic tragacanth. Public comment prior to the Spring 2018 NOSB meeting was very limited, with one organization opposed to the listing because they believed potential health effects hadn't been taken into account, as well the possible impacts of non-organic production.

Additional information requested by Subcommittee

Is organic tragacanth now commercially available?

Subcommittee vote

Motion to remove tragacanth gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Sodium chlorite, for the generation of chlorine dioxide gas
June 5, 2018

Summary of Petition (initial petition; petition addendum; technical report)

On October 8, 2015, the NOP received a petition from ICA TriNova, LLC to add chlorine dioxide (CDO) (CAS #10049-04-4) dry gas to §205.605(b) of the National List, nonagricultural (nonorganic) synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." The petition was revised November 30, 2015, revised again on December 1, 2015, and forwarded to the Handling Subcommittee (HS) December 2, 2015. The petitioner presently manufactures and markets CDO as the formulated product Z-Series FruitGard (FCN 949, EPA Reg. #79814-5).

Use

This material is petitioned for use as an anti-microbial pesticide, sanitizer and/or disinfectant for fruits and vegetables. CDO gas is used in post-harvest handling for the direct treatment of fruits, vegetables and nuts during storage, transportation and food preparation applications to reduce spoilage and pathogenic organisms with no requirement for post treatment rinse. CDO acts as a killing agent of pathogenic organisms.

Chlorine dioxide gas is well known for its antimicrobial effects through oxidative inactivation (Stubblefield et al., 2014; Lee et al., 2015; Park and Kang, 2017). When used as a fumigation agent, there are no residual traces of the CDO disinfectant, or disinfection by-products (DBP) of chlorite and chlorate (JECFA, 2008). The efficacy of CDO gas against a wide range of microorganisms has been demonstrated in several studies across a variety of fruits and vegetables (2018 TR 97 – 99). These studies also relate the increased efficacy of CDO in gas form, compared to its use in aqueous solution, which is primarily due to the increased penetration of the gas treatments, as well as the ability to effectively treat irregular surfaces (Stubblefield et al., 2014; Lee et al. 2015; Park and Kang, 2017).

Chlorine dioxide is permitted by the FDA as an antimicrobial treatment for a range of food products, including fruits and vegetables and poultry processing (21 CFR §173.300). CDO is also used as a bleaching agent in both flour and whole wheat flour (21 CFR §137.105(a) and 137.200(a)). CDO is also widely used in the sanitation and treatment of water systems and is allowed by the FDA as a disinfectant in bottled water (21 CFR §165.110(b)).

In organic production, CDO is currently allowed for use in liquid solution in crop production as a pre-harvest algicide, disinfectant, and sanitizer, including in irrigation system cleaning systems (7 CFR §205.601(a)(2)(ii)); in organic livestock production for use in disinfecting and sanitizing facilities and equipment (7 CFR §205.603 (a)(7)(ii)); and in organic handling for disinfecting and sanitizing food contact surfaces (7 CFR §205.605(b)). For these uses, residual chorine levels in the water cannot exceed the maximum residual disinfectant limit under the Safe Water Drinking Act. The petition seeks to extend the use of CDO in gaseous form for the antimicrobial treatment of products labeled "organic" or "made with organic (specified ingredients or food group(s))."

Sodium chlorite, from which chlorine dioxide gas is produced, is not presently allowed in USDA organic regulations, however acidified sodium chlorite is permitted at 7 CFR §205.605(b) for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing."

Manufacture

Chlorine dioxide gas is produced by impregnating zeolite with sodium chlorite and then activating the zeolite, which is then treated with solid or liquid acids such as citric acid. If a liquid acid is used, as in the product manufactured by the petitioner, an unspecified buffer is used to control the formation and release of the CDO gas. The ability to produce the desired CDO gas from sodium chlorite with any acid allows for the selection of one of several GRAS acid sources (e.g., citric acid).

Several industrial synthetic procedures are used in the production of sodium chlorite, including the following: the treatment of chlorine dioxide with sodium hydroxide and a reducing agent (e.g., sodium sulfite), the treatment of chlorine dioxide with sodium peroxide (Na_2O_2), or an alkaline solution of hydrogen peroxide (H_2O_2) (TR 2018, 72-75).

Due to its reactivity and explosive nature when concentrated, CDO is generated on-site prior to required usage. There are several methods for the generation of CDO gas from sodium chlorite, all of which involve the oxidation of the chlorite ion to the neutral radical species. This oxidation process can be completed by treatment with H^+ from an acid, or electrochemically by the electrolysis of a sodium chlorite solution, and by treatment with chlorine gas (Cl_2) (TR 2018, 296-297).

Chlorine dioxide is applied as a dry pure gas in closed containment. Treatment is conducted over several hours until the substance is completely consumed by reactions with a wide variety of organic matter. CDO is converted to a chloride ion on the food products. In processing facilities, this material is used as an oxidizer, surface and equipment cleaner, and deodorizing agent. It is applied as a dry pure gas at the point of need. Application rates vary.

Summary of Review

The Handling Subcommittee's initial review of the petition determined a need for revision by the petitioner. The HS found the initial petition sought to list a process rather than a material. If reviewed as petitioned, the HS would have reviewed several materials: sodium chlorite, zeolite acting as a carrier which is impregnated with sodium chlorite, acidic chlorine dioxide activators and related buffers. When used together as directed, these materials produce CDO gas.

The HS returned the petition to the petitioner April 18, 2016, with a request to revise the title to "*Sodium chlorite, for the generation of chlorine dioxide gas*." The HS believed a petition considering sodium chlorite for the particular use of gas generation is more consistent with how other sodium chlorite materials have been reviewed. The proposed use is similar to the acidified sodium chlorite that is already listed at 205.605(b) for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing." That substance was petitioned and added as a solution, whereas this listing would be used as a fumigant gas for direct food contact with no requirement for post treatment rinse.

Under the current title, certifiers and/or material review organizations would review the sodium chlorite product and the attendant components noted above. In its revision request, the HS also asked the petitioner if, as with use of other sodium chlorite materials, produce treated with ClO_2 dry gas requires a potable water rinse sufficient that residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

A petition addendum responding to these two requests was received by the HS May 5, 2016.

The petitioner responded to the two HS requests above, resubmitting the petition as "*Sodium chlorite, for generation of chlorine dioxide gas*" and, in response to the question regarding need for a post-treatment potable water rinse, the petitioner noted that CDO gas rapidly reacts with produce surfaces and potential residues of concern, primarily CDO or chlorite ion, do not persist. Water solution applications and precautionary potable rinses are not required for gas applications (Smith et al., 2015).

Because of this material's intended use as killing agent for pathogenic organisms, the petitioner's formulated product is EPA registered. While the petitioner notes the target use of CDO gas is for vegetables and fruit, the EPA label for the formulated product only allows for use on stored potatoes.

Summary of Public Comments

In advance of the Fall 2016 meeting during which this material was reviewed, the Board received a number of comments from the public; some supported the listing while others cited concerns.

- Several commenters noted the material should be petitioned or listed as "chlorine dioxide gas" with an annotation restricting the form to "generated from sodium chlorite." One commenter noted if "sodium chlorite for the generation of chlorine dioxide gas" appears on the National List, it is unclear how other precursors and activators other than sodium chlorite would be reviewed. It is important to note the initial petition was submitted in this way; however it was the HS's opinion that since the material would not be sold or distributed as the finished product of chlorine dioxide gas, it should be petitioned as stated in the proposal.

- A number of commenters noted that CDO gas does not have a place in organic production and see this as a substitute for good care and handling of produce. While care and handling certainly play a role in reducing microbial contamination, increased scrutiny of food safety measures and additional regulations are driving industry to identify other tools. The NOSB currently has a work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials.

- Several commenters expressed concern for worker safety when using this material. Several commenters requested the HS review this material in relation to other sanitizers and/or chlorine materials. Some commenters noted the need for a technical report (TR) to provide more neutral input on this material and to address some of the concerns noted above.

- Several commenters noted the addition of CDO gas as a step forward for reducing microorganisms on fruit and vegetables and it would add another option for sanitation.

Given public comment citing the above questions and concerns, the Board referred the material back to the Handling Subcommittee for further review and subsequently requested a TR on June 6, 2017.On January 9, 2018, the NOP provided the TR to the Handling Subcommittee for review.

Allowance under other organic standards

- **Canadian General Standards Board Permitted Substances List**
  Sodium chlorite is not listed in CAN/CGSB-32.311-2015.

  Chlorine dioxide is listed in CAN/CGSB-32.311-2015, Table 7.3 "Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event," with the exception that CDO levels do not exceed maximum levels for safe drinking water, Table 7.4. "Cleaners, disinfectants, and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory," with permission for use "up to maximum label rates."

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -**
  Neither sodium chlorite nor chlorine dioxide are listed in the GL 32-1999 CODEX.

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**
  Neither sodium chlorite nor chlorine dioxide are listed in EC No. 834/2007 and 889/2008.

- **Japan Agricultural Standard (JAS) for Organic Production**
  Neither sodium chlorite nor chlorine dioxide are listed in the JAS for Organic Production.

- **International Federation of Organic Agriculture Movements (IFOAM)**
  Sodium chlorite is not listed in the IFOAM Norms. Chlorine dioxide is listed in the IFOAM Norms in Appendix 4, Table 2, "Indicative List of Equipment Cleansers and Equipment Disinfectants," with a limitation of "an intervening event or action must occur to eliminate risks of contamination."

Category 1: Classification

1. Substance is for: __**X**__ **Handling** _____ **Livestock**

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

   The substance is a chemical compound.

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

   The substance is not manufactured, produced or extracted from a natural source.

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

   N/A

Category 2: Adverse Impacts

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

   CDO gas is a known oxidizer. However, as described in the petition, when used in an enclosed environment such as a produce cold room, there are no known interactions with other substances used in organic production.

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)]

   CDO gas is not persistent and not a known bio-accumulative substance. However, it is a strong oxidizer and acutely toxic and would impact wildlife or other fauna if released in an uncontrolled fashion. Under the intended use in an enclosed environment there is minimal environmental hazard.

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

   Manufacturing sodium chlorite produces several byproducts, such as chlorine dioxide, which cannot be immediately released into the environment. This petition is for the use of sodium chlorite to generate chlorine dioxide gas. When used as intended, the CDO rapidly decomposes to chlorite and chlorate, with the final endpoint being chloride (GRN 000161; JECFA, 2007a; Lee et al., 2015; Clordisys Systems, Inc., 2016; Park and Kang, 2017). Chloride is prevalent in nature and physiology, and therefore, will not provide an adverse impact at anticipated concentrations (WHO, 2000).

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

   As noted in the petition, the primary concern of exposure to chlorine dioxide is acute toxicity resulting from airborne gas. Chlorine dioxide is a strong oxidizer and known irritant to the respiratory system, eyes, and other mucous membranes. Thresholds for irritation are not well defined (WHO, 2000; IPCS, 2002). In prior studies of CDO, intense irritation in humans was seen at concentrations of 5 ppm, and this level is considered immediately dangerous to life or health by NIOSH (ATSDR 2004b). Permissible exposure limits (PEL) in air is a time weighted average of 0.1 parts per million (ppm) during an 8-hour shift, over a 40-hour workweek, and the recommended exposure limit (REL) is 0.3 ppm for short term (15 minute) exposures (NIOSH 2016b). Symptoms or chronic diseases resulting from exposure to bleach and/or chlorine dioxide identified by the U.S. National Institute of Occupational Health (NIOSH), the U.S. Centers for Disease Control (CDC), and the Association of Occupational and Environmental Clinics include skin irritation; irritation of eyes, nose, and throat; cough, wheezing, asthma, bronchitis, pulmonary edema, and/or chronic bronchitis (AOEC 2017; NIOSH 2016b; ATSDR 2010; ATSDR 2002; ATSDR 2004a).

   Chlorine dioxide is highly reactive and is expected to rapidly decompose to chloride and chlorate when used as intended. Due to the rapid decomposition of CDO the proposed use, and appropriate application procedures and industrial hygiene controls that prevent human exposures, the proposed use is unlikely to result in the adverse human health effects from CDO (TR 2018 428-429).

   Both chlorite and chlorate are readily absorbed in the body; however, due to the physiological prevalence of chloride in the body, there are no reliable analytical methods to track their metabolism (EPA, 2000; WHO, 2000). Current studies suggest that following ingestion of chlorate and chlorite, both oxychloro anions are reduced to chloride, which is excreted in urine (EPA, 2000).

The European Food Safety Authority (EFSA) has recently reviewed the possible effect of antimicrobial treatments for the emergence of antimicrobial resistance and has reported that there are no documented cases of antimicrobial resistance from CDO treatments (EFSA, 2008).

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

   The substance is used in an enclosed handling environment and not applied to soil or livestock. When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts in the agroecosystem.

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

   When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts on biodiversity.

Category 3: Alternatives/Compatibility

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

   Preventive practices are an essential aspect of organic production, and keeping fresh produce free of soil and reducing the potential for bacterial contamination of produce during pre- and postharvest is an FDA requirement. There are some fluid alternatives such as sodium hypochlorite or chlorine dioxide in liquid form, the latter of which is already listed on the National List. Presently the only non-fluid anti-microbial pesticide, sanitizer or disinfectant alternative on the National List is ozone (7 CFR §205.605(b)).

   Natural alternatives include weak organic acids such as alginic, citric and lactic acids, which are included on the National List (7 CFR §205.605(a)). However, the use of acids as disinfecting and sanitizing agents may result in changes to the organoleptic properties of the products, including flavor and other sensations (Meireles et al., 2016).

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

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

   The substance is a chemical compound.

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

   As noted above, when used as intended, the substance rapidly degrades to chlorite and chlorate ions that have little adverse effects on the environment. Due to the lack of appreciable residues of chlorine dioxide, chlorate, or chlorite post CDO gas treatment, there is no need for the potable water rinse that is currently required for aqueous treatments, such as with acidified sodium chlorite. The ability to eliminate the requirement for the post-treatment rinse allows for a reduction in waste water effluent, further protecting environmental concerns (Clordisys Systems, Inc., 2016).

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

   Neither the nutritional quality of the food nor human health is impacted with use of CDO gas, or its breakdown products of CDO or chlorite ions.

4. 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; (§205.600(b)(4))

   The petition and the 2018 TR describe the preservative qualities associated with the use of this substance. However, the preservative qualities are likely due to the inactivation of microorganisms that facilitate food spoilage and are secondary to its primary action (Gomez-Lopez et al., 2009; EFSA, 2016).

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

   Sodium chlorite, for the generation of CDO gas does not appear in the FDA GRAS inventory. However, CDO generated using sodium chlorite in calcined or sulfated kaolin clay (GRN 000161), and CDO generated from particles composed of sodium polyphosphate, magnesium sulfate, sodium silicate and sodium chlorite that are incorporated into low density polyethylene (LDPE) food-packaging films appear in the FDA GRAS inventory (GRN 000062).

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

   While other sanitizers and disinfectant substances appear on the National List, only ozone is currently present in gas form. In gaseous form, CDO reacts rapidly and completely, thereby reducing or negating the need for de-chlorination of waste water streams. Liquid forms of CDO mainly treat the rinse waters and are not as effective in treating microorganisms on produce. As noted above, dry gas applications appear to have greater effectiveness in penetrating coarse or porous produce. The use of CDO in gaseous form stands to reduce water usage.

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   As noted, acidified sodium chlorite is already listed at §205.605(b), and at the April 2016 NOSB meeting, the Board voted unanimously to add hypochlorous acid to §205.605(b). Like acidified sodium chlorite and hypochlorous acid, CDO gas has the added potential to offer handling operations a material that has strong antimicrobial properties on irregular surfaces, may reduce water use, and appears compatible with the fundamental principles of organic production.

Classification Motion: (The NOSB classified sodium chlorite as nonagricultural, synthetic in April 2016).

Motion to classify sodium chlorite, for the generation of chlorine dioxide gas as nonagricultural, synthetic.
Motion by: Scott Rice
Seconded by: Jean Richardson
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add sodium chlorite, for the generation of chlorine dioxide gas at §205.605(b)
Motion by: Scott Rice
Seconded by: Lisa DeLima
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

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National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Silver Dihydrogen Citrate
July 3, 2018

Summary of Petition:
Silver Dihydrogen Citrate it being petitioned by Pure Bioscience, Inc. as an antimicrobial processing aid for poultry carcasses and fruits and vegetables (excluding citrus and grapes for winemaking) and as a disinfectant/sanitizer for food contact surfaces and food processing equipment (Petition pg. 1, TR 31-34, 127-132). As such it is being petitioned to be listed on the National List at 7 CFR 205.605(b), synthetic nonagricultural (nonorganic) substance allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)." The petition was received on 1/18/2017 (referred to as "petition") and amended on 8/1/17 and 6/29/18 (referred to as "addenda"). A Technical Review (TR) was completed and found sufficient on 5/15/2018 (referred to as "TR"). The NOSB is recommending an annotation stating: "limited to particle sizes greater than 300nm"

Summary of Review:
Based on the information provided SDC appears to be of low risk to the environment and human health both in its use and disposal. Alternative materials, natural and synthetic, are available however these substances have limited applications or utilize a similar oxidative mode of action. There is a growing concern about the development of bacterial resistance to oxidative antibacterial agents. The Fall 2018 NOSB meeting will be the first time the NOSB will be adding this petition to our published agenda, as such we have not heard from industry on the need for this substance in light of the alternatives. The NOSB has received some public comment from interest groups that are concerned that the inclusion of SDC will allow the use of nano-silver and that nano-silver is necessary for the sanitizing efficacy of this substance. The petitioner denies nano-silver is a part of this formulation and the technical report speaks to the efficacy of this substance without nano-silver. In the Fall of 2010 the NOSB unanimously voted to prohibit engineered nano-materials of a size of 1-300NM in organic production and handling. In a policy memorandum in response to the NOSB recommendation, dated March 24, 2015, the NOP noted nanomaterials are generally of a size of 1-100 nm and to be used in organic production must be petitioned to the National List. To address public concerns and to stay consistent with previous NOSB actions, the NOSB is recommending this item only if it contains the annotation "limited to particles sizes greater than 300nm".

Category 1: Classification

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

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

"Silver dihydrogen citrate is a synthetic material solely manufactured by a chemical process, not extracted from naturally occurring plant, animal, or mineral sources. Silver dihydrogen citrate is produced electrolytically, through the immersion of silver electrodes in an aqueous solution of citric acid. " (TR 240-242).

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

"Silver dihydrogen citrate is a synthetic material solely manufactured by a chemical process, not extracted from naturally occurring plant, animal, or mineral sources. Silver dihydrogen citrate is produced electrolytically, through the immersion of silver electrodes in an aqueous solution of citric acid. " (TR 240-242)

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

   Not Applicable

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)]

   "SDC is incompatible with aluminum sulfate, aluminum ammonium chloride, aluminum orthophosphate, chlorides, sequestering agents designed to remove transition metals from solution, EDTA (above 1.5%), and calcium hardness above 300 ppm. These substances are not on the National List. The product is compatible with most metals including stainless steels. Ionic silver rapidly reacts with chlorides and some other anions that will result in low solubility silver salts. This reaction would potentially affect stability of the product. We recognize that two chloride salts, calcium and potassium, are permitted for use in organic processing, but the chloride salts are not expected to be used during the early processing stages. Therefore, the silver dihydrogen citrate would not be anticipated to have the opportunity to react with those substances and adversely impact the stability of the product." (Petition page 4) and (TR 100-103). This product is intended for processing use and not for use on farms or ranches – as such this is "no anticipated effects on soil organisms, crops, or livestock." (Petition Page 6)

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

   The Technical Report describes the mode of action as follows:
   The silver ion is well known to be effective against a broad range of microorganisms. The antimicrobial action of silver ions is multifaceted due to strong interactions with the purine and pyrimidine DNA bases and thiol groups (i.e., -SH or sulfhydryl groups) present in enzymes and proteins within the microorganism (Izatt et al. 1971, Bragg and Rainnie 1974). These interactions

markedly inhibit bacterial growth (Richards et al. 1984). Silver ions inhibit cell division, damage the cellular envelope, and create structural abnormalities that ultimately result in microbial death (Jung et al. 2008).

The citrate counter ion also significantly contributes to the efficacy of the silver ions antimicrobial properties. Citrate ions stabilize the ionic form and antimicrobial properties of silver(+1), as they do not show a tendency to be oxidized by silver ions (Ag+) which results in Ago (Djokić 2008). Citric acid is a major constituent of the Kreb's cycle, providing many precursors required for energy metabolism. It is readily recognized by bacteria as either a sole source of carbon and energy or as a co-metabolite in the presence of a food source, such as glucose. Thus, bacteria have both passive diffusional and active transport mechanisms for incorporation of citrate, which increases the permeability of the antimicrobial silver ion when it serves as a citrate cofactor (MacDonald and Gerhardt 1958, Korithoski et al. 2005, Pudlik and Lolkema 2011, Mortera et al. 2013). (TR 165-181)

The Technical Report describes concerns with silver being considered toxic hazardous waste at certain levels:
Silver is classified by the EPA as a toxic hazardous waste if detected at 5 mg/L by Toxicity Characteristic Leaching Procedure-EPA method 1311 (EPA HW No. D011; 40 CFR 261.24). According to the 1992 Reregistration Eligibility Decision for silver (EPA-738-F-93-005), the EPA determined that the available acute toxicity data indicate that silver, which persists in the aquatic environment, is highly toxic to fish, aquatic invertebrates, and estuarine organisms. The active disinfectant ingredient, silver dihydrogen citrate (SDC), has an acute LC50 for freshwater fish that ranges from 3.9 to 280 µg/L (ppb).

According to classification provided to the European Chemicals Agency (ECHA), silver dihydrogen citrate (i.e., citric acid and silver citrate EC List No. 460-890-5) is classified as Aquatic Chronic 1 and very toxic to aquatic life with long lasting effects (ECHA 2017). (TR 328-337)

The Technical Reports describes the other components of SDC as low concern:
The environmental assessments also concluded that the remaining components, citric acid (21 CFR 339 184.1033) and sodium lauryl sulfate (21 CFR 172.822), are of a low order of environmental toxicity and the 340 potential impacts from use of the product in the intended applications are well within safe thresholds. (TR 339-341)

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

The Technical Report describes the environmental contamination during use and disposal as follows: The environmental impacts of the product from its intended uses have been evaluated by both FDA and EPA. FDA reviewed the environmental impacts resulting from use in poultry and produce processing, while EPA reviewed the impacts as part of the pesticide registration process. During the treatment of the process water at on-site wastewater treatment facilities, the silver component is expected to partition to sludge (94 %) and waste water (6 %) with environmental introduction concentrations of 238 nanograms (ng) per liter (L) and 1.5 ng/L, respectively (US FDA 2015). The concentration of silver in the sludge is 20,000 times lower than the level requiring disposal as toxic waste (US FDA 2015). Furthermore, the concentration of silver in waste water is approximately 200 times less than naturally occurring levels of silver in the environment in surface waters (0.2-0.3 µg/L) and is not predicted to impact the natural variation of background silver (US FDA 2015). These environmental assessments, with the FDA's

Findings of No Significant Impact (FONSI) concluded that silver dihydrogen citrate, when used as intended, does not present any significant environmental impacts.

The toxicity of silver in the aquatic environment is a concern with this substance but as described in the TR based on FDA evaluations, the waste water is released at a level below naturally occurring background levels of silver and is not expected to impact levels of silver found in the environment.

The environmental impacts of manufacturing or misuse were not described.

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

The Technical Review describes the impacts on human heath as follows:
Antimicrobial agents are used in the production and processing of agricultural products due to their effectiveness to kill or inhibit growth of microorganisms in and on foods. This is done to improve food safety for the consumer, as well as to extend the shelf life of food products. There are no known reported positive or adverse effects on human health from use of silver dihydrogen citrate. The high-grade silver and citric acid (used electrolytically to prepare silver dihydrogen citrate) have some potential adverse effects on human health. Citric acid is an irritant of the skin, eyes, and respiratory tract; and chronic exposure to silver and silver salts is most commonly associated with a permanent grey or blue discoloration of the skin (i.e., argyria) and other organs (ATSDR 1990, White et al. 2003, Drake and Hazelwood 2005), but the EPA considers the effect to be a cosmetic and not a toxicological effect and has approved pesticide registrations on the basis that using the product within safe regulatory levels prevents this effect.

In general, silver has low acute human toxicity. It has been placed in the EPA Toxicity Category III for acute oral and dermal toxicity, but it is not an eye or skin irritant (Toxicity Category IV). Silver is also not a skin sensitizer. Although repeated contact may cause argyria, this is highly unlikely to be a concern at the highly diluted levels used in food facilities. The EPA has summarized its review of the toxicity data for silver and silver compounds as part of a recent re-registration process evaluating the effects on human health from pesticidal use (US EPA 1993). The EPA concluded that no new toxicity studies were required for non-zeolite silver compounds other than a repeat dose inhalation study for silver aerosols. There are also some reports that suggest exposure to high levels of silver salts and other soluble forms of silver may produce other toxic effects, including liver and kidney damage, irritation of the eyes, skin, respiratory, and intestinal tract, and changes in blood cells (Drake and Hazelwood 2005).

The safety of the petitioned substance for use in processing of poultry and produce for human consumption has been evaluated by FDA through FCNs 1768, 1569, and 1600. The product's use in food contact surface sanitization has been evaluated by EPA through the pesticide registration process and through evaluation for the exemption from the requirement of a tolerance of silver in the form of silver dihydrogen citrate. Exposures to silver from the intended use of SDC presents no concern for the safety of human health or the environment, as established by FDA through its review of FCNs 1768, 1569, and 1600. The effective FCNs represent FDA's conclusion that the intended uses of SDC are safe for human health, while FDA's environmental reviews concluded that allowing these FCNs to become effective does not significantly affect the quality of the human environment. A safety assessment for citric acid is not included because FDA has affirmed the substance as generally recognized as safe for direct use in human food under 21 CFR 184.1033. (TR 351-384)

Silver is stated to be low acute human toxicity but has been placed on an EPA list for acute oral and dermal toxicity. It is not an eye or skin irritant. Exposure to chronic high levels of SDC can result in liver and kidney damage, irritation of bodily organs and changes in blood cells. It is unclear from the technical report if usage in described food sanitation applications is likely to result in chronic high level exposure for workers.

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)]

   See Questions 2 and 3. Additionally, this product is intended for processing use and not for use on farms or ranches – as such this is "no anticipated effects on soil organisms, crops, or livestock."

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

   See Questions 2 and 3.

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)]

   The TR describes sanitations practices and use of SDC as follows:
   When processing agricultural products, biocides like SDC are paramount in ensuring the safety of consumer. There is no reported literature describing other antimicrobial practices that are available for direct and indirect food contact sanitization in the processing of agricultural products other than the application of biocide solutions. (TR 385-388)

   The TR describes alternative materials as follows:
   There are other antimicrobial products available for use in organic agricultural processing and sanitization of food contact surfaces: acidified sodium chlorite (NaClO2), chlorine, ozone, and peroxy derivatives (7 CFR 205.605). (TR 388-390)

Despite available information and government programs' efforts to reduce the incidence of *Salmonella*, it continues to be a concern for the meat and poultry industries. Organic acids are excellent antimicrobials against bacteria including *Salmonella (Mani-López et al. 2012)*. Organic acids offer several advantages as antimicrobials because they are GRAS, have no limited acceptable daily intake, are low-cost, easy to manipulate, and effect minor sensory changes on the product. For example, an application of 2% acetic acid reduced the incidence of *Salmonella* on pork cheek meat in addition to significantly reducing aerobic plate and coliform counts (Frederick et al. 1994) More than one treatment was found to sometimes help on the bacterial reduction and produces lesser effects on food quality. Also, poultry scald water containing 0.1% acetic acid at 52 C decreased levels of *S.* Typhimurium and *Campylobacter jejuni (Okrend et al. 1986).* However, it is important to use these acids according to good manufacture practices to avoid the development of *Salmonella* strains resistant to acidic conditions.

Lactic acid, produced from fermentation, is currently listed on the National List (7 CFR 205.605(a)) as a non-synthetic material with no restrictions on use and is established as GRAS for using lactic acid as an antimicrobial agent as defined in 21 CFR 170.3(o)(2). The use of lactic acid as an antimicrobial agent is limited to meat products. Lactic acid has been found to be more effective than chlorine treatments of raw meat in poultry processing facilities (Killinger et al. 2010). The acidic nature imparts a mellow and lasting sourness to many products including confectionery.

However, on the National List, there are some synthetic substances allowed as disinfectants and sanitizers for use on food contact surfaces. These are listed under the 7 CFR 205.605 which delineates the nonagricultural (nonorganic) substances that may be used as ingredients in or on processed products that are listed as "organic" or as "made with organic [ingredients or food groups]."

For example, peracetic acid can be substituted for SDC (7 CFR 205.605(b)). Peracetic acid is a mixture of acetic acid and hydrogen peroxide. It is a very strong oxidizing agent and has a strong pungent acetic acid odor. The primary mode of action is oxidation, which differs from SDC. In addition, peracetic acid is considered environmentally safe. Acidified sodium chlorite (using citric acid) and chlorine dioxide, which have the same mode of action as peracetic acid, can also substitute for SDC. (See the NOP petitioned substances database.)

However, bacterial resistance to traditional agricultural biocides is of growing concern (SCENIHR 2010). A number of gram-positive, vegetative bacteria have been isolated from equipment that used chlorine dioxide for high-level disinfection, and several strains, *Bacillus subtilis* and *Micrococcus luteus, showed stable high-level resistance to the standard use concentration of chlorine dioxide* (Martin et al. 2008). The *Bacillus* isolate was also cross-resistant to hydrogen peroxide (7.5%) (Martin et al. 2008). Such reports of bacterial resistance have not been reported for the petitioned substance.

The United States Food and Drug Administration (FDA) regulations allow a number of uses for ethanol in food preparation/storage for humans and animals. For humans, FDA considers ethanol to be "Generally Recognized As Safe" (GRAS) when added directly to human food (21 CFR 184.1293). Ethanol is an approved synthetic substance on the National List for organic livestock production as a disinfectant and sanitizer only (7 CFR 205.603). In addition, ethanol is an approved synthetic substance on the National List for organic crop production when used as an algicide, disinfectant, and sanitizer, including the cleaning of irrigation systems (7 CFR 205.601). Alcohols, including ethanol and isopropanol, are capable of providing rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores (McDonnell and Russell 1999). The antimicrobial action of ethanol is due to rapid denaturation of proteins. A study found that a 7% ethanol solution prevented the growth of four common foodborne microorganisms: Listeria monocytogenes, Salmonella typhimurium, Staphylococcus aureus and Escherichia coli O157:H7 (Ahn et al. 1999), however, the CDC recommends against the use of ethanol or isopropanol as the principal sterilizing agent because these alcohols are insufficiently sporicidal (i.e., spore killing) and cannot penetrate protein-rich materials (CDC 2008). Other shortcomings of ethanol are that it can damage rubber and plastic tubing after prolonged use, is highly flammable and must be stored in cool, well-ventilated areas, and evaporates quickly due to its high volatility, which makes extended exposure time difficult to achieve (CDC 2008)

There are no literature reports to our knowledge that directly compare the efficacy of SDC to that of other organically allowed synthetic substances (e.g., chlorine dioxide, acidified sodium chlorite, ozone, etc.). One important distinction of SDC from these common synthetic substances for disinfection of food and food contact surfaces is the action of the substance. Most of the common synthetic substances are strong oxidizers; thus their antimicrobial efficacy generally increase with oxidation potential (i.e., chlorine dioxide < acidified sodium chlorite < ozone). The efficacy of SDC arises from it proceeding from a different mechanism of action, interference with cellular processes. In a closely related study, the antimicrobial effects of chlorine (Cl2), an oxidizer, and Ag+ ions on bacterial biofilms were compared (Kim et al. 2008). The antimicrobial activities on biofilm cells were investigated by three methods, each of which used a different analytical principle for the determination of antimicrobial activity. The study found that the resistance of the biofilm cells to the oxidant, chlorine, was increased almost 250 times compared with the resistance to the Ag+ ion. Thus, due to the different mode of action, Ag+ ions and SDC, in particular, represent a viable alternative for eliminating pathogenic bacteria that demonstrate resistance to common oxidizing antibacterial agents.

In summary, there is no literature that directly compares SDC to other organically allowed synthetic substances. Acetic and Lactic acid were effective in meat environments but lactic acid is solely limited to this manufacturing environment. There are concerns of acid resistant salmonella in certain manufacturing conditions. Chlorine, Peracetic acid and acidified sodium chlorite are effective oxidative alternatives, however there is a growing concern over resistance of bacteria to oxidative reactions. While ethanol and isopropanol are effective against some pathogens they are not effective against bacterial spores – and are not recommended by the CDC as principle sanitizing agents. SDC works using an alternative mode of action to oxidation antibacterial agents – silver compounds so far have not experienced the growing resistance to treatment as seen with oxidation antibacterial agents.

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

   N/A

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

   The substance cannot be produced from natural sources. See Category 1 question 2. Alternatives Substances are discussed in Category 3 Question 1.

   The Technical report discusses other alternative practices as follows:
   While agricultural and/or natural antimicrobials may be effective in one way, they may be ineffective in another and do not possess broad spectrum antimicrobial properties (Sebranek and Bacus 2007). This stresses the necessity of further research in order to ensure that the food safety of these materials is properly assessed. While current research suggests that natural plant extracts can be effective in controlling pathogens in meat products, the most favorable results tend to result from multiple-barrier food preservation systems, which use combinations of agricultural and/or natural antimicrobials and sodium or potassium lactate (or other synthetic

antimicrobial ingredients). However, decreasing the shelf life of a product to accommodate the strict use of natural antimicrobials is another option. A survey of organic agricultural antimicrobials is discussed below.

The USDA organic regulations do not permit the addition of nitrite to organic processed meat. Alternative methods like the use of celery powder, which is listed at 7 CFR Part 205.606 and allowed for use in products labeled as "Organic" only when an organic form is not commercially available, are commonly used in meat products. Trials studying natural antimicrobials for the inhibition of *Listeria monocytogenes* on naturally cured frankfurters have been conducted (Xi et al. 2013). Using celery powder containing 12,000 ppm of nitrite, the concentration of nitrite (when the celery powder was used at 0.4% of the frankfurter formulation) resulted in 48 ppm of nitrite added to the frankfurter mixture. In a conventional curing process, 156 ppm of nitrite is added. The research found that the celery powder achieved the expected color, flavor and other properties of cured meats, but it resulted in lower nitrite levels than occurred with the use of synthetic preservatives.

In the same study by Iowa State University in 2013, powdered concentrates from cranberries, cherries, limes and a blend of cherry, lime and vinegar were evaluated alone and in various combinations for antimicrobial impact on the growth of *L. monocytogenes* in naturally cured frankfurters (Xi et al. 2013). The results showed that cranberry powder at 3% of the formulation, combined with celery powder, achieved inhibition of *L. monocytogenes* following the inoculation of naturally cured frankfurters that was equivalent to that of conventionally cured frankfurters during 49 days of refrigerated storage. Cranberry powder at 1% and 2% in combination with other natural antimicrobials inhibited growth for up to 35 days, while the naturally cured frankfurters without additional antimicrobial ingredients showed growth after 28 days. However, quality assessment of the products showed that 3% cranberry powder was detrimental to the color and sensory and textural attributes of the frankfurters, possibly due to the acidic nature of the cranberry concentrate. It was concluded that, while cranberry concentrate has potential as a natural antimicrobial, it is necessary to develop a means of compensating for the acidic nature of this ingredient to achieve practical applications in organic cured meat products. In addition, for the meat to maintain its organic status, the cranberry powder would also need to be a certified organic ingredient and, per the requirements of 7 CFR 205.606, attempts would need to be made to source organic celery powder.

The effectiveness of essential oils in controlling *L. monocytogenes* has also been investigated (Campos et al. 2011). The results of the study were promising; however, in many instances, combinations of additives or preservative treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical composition and the physical conditions of various foods. Essential oils (EOs) are oily liquid mixes of volatile and complex compounds that are extracted from different parts of aromatic plants. They are synthesized by plants as secondary metabolites and can be obtained mainly by steam distillation or super critical fluid extraction. Essential oils can contain 20-60 components, depending on the material they come from and the extraction method used. Terpenes and terpenoids make up the constitute majority of the components with the remainder consisting of aromatic and aliphatic compounds of low molecular weight.

Essential oil efficacy against Listeria growth in laboratory media was highly variable (Campos et al. 2011). EOs of bay, coriander, cinnamon, clove, licorice, nutmeg, pepper, oregano, winter savory, spruce and thyme showed the highest inhibitory activity. The effectiveness of oils of basil, lemon balm, marjoram, mastic tree, rosemary and sage were lower than those mentioned above, whereas Listeria showed high resistance to EOs of aniseed, caraway, fennel, garlic, ginger, onion and parsley.

According to the research, the antimicrobial activity of EOs is largely dependent on their composition; however, the mechanism of antimicrobial action of EOs is not well understood. Inhibitory actions are mostly related to the identity of the majority terpenes and terpenoid components, but the minor components have a strong influence on the effectiveness of their antimicrobial action. The main components often consist of: carvacrol, thymol, linalool, eugenol, trans-cinnamaldehyde, p-cymene, 1,8-cineole (eucalyptol) and γ-terpinene, and the research suggests that several components of EOs are involved in the fixation on cell walls and cellular distribution. It's reported that EO components may degrade the cell wall, damage the cytoplasmic membrane and proteins of the membrane, leak vital intracellular compounds, coagulate cytoplasm and deplete the proton motive force, and that EOs also interact with one another, potentially leading to synergistic antimicrobial effects between various oils (Campos et al. 2011). For example, the growth of *L. monocytogenes* was suppressed in laboratory media more when a combination of oils was used (oils of oregano and rosemary; oils of basil, rosemary or sage; and oils of rosemary and licorice) than when these oils were used alone.

Further results in various samples suggested that EOs have lower activity in foods with high fat content. This may be due to: (i) EO dissolution in the lipid fraction of the food, decreasing the concentration in the aqueous phase, together with antimicrobial action; (ii) the reduced water content in foods, particularly in fatty foods, in relation to culture media, which may slow down the movement of the preservative to the active site in the microbial cell; and (iii) the presence of fat in the food which may produce a protective layer around the bacteria (Campos et al. 2011).

Storage temperature, pH, physical structure of food, fat, protein, sugar content, and sensory properties all need to be considered when deciding whether EOs will be affective for controlling pathogens. It was reported that chicken frankfurters treated with 2% v/w of clove oil were unacceptable to the consumer, whereas samples with 1% were accepted. The latter level had effective antilisterial activity in the food. It was found that combining EOs would allow the use of lower levels to reduce Listeria growth, minimizing the unacceptable sensory changes in the food. Indirect uses of EOs, for example in water to wash vegetables similar to the use of chlorine, or in the impregnation of porous surface of wood in cheese ripening to improve sanitary safety, are also being considered. (TR 470-552)

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

   Refer to Question 3 of Category 2.

3. 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; (§205.600(b)(4))

   According to the technical report: "There is no information to suggest that silver dihydrogen citrate is used to recreate or improve flavors, colors, textures, or nutritive values lost in the processing of agricultural products. The petition requests to permit the use of SDC solutions as a processing aid in the wash and/or rinse water for direct and indirect food contact. (TR 290-293)"

4. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

   According to the technical report, silver dihydrogen citrate is not categorized as generally recognized as safe (GRAS). The USDA Food Safety Inspection Service has reviewed and approved silver dihydrogen citrate for use as a food contact substance in applications for treating poultry (FCN 1569 and FCN 1768) and fruits and vegetables (FCN 1600). The substance has been reviewed and approved by the EPA for use as an antimicrobial, disinfectant, fungicide, and virucide, and food contact surface sanitizer (EPA Registration Nos. 72977-1, 72977-3, 72977-4, 72977-5, and 72977-6). The substance is the subject of an exemption from tolerance for residues of silver in foods from food contact surface and processing equipment sanitizing applications (40 CFR 180.950).

   Silver dihydrogen citrate has been certified by NSF International, an independent public health and safety organization, for use as a sanitizer on all surfaces and as not always requiring a rinse in and around food processing areas (NSF Registration No. 144518).

   The petitioned substance has been added to the list of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products by the USDA (FSIS Directive 7120.1 Rev. 42).

   Citric acid is affirmed by the FDA (21 CFR 184.1033) as generally recognized as safe (GRAS) and may be used with no limitations other than good manufacturing practice. Sodium lauryl sulfate can be introduced intentionally during manufacturing to act as a solution stabilizer and is permitted for direct addition to food for human consumption by the FDA (21 CFR 172.822). (TR 254-272)

5. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))
   The decision here is to balance the environmental and human health impacts from this substances against the food safety benefits considering the alternatives. Overall the environmental and human health risks seem low and with a growing level of resistance to current antibacterial agents on this list, appear to offer unique and necessary food safety attributes. So far, no input has been received from industry on the need or non-need for this substance.

   Concerns have been raised about nanoparticles and this substance. The petitioner states "the product does not contain nano silver (Petition page 7). Additionally the technical review notes that nanoparticles could augment the efficacy of the SDC by increasing the concentration of silver – but that nanoparticles are not necessary for SDC as petitioned to be effective and alternative ways exist to increase silver concentration. (TR 109-121).

6. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   There is little risk with regard to environmental and human health concerns. If nano-particles are prohibited then compatibility with organic systems is also not a concern. The question arises around the essentiality of this substance in light of alternative options and if there is a sufficient need demonstrated for this substance by industry.

Category 5: Additional criteria for <u>agricultural</u> substances used in handling (review of commercial unavailability of organic sources):

This section is not applicable

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

   This section is not applicable

   Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>form</u>** to fulfill an essential function in a system of organic handling?

   This section is not applicable

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quality</u>** to fulfill an essential function in a system of organic handling?

   This section is not applicable

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quantity</u>** to fulfill an essential function in a system of organic handling?

   This section is not applicable

4. Does the industry information about unavailability include (but is not limited to) the following?:
   Regions of production (including factors such as climate and number of regions);
   This section is not applicable

   a. Number of suppliers and amount produced;

   b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

   c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

   d. Other issues which may present a challenge to a consistent supply?

5. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   This section is not applicable

Classification Motion:

Motion to classify silver dihydrogen citrate as synthetic
Motion by: Tom Chapman
Seconded by: Lisa de Lima
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add silver dihydrogen citrate, limited to particles sizes greater than 300nm, at §205.605(b)
Motion by: Tom Chapman
Seconded by: Steve Ela
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Japones Chile Peppers
July 17, 2018

Summary of Petition
The petition requests to add non-organic Japones Chile Pepper to the National List at § 205.606, and to allow its substitution when an organic alternative is unavailable.

Summary of Review:

Specific Uses of the Substance:
As discussed in the petition, the Japones Chile (*Capsicum frutescens*) is a small, pointed chile, 2-3 in long and 0.5 in wide. This chile is similar in appearance to the De Arbol, though the walls of the Japones are thicker. On the heat scale, this chile is 5-6 out of 10, or in Scoville heat units 15,000 to 35,000. Japones chiles are medium hot and frequently found in spicier Asian and Oriental dishes.

Manufacture:
According to the petitioner, pepper varieties in *Capsicum frutescens* can be annual or short-lived perennial plants. Flowers are white with a greenish white or greenish yellow corolla and are either insect or self-fertilized. The plant's berries typically grow erect with ellipsoid-conical to lanceoloid shape. They are usually very small and pungent, growing 10-20 mm long and 3-7 mm in diameter. Fruit typically grows a pale yellow and matures to a bright red but can also be other colors. *C. frutescens* has a smaller number of subspecies, likely because of the lack of human breeding compared to other capsicum species. More recently, however, *C. frutescens* has been bred to produce ornamental strains because of its large quantities of erect peppers growing in colorful ripening patterns.

Category 1: Classification

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

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

The petition is for Japones Chile peppers as an ingredient in a product. There are no chemical processes involved that would change its structure as a Japones Chile pepper.

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)]

   There is little potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems.

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

The substance responsible for Chile peppers' "heat" is capsaicin, 8-methyl-N-vanillyl-6- nonenamide (CH3)2CHCH=CH(CH2)4CONHCH2C6H3-4-(OH)-3-(OCH3). This is the active component of Chile peppers, which belong to the genus *Capsicum*, and it produces a burning sensation when in contact with human or mammal tissue. There is little information about the substance's breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

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

   There is little information regarding environmental contamination during manufacture, use, misuse, or disposal of Japones Chile peppers.

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

   There is no information provided in the petition about the effect of Japones Chile pepper on 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)]

   There are no effects on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms.

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

   No, there are no known adverse impacts on biodiversity.

Category 3: Alternatives/Compatibility

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

There are possible substitutes for Japones Chile peppers such as Thai chile peppers, Arbol chile peppers or Guajillo chile peppers. Each of these peppers has slightly different Scoville units, but few of these Chile peppers have organic sources according to the petitioner.

On July 18, 2017, during review by the Handling Subcommittee, the possibility of contracting a grower to produce Japones peppers was raised; however, because that was not a question listed in the petition, this question would be posed directly to the petitioner. While alternatives were listed, there was a question as to whether the alternatives would suffice. There was a question as to whether Japones pepper are not in great supply because of the lack of growers or the lack of processing equipment. The review was deferred, and two questions were posed to the petitioner:

1) Has the petitioner contacted growers to inquire about contract growing for the organic Japones peppers?

2) There are several listed alternatives for Japones peppers such as Thai chile peppers, Arbol chile peppers or Guajillo chile peppers, some of which are grown organically. Are these organic peppers acceptable alternatives? If no, why not?

On September 1, 2017, the petitioner, Brother Bru Bru answered the questions in a letter to the NOP.

For question one, the petitioner stated, "We have contacted growers about contract growing organic Japones chile peppers, and we are not able to get them in the quantities we would require." No other information was given.

For question two, the petitioner stated, "Brother Bru Bru's has been producing its African hot pepper sauce for 25 years. We have loyal fans and do not want to change the taste, including the heat level. The peppers [sic] suggested as possible alternatives would not be acceptable as there are marked differences in how hot the various peppers are. Japones Chile Peppers have a Scoville Heat Unit (SHU) of 15,000-30,000. The substitution of Thai Chile Peppers with a SHU of 90,000 would increase the heat level; substitution of Guajillo Chile Peppers with a SHU of 2,500-5,000 would reduce the heat level." No other information was given.

Category 5: Additional criteria for <u>agricultural</u> substances used in handling (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

   According to the petitioner, there are insufficient quantities of organic Japones peppers available to produce their product (see Category 3 section 1 for information about questions/answers posed to the petitioner.)

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>form</u>** to fulfill an essential function in a system of organic handling?

   The petitioner stated in the original petition, "There is no research as to why organic Japones peppers are not produced in large quantities. At the moment, the only organic Japones peppers found were sold through Amazon from Country Creek Acres for 1 pound increments for $21.49 per pound (https://www.amazon.com/JAPONES-PEPPER-WHOLEDRIED-LB/dp/B0118DJKRQ)." The petitioner asserted that using the Amazon supplier would be inadequate because they could not provide the quantities needed.

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quality</u>** to fulfill an essential function in a system of organic handling?

   There is no current or historical industry information, research, or evidence provided to explain why the Japones pepper cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling.

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quantity</u>** to fulfill an essential function in a system of organic handling?

There is no current or historical industry information, research, or evidence provided explaining how or why the Japones substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling.

5. Does the industry information about unavailability include (but is not limited to) the following?: Regions of production (including factors such as climate and number of regions);

   Japones Peppers are native to China and are commonly used in Caribbean and Latin American cuisines. This Chile is popular among the southern Asian countries because of its pure simple heat that does not have a complex flavor profile.

   a. Number of suppliers and amount produced;

      Number of suppliers and amount produced is not readily available.

   b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

      No information is available for weather events.

   c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

      No trade-related issues are available.

   d. Other issues which may present a challenge to a consistent supply?

6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   As *Capsicum frutescens* is grown in many regions, there may be a variety of production techniques in use. More information is needed on production of Japones Chile peppers.

Classification Motion:
Motion to classify Japones pepper as agricultural
Motion by: Lisa de Lima
Seconded by: A-dae Romero-Briones
Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

National List Motion:
Motion to add Japones pepper at §205.606
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 2 No: 2 Abstain: 0 Absent: 3 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Ethiopian Pepper
July 17, 2018

Summary of Petition
The petition requests to add non-organic Ethiopian pepper to the National List at §205.606, and to allow its substitution when an organic alternative is unavailable.

Summary of Review:

Specific Uses of the Substance:
The petitioners noted that they use Ethiopian pepper, *Xylopia aethiopica* (Dunal) A. Rich, in their hot sauces: African Hot Pepper Sauce; Chipotle Pepper Sauce; and Chili Pepper Sauce. Ethiopian pepper is quite pungent and slightly bitter, comparable to a mixture of cubeb pepper and nutmeg. This fruit is often smoked during the drying process, resulting in an attractive smoky-spicy flavor. No other spices give the same bitter, yet aromatic, flavor.

Action of the Substance:
X. aethiopica is a slim, tall tree of about 60–70 cm in diameter that can reach up to 15 to 30 m tall, with a straight stem and a slightly stripped or smooth bark. The fruits are rather small and look like twisted bean-pods. When dry, the fruit turns dark brown, cylindrical, 2.5 to 5 cm long and 4 to 6 mm thick. The contours of the seeds are visible from outside. Each pod contains 5 to 8 kidney shaped seeds of approximately 5 mm in length. The hull is aromatic, but not the seeds.

Manufacture:
X. aethiopica is native to the lowland rainforest and moist fringe forest in the savanna zones of Africa, but largely located in West, Central and Southern Africa. These trees are widely distributed in the humid forest zones of West Africa especially along rivers in the drier area of the region. In tropical and highlands of Africa (from Ethiopia to Ghana), both species *X. aethiopica* and *X. striata* occur and are used for local cooking. In South America, a third species, *X. aromatica* (burro pepper), has found similar applications among Brazilian Indios. The tree prefers high rainfall areas and well-drained soils. While *X. aethiopica* thrives in the forest regions, the tree can also be found in transitional zones. Loamy and sandy loamy soils are conducive for the cultivation of the plant. The plant can successfully be intercropped with other staple food items in the first four years. Propagation is easily accomplished by seeds. Seedlings are transplanted to the field within three to five months after sowing. The plant grows rapidly the first three years. Trees are planted eight meters apart. In West Africa, the tree flowers twice per year, in March to July and in October to December. Fruiting takes place in December to March and June to September. Harvesting time runs from February to May and again from August to October. The fruits are harvested with the inflorescence. After picking, the fruits are sun- dried for four to seven days. After drying, the fruits are removed from the inflorescence stalks. Fruits should not be dried on the ground, but on a protective cloth, net, screen or shelving system to minimize any microbial contamination. Typical fruit yields are about two to three metric tons per annum per hectare.

Category 1: Classification

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

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

The petition is for Ethiopian peppers as an ingredient in a product. There are no chemical processes involved that would change its structure as an Ethiopian pepper.

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)]

   There is little potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems.

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)]

   There is little information about toxicity or mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

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

   There is little information regarding environmental contamination during manufacture, use, misuse, or disposal of Ethiopian peppers.

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

   There are instances of Ethiopian pepper powder being rejected by the EU for having unsafe levels of aflatoxins and ochratoxins during testing at entrance laboratories in European countries.

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)]

   There are no effects on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms.

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

   No, there are no known adverse impacts on biodiversity.

Category 3: Alternatives/Compatibility

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

   There are no known substitutes for Ethiopian pepper.

Category 5: Additional criteria for <u>agricultural</u> substances used in handling (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

   The petition stated there is no organic form of Ethiopian pepper on the market. However, there is a possibility of wild crop certification of Ethiopian pepper that has not been fully explored. The petitioner described the Ethiopian pepper as "de facto organic" in that the Ethiopian pepper is hard to grow commercially because it is grown in the wild. The petitioner stated, "The Ethiopian peppers grow in the lowland rainforests in the savanna zones of West Africa. Because of the unique environment in which this wild-crafted plant lives, it is not something that lends itself to cultivation by organic growers. It is a plant that is by nature "de facto organic. We have contacted farmers about growing this in such a way that it could be certified. However, the growing conditions necessary combined with the small volume of use make it impossible to find a commercial grower for this substance."

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>form</u>** to fulfill an essential function in a system of organic handling?

   No, there is little to no current or historical industry information, research, or evidence provided to explain how or why the material/substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling.

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quality</u>** to fulfill an essential function in a system of organic handling?

   There is no current and historical industry information, research, or evidence provided to explain how or why the material/substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system or organic handling.

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **<u>quantity</u>** to fulfill an essential function in a system of organic handling?

   There is little current or historical industry information, research, or evidence provided explaining how or why the Ethiopian substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling.

5. Does the industry information about unavailability include (but is not limited to) the following?: Regions of production (including factors such as climate and number of regions);

Ethiopian pepper is native to the rainforests of West Africa.

a. Number of suppliers and amount produced;

   Number of suppliers and amount produced is not readily available.

b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

   No information is available for weather events.

c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

   At the end of 2016, Ethiopian pepper powder was returned to Ethiopia from European markets when it was found to have unsafe levels of aflatoxins and ochratoxins during testing at entrance laboratories in European countries. This has affected supply.

d. Other issues which may present a challenge to a consistent supply?

6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

Based on the information provided in the petition, it appears that Ethiopian pepper is could be compatible with a system of sustainable agriculture and could be compatible with organic handling. Ethiopian pepper is an agricultural product grown in more than 20 African countries spanning from Ethiopia to Sierra Leone. More information is needed about the supply of the pepper and the production methods used in the various supply chains to make an affirmative determination of compatibility.

Classification Motion:
Motion to classify Ethiopian pepper as agricultural
Motion by: Lisa de Lima
Seconded by: A-dae Romero-Briones
Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

National List Motion:
Motion to add Ethiopian pepper at §205.606
Motion by: Lisa de Lima
Seconded by: A-dae Romero-Briones
Yes: 2 No: 2 Abstain: 0 Absent: 3 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Tamarind Seed Gum
June 5, 2018

Summary of Petition [Tamarind Seed Gum]:

Tamarind seed gum is being petitioned as a nonorganic agricultural ingredient allowed in or on processed products labeled as "organic," §205.606. Tamarind seed gum is a water-soluble, high molecular-weight polysaccharide categorized as xyloglucan, with glucose as the main chain and xylose and galactose as side chains. It may be used as a thickener, stabilizer, or gelling agent for various foods and exhibits properties that may be different than other materials currently being used.

Use: As with other gums, the viscosity of tamarind seed gum depends largely on its concentration in solution. The 2018 Technical report (TR) states that at low concentrations, the viscosity of a tamarind seed gum solution is dependent only on temperature whereas at higher concentrations the viscosity of a solution decreases as shear rate increases. The moderate viscosity of tamarind seed gum compared to other typical hydrocolloids allows stability without excess viscosity and a rich pleasant mouth feel rather than the gummy or pasty textures associated with other hydrocolloids. Tamarind seed gum also has less stringiness, which gives improved handling when subdividing and filling liquid products. The 2018 TR notes that temperature affects the viscosity of tamarind seed gum solutions, over a range of concentrations. Tamarind seed gum has been cited as being relatively heat resistant, but the TR cites research that indicates that as temperature increases, viscosity decreases. This property allows a solution to be mixed and processed easily as opposed to some polysaccharides, including xanthan gum, which maintain constant viscosity regardless of temperature.

While all hydrocolloids thicken aqueous dispersions, comparatively few gums form gels. Tamarind seed gum does not form a gel in isolation, but does gel in the presence of alcohol and sugars, and exhibits sol to gel transition at certain temperatures (TR, 2018). These gels show low syneresis, meaning they do not tend to separate or weep liquid.

According to the 2018 TR, tamarind seed gum can be used as a thickening and gelling agent to improve the viscosity of certain foods, modify the texture of foods, and emulsify and stabilize foods. It may be used in place of pectin in jams and jellies. It can also be used to replace gluten as a dough-binding agent in gluten-free food products. Added to foods, tamarind seed gum can enhance characteristics such as maintenance of viscosity over a wide range of shear rates, water-holding, and a food's resistance to heat, salt, and pH treatments used during processing.

Manufacture: Tamarind seed gum is obtained from the endosperm of the seeds of the tamarind tree. Through mechanical processes the endosperm is separated from the other parts of the seed and made into a powder. This tamarind kernel powder is stirred into a solution of food-grade methyl alcohol. After stirring, food-grade sodium hydroxide is added and the mixture is again stirred at a controlled temperature. The polysaccharide is separated from other parts of the endosperm such as the protein, lipid, and minerals by centrifugation and food-grade citric acid is added as needed to adjust the pH to the desired level. The polysaccharide is dried, pulverized, and sieved through a screen.

International Acceptance (from the TR, 2018):

Canadian General Standards Board Permitted Substances List

Tamarind seed gum is not permitted as an ingredient on Table 6.3 of the Permitted Substances List. The listing for Gums on this table states that "[t]he following gums are permitted: arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum." However, non-organic agricultural ingredients are permitted as a processing aid if organic forms are not commercially available (see CAN/CGSB 32.310 section 9.2.1(d) and 9.2.2(d)).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Under the CODEX Alimentarius Guidelines, carob bean gum, guar gum, tragacanth gum, gum arabic, xanthan gum and karaya gum are all permitted with certain restrictions at GL 32-1999 Table 3 "Ingredients of non-agricultural origin referred to in section 3 of these guidelines." Tamarind seed gum, however, does not appear on this table.

Section 3.4 of the guidelines states: "Certain ingredients of agricultural origin not satisfying the requirement in paragraph [3.3b, which requires agricultural ingredients to be produced organically] may be used, within the limit of maximum level of 5 percent (m/m) of the total ingredients excluding salt and water in the final product, in the preparation of products as referred to in paragraph 1.1(b); where such ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the requirements of Section 4 [organic production practices] of these guidelines." As such, agricultural forms of tamarind seed gum could be permitted under this section.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Article 28 states that non-organic agricultural ingredients listed in Annex IX to this Regulation can be used in the processing of organic food, however, tamarind seed gum is not included in on this list. Tamarind seed gum is also not listed under "Food Additives, Including Carriers" in Annex VIII, Section A of EC No. 889/2008. Other gums including carob bean gum, guar gum, Arabic gum, and xanthan gum are listed in this section.

Article 29 describes the authorization of non-organic food ingredients of agricultural origin by member states for agricultural ingredients not appearing in Annex IX. Such non-organic agricultural ingredients may be used according to the conditions laid out in Article 29, which include requirements for evidence of lack of commercial organic supply and notification, among others. Tamarind seed gum could be approved under this provision.

Japan Agricultural Standard (JAS) for Organic Production

Tamarind seed gum is not listed in Table 1 "Additives" of the Japanese Agricultural Standard for Organic Processed Foods Notification No. 1606, partially revised March 27, 2017. Other gums—including carob bean gum, guar gum, tragacanth gum, Arabian gum, xanthan gum and karaya gum—do appear in Table 1.

Article 4 describes provisions for lack of commercial organic supply: "In case of difficulty to obtain organic plants, organic livestock products or organic processed foods with the same categories of those used for ingredients, those prescribed in items 2 or 4 may be used." Items 2 and 4 describe plants and livestock products that are not in the same categories as organic ingredients, and have not undergone ionizing radiation or recombinant DNA technology. Tamarind seed gum, if not considered in the same category as other listed gums, could be allowed under this provision.

IFOAM – Organic International
Appendix 4 Table 1, "List of Approved Additives and Processing/Post-Harvest Handling Aids," lists locust bean gum, guar gum, tragacanth gum, Arabic gum, and xanthan gum. Tamarind seed gum is not included.

Section 7.2.1 states: "All ingredients used in an organic processed product shall be organically produced except for those additives and processing aids that appear in Appendix 4. In cases where an ingredient of organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic raw materials, provided that:

a. they are not genetically engineered or contain nanomaterials, and
b. the current lack of availability in that region is officially recognized[1] or prior permission from the control body is obtained.
c. the requirements in section 8.1.3 [requirements for percentages of organic ingredients] shall be met."

Tamarind seed gum could be permitted under the above provision.

Environmental Issues: No toxicity, environmental persistence, or detrimental health effects on humans, soil organisms, crops, or livestock are expected as xyloglucan is ubiquitous in plant cell walls of all vegetation. It is, therefore, a naturally occurring fiber which adds viscosity in the small intestine and is fermented by symbiotic bacteria in the colon part of human and livestock diets. The structure of tamarind seed gum xyloglucan is the same as that of cellulose and is easily degraded by cellulase enzymes. Soil bacterium existing in the natural environment have cellulase enzymes. As tamarind seed gum can be degraded by such bacterium it has low impact if it is discarded into the environment.

Tamarind seeds are collected from native-grown trees. The multiple layers of the supply chain have meant to date that there are no organically certified tamarind seeds or tamarind kernel powder available.

Summary of Review:
While the National List already contains other gums that may have similar properties to tamarind seed gum, tamarind seed gum does have several properties that makes its use in particular products superior to currently listed products.

Traditional substances which are not hydrocolloids, such as starches and gelatin, can be used. The choice of gum for a particular food application is dictated by the functionalities required, but is strongly influenced by price and security of supply. Therefore, starches, which are very economic, are the most commonly used thickening agents, and corn starch, tapioca, wheat arrowroot, and rice starches are all available in organic forms. However, starches do not provide the same function as the hydrocolloid gums. For example, tamarind seed gum imparts a viscosity similar to that of starch, however, its viscosity does not deteriorate in the presence of acids, bases, salts and heat like starch does (TR, 2018).

Other hydrocolloids may be used in products however, they have different textures and mouthfeels. As has been noted with other approved gums, each has its own area of use where one gum may be more appropriate than another. Tamarind seed gum has similar solution properties to locust bean gum and

[1] This may be by inclusion on a government or certification body list of permitted non-organic agricultural ingredients.

guar gum. However, guar gum is superior to tamarind seed gum in dispersion and suspension: it is readily soluble in cold water, whereas tamarind seed gum takes longer to achieve full viscosity. On the other hand, tamarind seed gum has better thermal stability than guar gum and also tolerates higher pH conditions. Tamarind gum was compared with guar gum and xanthan gum and found to be at least as effective in maintaining viscosity. Data for some of the tests measuring acid resistance and freeze-thaw resistance showed that tamarind gum could be more effective (TR, 2018). The 2018 TR goes into much greater details on various comparisons, however, it becomes clear that each gum may have a specific use in which it is better than the alternatives.

Table 1. Comparison of properties between tamarind seed gum and other gums on §205.605-606 (from TR, 2018).

Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only becomes viscous at concentrations greater than 50%)	Moderate viscosity	X					
High Viscosity at 1 % concentration			X				
High Viscosity at low concentrations (but above 1%)						X	X
Viscosity remains unchanged over time at low shear rates	X		X				
Viscosity decreases over time at low shear rates				X			
Forms thermo-reversible gels						X	
Thermally reversible						X	X
Thermally irreversible			X		X		
Insoluble in ethanol	X	X	X	X	X	X	X
Stable under acid conditions	X		X	X	X		X
Controls syneresis (weeping)	X			X	X		X

Category 1: Classification

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

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

The substance is originally harvested from tamarind trees. The seeds are separated from the pulp and then further processed. While extracts are used to separate the gum from other seed materials, the extracts do not chemically change the gum. The solvents are removed such that they do not have a technical functional effect in the final product. Thus, according to NOP 5033-2, the material is agricultural.

Non-acid-hydrolyzed tamarind seed gum may be classified as a non-synthetic agricultural material based on NOP Guidance 5033. However, acid-hydrolyzed forms and/or forms that include synthetic additives would render the final product synthetic. Thus, for the material to be specified as agricultural, non-synthetic, an annotation would need to be added limiting uses to non-acid hydrolyzed forms.

   b. If the substance is **Non-agricultural**, is the substance ____ **Non-synthetic** or ____ **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: **N/A**

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

Category 2: Adverse Impacts

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

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

   The structure of tamarind seed gum is the same as that of cellulose and is easily degraded by cellulase enzymes. Soil bacterium existing in the natural environment have cellulose enzymes, thus tamarind gum can be degraded by such bacterium and it has a low impact if it is discarded into the environment.

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

   The 2018 TR states that "no sources reviewed for this report discuss any environmental pollution resulting from the processing of tamarind seeds into the purified polysaccharide." The product itself is likely of low concern given that it can be broken down by naturally occurring cellulase enzymes in bacteria. The manufacturing processes described should not result in any detrimental environmental releases.

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

   There are no toxicologically significant effects documented. The substance is non-mutagenic and non-carcinogenic. Tamarind seed gum, under the chemical name Tamarind Seed Polysaccharide, is Generally Recognized as Safe (GRAS) under GRAS Notice No. 503 (JHeimbach LLC, 2014). The GRAS notice covers the use of tamarind seed polysaccharide as a thickener, stabilizer, emulsifier and gelling agent in 12 food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from 0.2–1.5 percent of product composition (TR, 2018). Tamarind seed gum's xyloglucan polysaccharide has the same molecular skeleton as cellulose, and like cellulose, is not readily digested by enzymes found in the human digestive tract. It therefore serves as dietary fiber.

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)]
   N/A

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

Category 3: Alternatives/Compatibility

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

1. Traditional substances which are not hydrocolloids, such as starches and gelatin, can be used. The choice of gum for a particular food application is dictated by the functionalities required, but strongly influence by price and security of supply. Therefore, starches, which are very economic, are the most commonly used thickening agents, and corn starch, tapioca, wheat arrowroot and rice starches are all available in organic forms. However, starches do not provide the same function as the hydrocolloid gums. For example, tamarind seed gum imparts a viscosity similar to that of starch, however, its viscosity does not deteriorate in the presence of acids, bases, salts and heat like starch does (TR, 2018).

Other hydrocolloids may be used in products however, they have different textures and mouthfeels. As has been noted with other approved gums, each has its own area of use where one gum may be more appropriate than another. Tamarind seed gum has similar solution properties to locust bean gum and guar gum. However, guar gum is superior to tamarind seed gum in dispersion and suspension: it is readily soluble in cold water, whereas tamarind seed gum takes longer to achieve full viscosity. On the other hand, tamarind seed gum has better thermal stability than guar gum and also tolerates higher pH conditions. Tamarind gum was compared with guar gum and xanthan gum and found to be at least as effective in maintaining viscosity. Data for some of the tests measuring acid resistance and freeze-thaw resistance showed that tamarind gum could be more effective (TR, 2018). The 2018 TR goes into much greater details on various comparisons, however, it becomes clear that each gum may have a specific use in which it is better than the alternatives.

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

   Tamarind trees are leguminous and can be an integral part of many agricultural and wild ecosystems. The 2018 TR and the petitioner both note that tamarind trees are widely cultivated in the tropics worldwide and can be certified organic. At the time of the TR, there were nine sources of organic tamarind (fruit) and one source of tamarind powder listed in the NOP Organic Integrity Database (NOP 2017). The petitioner notes that since tamarind kernels do not currently have other organic uses, organic supply chains do not exist for their collection and processing. These could be developed, but will take time to implement. Due to multiple steps and handlers, certifying organic integrity through each step of the supply chain is not currently viable. Thus, it seems that this system could be compatible with a sustainable agricultural system and that there is the potential in the future to source this material organically.

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

4. 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; (§205.600(b)(4))

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

Category 5: Additional criteria for agricultural substances used in handling (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

   The petitioner states that there is no organic tamarind seed available for processing. The current system for accumulating tamarind seeds does not segregate organic and conventional and organic supplies may not be adequate for the potential need.

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?

   The petitioner states that seeds are available from native-grown trees and that due to multiple supply chain layers, the product is not available organically. It is not clear whether organic production could be developed or encouraged in the future, but it seems likely that this could be a stepping stone to creating a supply chain that could be organically certified.

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?
   N/A

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?
   See #2 above

5. Does the industry information about unavailability include (but is not limited to) the following?: Regions of production (including factors such as climate and number of regions);
   a. Number of suppliers and amount produced;

      No sources of organic tamarind seed gum or organic TSP are identified in the NOP Organic Integrity Database. Tamarind trees are widely cultivated in the tropics worldwide and can be certified organic. At the time of this report, there are nine sources of organic tamarind (fruit) and one source of tamarind powder listed in the NOP Organic Integrity Database (NOP 2017). The petitioner notes that tamarinds may be grown in a number of areas and that India and Thailand are the main source regions.

b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;
N/A

c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or
N/A

d. Other issues which may present a challenge to a consistent supply?

Wild harvesting and dispersed plantings may create issues with consistent supply.

6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

Tamarind seed gum meets the criteria to be compatible with a system of sustainable agriculture and is compatible with organic handling. Since many tamarind trees are wild grown or minimally cultivated, and are inherently resistant to many insects and diseases, they fit a sustainable agriculture system. Furthermore, organic tamarind is being grown, and it is possible that in the future organic supplies of tamarind seed gum might become available.

Classification Motion:

Motion to classify tamarind seed gum as agricultural, non-synthetic.
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add tamarind seed gum, limited to non-acid-hydrolyzed forms at §205.606
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board
Handling Subcommittee Petitioned Material Discussion
Pullulan
June 5, 2018

Summary of Petition:

A petition has been submitted to add pullulan to the National List at §205.605(a) as an allowed non-agricultural, non-synthetic ingredient used in tablets and capsules for dietary supplements labeled "made with organic". The petition was submitted by the Organic Trade Association (OTA) on behalf of its National List Innovation Working Group. The OTA states that the purpose of the petition is two-fold: to protect the continued production and availability of USDA-NOP certified dietary supplements and to support the commercial development of certified organic pullulan.

For dietary supplements, the capsule is considered an "ingredient" and must either be "certified organic" or made up of ingredients compliant with the National Organic Program's (NOP) National List of Allowed and Prohibited Substances. Since the early 2000s accredited certifying agents have classified pullulan as agricultural and it was allowed in encapsulated dietary supplements certified in the "made with organic" category. Since the release in late 2016 of the NOP's Classification of Materials guidance document (NOP 5033), certifying agents are in general agreement that pullulan should be classified as a non-agricultural and non-synthetic substance. Under this classification, pullulan would need to appear on the National List in order for it to be included in certified organic products.

There are no other NOP compliant vegetarian options available for producing organic encapsulated supplements. Organic pullulan is currently not commercially available in the United States. According to the petition, Capsugel is the owner of US patents covering pullulan capsules, and they are in the process of developing organic pullulan.

The only alternative practice for supplement manufacturers would be to use gelatin capsules. Gelatin is listed at §205.606 of the National List, but its use is problematic for consumers looking for a vegetarian, kosher, or halah product. Otherwise, to continue producing vegetarian products manufacturers would have to lose their organic certification. According to the petition, the 2018 forecast for pullulan capsules is approximately 2.5 billion capsules. They go on to calculate that a conservative estimate of $10 per 30 count bottle would represent an economic value of over $825 million.

In 2004, Capsugel submitted a petition to the NOSB to add pullulan to §205.605. The petition was put on hold and no recommendation was ever made. It is unclear why this is as no references to it were found in the NOSB meeting minutes.

The manufacturing process of pullulan is described in the OTA's petition, page 3:
Pullulan is produced by mesophilic fermentation of *A. pullulans* in a suitable starch syrup. During fermentation, pullulan is secreted extracellularly by the organism into the culture medium from which it is then recovered and purified. At the completion of fermentation, the resulting broth consists of microbial cells and cellular debris, as well as the extracellular metabolites produced and excreted during the fermentation (e.g., pullulan). The microbial cells and cellular debris are first removed by microfiltration. The cell-free filtrate is heat sterilized and then purified by a deionization process. The deionized solution is concentrated to a solids content of about 12%, treated with activated carbon to remove pigments and other impurities, and filtered using diatomaceous earth. The filtrate is

concentrated by evaporation to a solids content of about 30% and dried in a drum dryer. The dried pullulan is pulverized to a specified particle size and packaged.

According to the petition, there are no known negative environmental impacts resulting from the use or disposal of pullulan. It is a biodegradable polysaccharide that is easily metabolized by many microorganisms found in nature. Furthermore, pullulan may be used as a base material in novel flocculants that have been developed for the removal of contaminants in wastewater (Ghimici & Constantin, 2011).

The petition also cites a number of studies looking at the effects of pullulan on human health. The petition concludes that no adverse effects of toxicological significance have been observed for pullulan in a variety of assays. And that the safety of pullulan is supported by 30 years of human consumption in Japan and by the absence of adverse events in human trials at doses of 10g pullulan/day to evaluate metabolism and digestion.

Summary of Review:

In April 2018 the Handling Subcommittee found the petition for pullulan to be sufficient. A request for a technical report was submitted by the Subcommittee to the NOP. At this time, the technical report is under development. This petitioned material discussion document is being put forward with the intent of gathering public comment and allowing for discussion by the full Board at the Fall 2018 NOSB meeting.

Questions:

1. If you are currently using pullulan in a certified organic encapsulated supplement, what effect would the disallowance of pullulan be on your product/business?
2. Using the NOP's Classification of Materials guidance document (NOP 5033), do you consider pullulan to be agricultural or not? Please explain your rationale.

Subcommittee vote
Motion to accept the discussion document on Pullulan
Motion by: Lisa de Lima
Seconded by: Tom Chapman
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

National Organic Standards Board
Handling Subcommittee Petitioned Material Discussion Document
Collagen Gel
August 6, 2018

Summary of Petition

A petition has been submitted by Devro, Inc. to add collagen gel in Section 7 CFR 205.606, Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." The USDA organic regulations define an agricultural product as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock…".

The manufacturing process of collagen gel is described in the Devro, Inc's petition: Collagen gels are derived from the corium layer of skins from cows, pigs, chickens and/ or turkeys. Skins are washed and treated with acetic acid, lactic acid, or hydrochloric acid to adjust pH in preparation for further production into collagen gel. Washed and treated skins are physically sieved through a two stage particle size reduction, resulting in a collagen pulp. Water is added and the pH reduced which causes the collagen to absorb water; the blend is physically agitated to produce a collagen gel which is physically worked and filtered to produce a fine gel. The finished collagen gel is packaged and stored in cold storage.

Cellulose powder, derived from plant sources, is an ancillary substance in collagen gel. Cellulose adds permeability to the sausage's skin, allowing for the release of the meat emulsion's oil and fats during the sausage's cooking process. In finished collagen gel, cellulose is present in the range of 2 – 5%, depending on targeted product characteristics.

Collagen gel can be used in sausage production using a co-extrusion system. Typical products produced using this ingredient include cooked and smoked sausages. In these co-extrusion systems, collagen gel enrobes the sausage meat like a casing as the meat is extruded and holds the form of the meat product. The collagen gel is considered an ingredient in the finished product. Current organic options (casings, from processed intestines) will not function in this type of co-extrusion sausage production. Collagen, in the form of pork collagen appears on the FDA's "GRAS Notice Inventory," at GRN No. 21, with an intended use "in meat products as a binder and purge reducing agent at levels of 1.0 to 3.5 percent."

According to the petition, collagen is a naturally occurring structural protein made up of essential amino acids and is present in all living organisms. It has no known toxicities and breaks down into its constituent amino acids on digestion. It has no environmental persistence and use of collagen is unlikely to have any adverse impact on the environment. Collagen is harvested from the skins of edible species of commercially harvested livestock processed at USDA inspected facilities following all pertinent regulations. It is a co-product of the animal production industry, thereby providing a raw material that otherwise has less value.

Although collagen is used directly in the food industry, it is more widely used in its denatured form, as gelatin. Collagen is the native form of gelatin and chemically the two are indistinguishable. The two forms of this single protein are only separated by their physical structure; collagen retains the natural triple helical structure that defines it in nature. As gelatin, collagen is widely used in the food industry.

Besides its direct consumption as a natural meat component, purified collagen has also been used for decades in the manufacture of sausages. Gelatin is currently listed under §205.606: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Summary of Review:

In May of 2018 the Handling Subcommittee found the petition for collagen gel to be sufficient. A request for a technical report was submitted by the Subcommittee to the NOP. At this time, the technical report is under development. This petitioned material discussion document is being put forward with the intent of gathering public comment and allowing for discussion by the full board at the Fall 2018 NOSB meeting.

Questions:

1. Are there organic sources of collagen gel (e.g., from skins of organically raised livestock) that preclude listing as a non-organically produced agricultural product allowed as ingredients in or on processed products labeled as “organic?”
2. Is there demand or need for this material in the market place?
3. Are acids other than acetic acid, lactic acid, or hydrochloric acid used in the production of collagen gel? Are food-grade acids used for the production of collagen gel?
4. Are there uses of this material other than for manufacturing meat products (such as an ingredient in joint health products, bone broth concentrate, or other foods or supplements, etc.)? What are they?

Motion to accept the discussion document on collagen gel (casing)
Motion by: Asa Bradman
Seconded by: Scott Rice
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

Sunset 2020 Meeting 2 - Review
Crops Substances §205.601, §205.602
October 2018

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 date. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments

Written public comments will be accepted through October 4, 2018 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Note: With the exception of sodium carbonate peroxyhydrate, aqueous potassium silicate, and sulfurous acid, the materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

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

Reference 7 CFR §205.602 Prohibited nonsynthetic substances

Alcohols (ethanol)

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (1) Alcohols. (i) Ethanol.

Technical Report(s): 1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol

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 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review

The United State Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the U.S. as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers, and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products.

Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. There are a variety of methods available for the fermentative production of ethanol from carbon sources such as starch, sugar, and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations.

Several international organizations provide guidance on the application of synthetic ethanol in organic crop and livestock production and the processing of organic foods. Among these organizations, there are international regulatory agencies (EU, Canada and Japan) and independent organic guidelines and standards organizations (Codex and IFOAM).

Although ethanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of ethanol under the prescribed use pattern in organic crop production are unlikely. Ethanol is readily biodegradable in air, soil, and water. According to the US EPA, ethanol is practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies.

Public comments were largely in favor of relisting both ethanol and isopropanol because these materials are good examples of why there are several sanitizers and disinfectants listed for organic uses. However, one commenter suggested that the NOSB investigate the availability of non-synthetic ethanol from non-GMO fermentation organisms and feedstock, as well as the availability of organic ethanol. They said the NOSB should ask suppliers the question, "Would you be able to meet the need for non-synthetic/non-GMO and/or organic ethanol if the demand for it were created by eliminating the listing for synthetic ethanol?"

Subcommittee vote
Motion to remove ethanol from 205.601(a)(1)(i) - as algicide, disinfectant, and sanitizer, including irrigation system cleaning based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Jesse Buie
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Alcohols (isopropanol)

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (1) Alcohols. (ii) Isopropanol.
Technical Report(s): 1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage. Regarding crop production, isopropanol may be effectively used to decontaminate the lines of irrigation systems as well as a variety of agricultural implements. Alcohols, including isopropanol and ethanol, can provide rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores (McDonnell, 1999).

Chemical synthetic procedures are used in the commercial production of isopropanol that is for the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011).

A small number of international organizations provide guidance on the application of synthetic isopropanol in organic crop and livestock production as well as the processing of organic foods. Among these are the Canadian General Standards Board and the International Federation of Organic Agriculture Movements (IFOAM).

Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely. Isopropanol may enter the environment because of its manufacture, in addition to its solvent and chemical intermediate uses. According to the U.S. EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 1995).

Public comments were largely in favor of relisting both ethanol and isopropanol because these materials are good examples of why there are several sanitizers and disinfectants listed for organic uses.

Subcommittee vote
Motion to remove isopropanol from 205.601(a)(1(ii) – as algicide, disinfectant, and sanitizer, including irrigation system cleaning based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Sodium carbonate peroxyhydrate

Reference: 205.601(a) As an algaecide (8) Sodium carbonate peroxyhydrate (CAS #-15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
Technical Report: 2006 TAP; 2014 TR
Original Petition: 2005 Sodium Carbonate Peroxyhydrate
Past NOSB Actions: 11/2007 NOSB recommendation; 11/2007 NOSB Crops Subcommittee Recommendation; 10/2014 NOSB sunset recommendation
Recent Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521). Sunset renewal notice published 06/19/15 (80 FR 35177).
Sunset Date: 6/22/2020

Subcommittee Review
Sodium carbonate peroxyhydrate is used as an algaecide in rice fields, ponds, ditches, and irrigation lines (TR lines 11-124). It was added to the National List in 2007 with the hope that growers would use it as an alternative to more problematic materials such as copper and chlorine; it has only been registered for use in rice since 2010. The 2014 technical report (TR) states that the material is a precursor to hydrogen peroxide and is used widely in household cleaners and detergents, as well as water bodies (lines 89-100). Sodium carbonate peroxyhydrate is a white granular crystalline powder and is produced by drying hydrogen peroxide in the presence of sodium carbonate. It rapidly dissolves in water and dissociates into hydrogen peroxide and sodium carbonate. It decomposes to leave only water, oxygen, and soda ash (TR lines 51-52 and 79-82).
An emission of sodium carbonate peroxyhydrate to the environment could potentially occur during production, formulation, and use of the substance (TR lines 323-24). Sodium, carbonate, and hydrogen peroxide do not adsorb to sediment (TR line 333). No new concerns were raised about human health or environmental effects since the earlier review in 2006; however, it is highly toxic to bees and it should not be allowed to drift to flowering plants or used when contact with bees might occur (TR lines 395-434).
In 2014, a new TR was commissioned to address alternatives and use patterns. Of the alternatives

presented, copper sulfate is the most problematic and also the most widely used (on 97,757 acres vs. 1,177 acres in California in 2010, representing 17.4 and 0.3% of California rice acreage, respectively) (TR lines 448 - 457). Some of the proposed alternative controls, including Chinese herbs, garlic extracts, or panchagavya and amruthajalam, have not been tested in the U.S. and may not be available (TR lines 487 - 497).

During the Sunset 2015 Review, the NOSB sought input comparing this material with copper sulfate for control of algal scum in rice production and asked if it could replace copper sulfate for that use. Limited and conflicting comments were received. Points raised in favor of renewing the substance stated that it provides better control of algae, and its breakdown components of water and oxygen are more favorable than the accumulation of elemental copper associated with copper sulfate. Additionally, when utilized in irrigation ponds sodium carbonate peroxyhydrate has fewer corrosion issues with irrigation equipment than copper sulfate. Those against renewing the substance stated that it does not fit any OFPA categories, and is not permitted in organic production internationally (TR lines 164-202).

The Crops Subcommittee conducted further investigation into points raised in public comment. In particular, a 2007 report of the California Rice Research Board studied the efficacy of this material and found it did not work well enough to recommend it for rice paddies. Further investigations into controlling algae by the same group in 2013 indicated that management of phosphorus fertilization can influence the severity of algal growth. Reducing phosphate concentrations in rice field water was not mentioned in the 2014 TR but may be a promising alternative practice.

During the spring 2018 meeting, the Crops Subcommittee requested additional information regarding the significantly lower use of sodium carbonate peroxyhydrate as compared to copper sulfate, despite its lower toxicity, as well as information on other applications for which producers are using the material. Relatively little public comment was received regarding this material, and it does not appear to be widely used. Based on public comments, its primary use is as an irrigation and water treatment.

Subcommittee vote

Motion to remove sodium carbonate peroxyhydrate from §205.601 (a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Emily Oakley
Seconded by: Jesse Buie
Yes: 2 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Newspaper or other recycled paper

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) Newspaper 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.
Technical Report: 1995 TAP; 2006 TAP; 2017 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
At the 2015 NOSB sunset review, it came to the attention of both the NOSB and the public that there are new, less toxic materials used in production of newspaper and other recycled paper products which could stimulate the NOSB to consider a change to the annotation for this material. A technical report (TR) was requested and subsequently completed in summer 2017. The TR revisited the ingredients and colored inks in newspaper as well as their effect on the environment.

While there has been progress towards less toxic materials used in inks, and more recycling of paper products since the original listings and annotation of newspaper and recycled paper, it is difficult to impossible to determine if the inks present in the newspaper are ones that are less problematic. There is no methodology for separation between color inks that might be more acceptable for direct application to organic land and those that are not. When reviewing the 2017 TR, the Crops Subcommittee decided the current annotation for newspaper and recycled paper, which prohibits glossy or colored inks, should remain. This conclusion was presented as an update to the full NOSB at the Fall 2017 NOSB meeting.

There was continued support for this material to remain on the National List with the current annotation. Certifiers, grower groups, and individual growers all submitted comments in favor of retaining this material in both locations on the National List. While some stated there was currently not much use of this material in organic crop production, they also stated it should continue to be allowed for those who wish to continue using it. One certifier noted that newspaper could be included in manure that is cleaned out of livestock barns, supporting the relisting as a compost feedstock.
Subcommittee vote
Motion to remove newspaper or other recycled paper based on the following criteria in the Organic Foods Production Act (OFPA) for both listings:
7 CFR 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspapers or other recycled paper, without glossy or colored inks.
7 CFR 205.601(c) - As compost feedstocks – newspapers or other recycled paper without glossy or colored inks.
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 1 Absent: 1 Recuse: 0

Plastic mulch and covers

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
Technical Report: 1995 TAP
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Plastic mulches and covers can be of various thicknesses and can be a film or woven type landscape cloth. Various colors are used for crop production enhancements, such as red to increase tomato fruiting, silver to reflect and deter pests, black to warm the ground, white to cool the soil, clear to "solarize" for weed and pest management and more. Clear and translucent plastics are typically used as coverings for heated greenhouses or unheated high or low tunnels. In the Fall of 2017, the NOSB completed a sunset review of biodegradable bio-based mulch films, a related material. Based on that review, the current annotation and National Organic Program guidance was retained. In addition to the allowance of plastic mulches and covers on the National List, the following statement is included within the regulations:

§205.206(c) Weed problems may be controlled through: (6) Plastic or other synthetic mulches: *Provided,* That, they are removed from the field at the end of the growing or harvest season.

When these plastic mulches/covers are used for perennial crops, many, but not all, organic certification agencies have interpreted the regulations to allow it to remain in place for perennial crop production, as the harvest season is continuous from year to year. Long-term breakdown of the plastic films or plastic woven cloth can occur, especially if not protected from the sun's ultraviolet light.

Plastic mulches and covers are thermoplastic resins of high melt viscosity, usually polyethylene. Resin pellets are melted into an extruder and pumped or blown through a die or tube to form the plastic in the desired shape.

Plastic mulches and covers are used extensively in both organic and nonorganic agriculture and are allowed for use under the EU, Canada and other organic standards. There has been strong support for continued listing of plastic mulch and covers by the organic community at each of the previous sunset dates. This product is used extensively in both organic and nonorganic production systems. When this product is used as a mulch on the soil, it tends to get coated with soil which makes it very difficult to recycle. Much of the plastic mulches and covers removed at the end of the harvest season are sent to a landfill. Greenhouse coverings and other uses of plastic where there is minimal soil attached, can usually be recycled, especially in agricultural regions where companies have specialized in the recycling of these materials. he Crops Subcommittee asked the following questions to obtain public comment for this current sunset cycle on this material:

1. Are there alternative methods or natural materials that could replace the functionality of this petroleum-based material in crop production?
2. Are you aware of plastic mulches (either films or woven cloth) being left in place on the ground for more than 1-2 years and are you seeing degradation? How do you lessen that degradation, or address degradation if it occurs? Are plastic shards or debris found in the soil that cannot be removed?
3. Should woven poly landscape cloth be addressed differently than plastic mulch films? Are there heavier weights and thicknesses of plastic film mulches that are similar to woven poly landscape cloth in its resistance to degradation?
4. When the plastic mulch or cloth is removed, is it piled on the farm, landfilled, recycled or processed in an appropriate manner?

5. Are you aware that burning plastic is illegal in many states due to the release of dioxin and other problematic chemicals into the atmosphere? If burning plastic is an issue in your state or country, would you like to see an annotation banning burning of plastic mulch or covers under the organic regulation?

In response to these questions, the public had very strong support for renewal of plastic mulches, covers and shade clothes with the current annotation. Many supported the addition of an annotation in the future, to ban burning of plastic as a disposal method. Others noted that there are current federal laws as well as state and local authorities who enforce bans on burning plastic and felt the organic regulation should defer to EPA and other governmental authorities on this issue.

Also mentioned in public comment was the issue of sending the plastic to landfills and the environmental concerns associated with this disposal method. At the same time as this issue was discussed, some commenters gave their support for a biodegradable mulch film that was not 100% bio-based, as currently required by the NOP, and instead requested an allowance for biodegradable mulch films that are fossil fuel based. Others mentioned the need to improve and increase the options to recycle agricultural plastics of all types.

Certifiers noted that they allow woven plastic landscape cloth to remain in a perennial crop field for numerous years, but if, at the annual inspection, it is noted that there is degradation, then the plastic cloth must be removed from the field. One advocacy group noted that use of black plastic heats the soil which results in loss of soil biological life, especially when kept in place for many years.

Lastly, one commenter felt the annotation should be changed to limit the use of plastic to situations where hay, straw, or other natural materials were shown to not meet the operator's desired mulch functionality within their organic system.

Subcommittee vote

Motion to remove plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)) from 205.601 (b) (2) (ii) -as herbicides, weed barriers, as applicable, based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Harriet Behar
Seconded by: Dave Mortensen
Yes: 0 No: 6 Abstain: 1 Absent: 1 Recuse: 0

Aqueous potassium silicate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (2) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR
Petition(s): 2002 Potassium Silicate; 2006 Potassium Silicate Supplemental
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation

Recent Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521). Sunset renewal notice published 06/19/15 (80 FR 35177).
Sunset Date: 6/22/2020

Subcommittee Review
Aqueous potassium silicate is used as an insecticide for insects and mites. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.
Internationally (Japan, Canada, EEC, CODEX, or IFOAM), natural sources of silica, not APS, are allowed (258-296).

Based on information in the January 6, 2014 technical report (TR), the following concerns were raised by the Crops Subcommittee during the 2014 Sunset review:

- Dermal exposure can lead to low to medium systemic toxicity and skin irritation (TR pp. 577-579);
- Treatment with potassium silicate may not be appropriate when crops are used for feeding or as forage for livestock because it makes some forages less digestible (TR pp. 477-481);
- The addition of potassium silicate as a foliar nutrient may result in the production of less tender fruits and vegetables or forage for grazing animals (TR pp. 479-481);
- Silica supplementation can result in elongation and thickening of stems, delayed antithesis and flower deformation in some species (TR pp. 487-490);

In 2007, the Crops Subcommittee recommended not to list aqueous potassium silicate (APS) because "multiple substitutes are available" and it is a "synthetic soil applied fertilizer not compatible with organic farming regulations." The rationale given for NOSB approval was, "Public comment at Nov. 2007 NOSB meeting well supported listing the substance as plant disease control by providing historical 2003 NOSB consideration of the material as well as more information from petitioner and other interested stakeholders." New information was provided in a January 6, 2014 TR. In 2014, the Crops Subcommittee voted 4 to 3 in favor of removing aqueous potassium silicate from the National List. At the Fall 2014 NOSB meeting in Kentucky, the motion to remove Aqueous Potassium Silicate from the National List was not supported by the Board by a vote of 7 to remove and 9 against removal. Those voting for removal pointed to the bulleted items above while those voting not to remove saw the compound as an important pest control option for organic growers.

Questions remain about the compound's mechanism of action, effects on farmworkers making the foliar application, and effects on human or animal consumers. It remains unclear if aqueous potassium silicate directly enhances plant protection or if its effects are indirect through regulation of phytoalexins and chitinases that, in turn, strengthen stroma and cell walls.

Questions

1) What is the efficacy of aqueous potassium silicate relative to available alternatives?

2) How would the removal of this product impact organic growers?

3) To what extent does listing aqueous potassium silicate result in reductions in use of copper and sulfur-based pest management?

4) If potassium silicate is taken up in the roots and moved throughout the plant via apoplast or symplast movement and then incorporated in sink tissue (the leaves), then the compound is behaving like a systemic, synthetic pesticide. Is this compound systemic?

5) What evidence exists documenting the safety of animal and human ingestion of plants and forages with elevated silicate levels in leaf tissue?

6) How does age or gender of animals and humans ingesting plant material with elevated silicate levels influence their range in vulnerability?

Subcommittee vote
Aqueous potassium silicate may cause deleterious human and animal health effects such as dermal toxicity and systemic effects as well as affecting digestibility of forages. Uncertainties about the mode of action make it unclear as to whether or not this material is moved systemically in the plant. Additionally, alternatives to this material exist, and this material is not necessary for organic production.

Motion to remove aqueous potassium silicate from 205.601(e) – As an insecticide (including acaricides or mite control) - The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand, based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Alternatives/Compatibility

Motion by: Dave Mortensen
Seconded by: Asa Bradman
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Aqueous potassium silicate

Reference: 205.601(i) As plant disease control. (1) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR
Petition(s): 2002 Potassium Silicate; 2006 Potassium Silicate Supplemental

Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation
Recent Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521). Sunset renewal notice published 06/19/15 (80 FR 35177).
Sunset Date: 6/22/2020

Subcommittee review
Aqueous potassium silicate is used as a crop protectant for disease control and suppression. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

Internationally (Japan, Canada, EEC, CODEX, or IFOAM), natural sources of silica, not APS, are allowed (258-296).

Based on information in the January 6, 2014 technical report (TR), the following concerns were raised by the Crops Subcommittee during the 2014 Sunset review:

- Dermal exposure can lead to low to medium systemic toxicity and skin irritation (TR pp. 577-579);
- Treatment with potassium silicate may not be appropriate when crops are used for feeding or as forage for livestock because it makes some forages less digestible (TR pp. 477-481);
- The addition of potassium silicate as a foliar nutrient may result in the production of less tender fruits and vegetables or forage for grazing animals (TR pp. 479-481);
- Silica supplementation can result in elongation and thickening of stems, delayed antithesis and flower deformation in some species (TR pp. 487-490);

In 2007, the Crops Subcommittee recommended not to list Aqueous Potassium Silicate (APS) because "multiple substitutes are available" and it is a "synthetic soil applied fertilizer not compatible with organic farming regulations." The rationale given for NOSB approval was, "Public comment at Nov. 2007 NOSB meeting well supported listing the substance as plant disease control by providing historical 2003 NOSB consideration of the material as well as more information from petitioner and other interested stakeholders." New information was provided in a January 6, 2014 TR. In 2014, the Crops Subcommittee voted 4 to 3 in favor of removing aqueous potassium silicate from the National List. At the Fall 2014 NOSB meeting in Kentucky, the motion to remove Aqueous Potassium Silicate from the National List was not supported by the Board by a vote of 7 to remove and 9 against removal. Those voting for removal pointed to the bulleted items above while those voting not to remove saw the compound as an important pest control option for organic growers.

Questions remain about the compound's mechanism of action, effects on farmworkers making the foliar application, and effects on human or animal consumers. It remains unclear if aqueous potassium silicate directly enhances plant protection or if its effects are indirect through regulation of phytoalexins and chitinases that, in turn, strengthen stroma and cell walls.

Questions

1) What is the efficacy of aqueous potassium silicate relative to available alternatives?

2) How would the removal of this product impact organic growers?

3) To what extent does listing aqueous potassium silicate result in reductions in use of copper and sulfur-based pest management?

4) If potassium silicate is taken up in the roots and moved throughout the plant via apoplast or symplast movement and then incorporated in sink tissue (the leaves), then the compound is behaving like a systemic, synthetic pesticide. Is this compound systemic?

5) What evidence exists documenting the safety of animal and human ingestion of plants and forages with elevated silicate levels in leaf tissue?

How does age or gender of animals and humans ingesting plant material with elevated silicate levels influence their range in vulnerability?

Subcommittee vote

Aqueous potassium silicate may cause deleterious human and animal health effects such as dermal toxicity and systemic effects as well as affecting digestibility of forages. Uncertainties about the mode of action make it unclear as to whether or not this material is moved systemically in the plant. Additionally, alternatives to this material exist, and this material is not necessary for organic production.

Motion to remove aqueous potassium silicate from §205.601(i) - As plant disease control - The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand, based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Alternatives/Compatibility
Motion by: Dave Mortenson
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Elemental sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (5) Elemental sulfur.
Reference: 205.601(i) As plant disease control. (10) Elemental sulfur.
Reference: 205.601(j) As plant or soil amendments. (2) Elemental sulfur.

Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2010 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Elemental sulfur can come either from a natural mined source, or be produced as a by-product from natural gas or petroleum operations and refinery processes. The latter appears to be the primary source of most elemental sulfur currently being used. Elemental sulfur has been used for centuries and approved for use in the U.S since 1920.

The European Economic Community (EEC) Council Regulation (EEC No 2092/91) carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production. The International Federation of Organic Agriculture Movement's (IFOAM) lists sulfur as an approved substance for use as pest and disease control, fertilizer/soil conditioner, and crop protectant and growth regulator. Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013). Sulfur is also allowed by Canadian Organic Standards. The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. Chemically synthesized substances cannot be added, and chemical treatment is prohibited. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed. The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance and as a substance for plant pest and disease control.

Sulfur is heavily used in agriculture worldwide for two distinct purposes with different application methods: as a plant nutrient and as a pesticide. It is the most heavily used pesticide in California, with over 50,000,000 pounds used annually, representing more than 25% of all agricultural pesticide use in the state. Accurate information on pesticidal use in the organic sector is not available.

An updated Technical Report was completed on April 19, 2018. No new information contradicts historical information that characterizes sulfur as an important and relatively safe material for organic agriculture. However there are some recent studies that suggest potential associations of between agricultural sulfur use and community respiratory health. Sulfur is an essential plant nutrient, naturally present in our food and soil, and is part of normal human biochemistry. Elemental sulfur is relatively innocuous in the environment when used according to the product label. It is also low in toxicity. It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels. Two previous Sunset Material Reviews (2005 & 2010) of elemental sulfur have resulted in continuing approval of all three uses. Although low in acute toxicity, sulfur is a respiratory, ocular, and dermal irritant and has significant impacts on farmworker health. Farmworker exposures can be mitigated if label recommendations and proper PPE recommendations are followed. A recent study also reported significant associations between agricultural use of sulfur and poorer respiratory health in children living near fields (https://ehp.niehs.nih.gov/ehp528/). Several agricultural commissioners in California have encouraged a shift to wettable formulations in vineyard applications and anecdotal information suggests fewer drift and regulatory problems.

Historically there has been strong support for the continued listing of sulfur, particularly for use against various bacterial and fungal diseases and other pests and as a plant and soil amendment. In October 2017, the NOSB recommended approval of sulfur use as a molluscicide. Public comment during the October 2017 meeting was strongly in support of continued listing of sulfur. Grape, strawberry, and other growers consider sulfur to be essential and described investments in equipment to apply sulfur, including dust application technologies to reduce drift. Several commenters, including environmental advocates and growers, did not support relisting of sulfur due to human health and potential environmental impacts or supported restrictions on use of dust applications.

Based on the extensive public comment and discussions, new technical reviews, previous committee votes & discussions, and historical public comment, it would appear that elemental sulfur is still necessary in organic crop production. The NOSB should continue to monitor sulfur use in organic agriculture and respond to any new information raising environmental or, in particular, public health concerns.

Subcommittee vote

Motion to remove elemental sulfur from the National List at §205.601 (e)(5), §205.601 (i)(10), and §205.601 (j)(2) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Asa Bradman
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Lime sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (6) Lime sulfur—including calcium polysulfide.
Reference: 205.601(i) As plant disease control. (6) Lime sulfur.
Technical Report: 1995 TAP (Livestock - hydrated lime); 2014 TR
Petition(s): N/A
Past NOSB Actions: 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As an insecticide, lime sulfur is used to control mites (spider mites and rust mites), aphid, and san jose scale in tree fruit and other organic crops. As a fungicide, it is used to control powdery mildew, anthracnose, scab, peach leaf curl, and several other plant diseases in tree fruit and berry crops. It is also part of a process that when used in conjunction (or in rotation) with other allowed materials, as a replacement for the two recently removed antibiotics, for assisting to control fire blight in organic apple and pear production.

Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [$CaOH_2$] and ground sulfur (2014 TR). Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.
Lime sulfur is allowed among other international certification bodies:

- Canada – allowed as a fungicide, insecticide, or acaricide/mite control. (CAN,21)
- Codex Alimentarius – although not mentioned specifically, organic production guidelines from Codex Alimentarius Commission (CAC GL 32-1999) permit the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013).
- European Union – permits the use of lime sulfur (calcium polysulfide).
- Japanese Ministry of Agriculture Forestry and Fisheries – permits the use of lime sulfur powder for plant pest and disease control.
- IFOAM – lists lime sulfur in Section II of Appendix 3: Crop Protectants and Growth Regulators (IFOAM, 2014).
- UK Soil Association – only allows the use of lime sulfur on a case-by-case basis, when there is a demonstrated major threat to a grower's crop. (Soil Association, 2014).

Lime sulfur has a long history of use for crop production. The original technical advisory panel report (TAP) used the 1922 USDA Farm Bulletin as part of its fact finding. The 2014 technical evaluation report (TR) provided an extensive list of alternative materials and practices, however, a benefit of lime sulfur is that it can act as both an insecticide and a fungicide. Alternative biological materials often need to be used preventatively whereas lime sulfur can sometimes be used to mitigate an existing crop issue. Lime sulfur can cause phytotoxicity in some crops, however, rates and timings can be used to avoid this problem. Similarly, the technical report notes that lime sulfur may impair some beneficial insects, but, once again, timing of use can minimize the negative effects. Lime sulfur is one leg of an integrated fire blight control program for pome fruits and has become especially important since antibiotics for fire blight control were removed from the National List.
The technical report noted potential human health concerns from lime sulfur primarily due to its high alkalinity or the release of hydrogen sulfide. This concern is largely mitigated during formulation or actual use if proper safety procedures are followed during manufacture and label directions are followed at application.

The vast majority of public comments during the Spring 2018 review were in favor of relisting lime sulfur for control of fungal and bacterial diseases as well as its uses for various insects. It has widespread and historical use across many crops and regions. Many comments note that there are not viable alternatives for its various uses, especially as part of an integrated fire blight control program. The few comments against lime sulfur primarily referenced the Technical Report in noting that later season use of the material may have a negative impact on beneficial insects and that large scale releases of the material could cause environmental impact.

Subcommittee vote
Motion to remove lime sulfur based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Emily Oakley
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Sucrose octanoate esters

Reference: 205.601(e) As insecticides (including acaricides or mite control). (10) Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)—in accordance with approved labeling.

Technical Report: 2005 TR

Petition(s): 2004 Sucrose Octanoate Esters; Amendment #1; Amendment #2

Past NOSB Actions: 08/2005 NOSB recommendation for addition to NL; 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 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review
Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SFAEs are surfactants (or surface-active agents) that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. Sucrose esters, as a class of related compounds, vary, depending on the number and locations of esters attached to the sucrose molecules. Sucrose has eight potential places where individual esters may attach (Montello Inc., n. d.). The substance under review is a mixture of mono-, di-and tri-esters (TR lines 24-31).

Sucrose esters were first isolated when researchers investigated the insecticidal properties of the tobacco leaf hairs. This insecticidal property of sucrose esters acts by dissolving the waxy protective coating (cuticle) of target pests, thus causing them to dry out and die (U.S. EPA, 2002b). SOEs marketed as biopesticides are intended to mimic the pest control properties of *Nicotiana gossei* Domin (wild tobacco) and other *Nicotiana* species. In addition to the tobacco plant, insecticidal sugar esters have been found in wild tomato and wild potato species and in the petunia plant (Chortyk et al., 1996) (TR lines 33- 38).

SOEs are approved for use as a contact-type biochemical insecticide/miticide (EPA Registration Number 70950-2, OPP No. 035300) to control soft-bodied insects (TR lines 69 - 70). SOEs are permitted by EPA for use as a biopesticide for foliar spray in field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals), as well as on mushroom growing media and on adult honey bees (U.S. EPA, 2002a).

According to the 2005 technical report, when SOEs are applied according to EPA approved labelled instructions, no direct exposure of birds or aquatic organisms is expected (U.S. EPA, 2002a). SOEs biodegrade within approximately five days at 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so there is minimal potential for exposure for insects, fish, and other non-target wildlife. (U.S. EPA, 2002a).

Many commenters during the Spring 2018 NOSB public comment period stated that they did not use SOEs on their operations; nevertheless, there were four positive public comments that stated that it was an effective tool used in rotation with other pest control materials that are allowed for use in organic production. There were no negative comments about the continued listing of SOEs on 205.601(e).

Additional information requested by Subcommittee

1. Is additional information available about the toxicity of SOEs to non-target organisms when exposed by spray (including predators, parasitoids, soil fauna, and aquatic organisms)?
2. Is this product still being used, or are there other approved synthetic or natural products that are more effective?
3. If SOEs are not being used, do we need it to keep in the crops toolbox to be rotated with other products?

Subcommittee vote

Motion to remove sucrose octanoate esters (SOEs) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Sue Baird
Seconded by: Jesse Buie
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Hydrated lime

Reference: 205.601(i) As plant disease control. (4) Hydrated lime.
Technical Report: 1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide
Petition(s): N/A
Past NOSB Actions: 04/1995 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee review

Hydrated Lime is used as a foliar application in combination with copper sulfate ($CuSO_4$). This mixture is also referred to as the 'Bordeaux mix.' The role of the hydrated lime ($Ca(OH)_2$) is that of a precipitating agent making the copper available to prevent infestations of mildews and other pathogenic fungi in a range of fruit production systems.

Manufacture
Hydrated Lime is considered a synthetic substance. The production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone - which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum and iron oxide compounds - is thermally transformed into quicklime. Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 ºC results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime. This thermal transformation occurs with liberation of carbon dioxide (CO_2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide ($Ca(OH)_2$). After hydration, the slightly moist slaked lime is conveyed to a separator where coarse fractions are removed, and the powder is dried.

International acceptance by other international certifying bodies
The Canadian General Standards Board, the European Union and the International Federation of Organic Agriculture Movements allow hydrated lime for use as a foliar application to plants for disease suppression.

Environmental/Health Issues
Careful procedures are needed for handling hydrated lime as it can severely irritate and burn the eyes, skin, and mucous membranes. The hydroxide anions (OH^-) generated from dissolution of calcium hydroxide in water or other fluids is the main driver of toxicity for the substance. The effects of the substance on biological and chemical interactions in the agroecosystem are limited given its use as a plant disease suppressant. It is important to note that much has been learned about the impact of hydrated lime as a soil liming agent to elevate soil pH. However, orders of magnitude smaller amounts of the substance are used in the requested application as the mixture is applied to the foliage of the plants to limit plant disease establishment and spread.
The primary environmental issues associated with production of hydrated lime include energy use and dust formation. Calcium oxide is obtained through thermal decomposition of calcium carbonate (limestone) in fuel-powered kilns, a process that requires large amounts of energy. Crushing and handling of limestone and the burning, processing and handling of quicklime and hydrated lime results in dust emissions. Significant advances in deploying filtration systems have mitigated these effects.

Discussion
Two Technical Advisory Panels *(TAPs)* and a Technical Report (TR) were compiled in 1995, 2001 and 2015, respectively. The use of hydrated lime as has been practiced in organic production is known to be an effective disease suppression practice. The use of hydrated lime in Bordeaux mix to make copper available for disease suppression is highly effective and widely used by fruit and vegetable growers. The Crops Subcommittee received many supporting letters for continued use of hydrated lime as an integral part of disease pest management. The past sunset review conducted in Fall 2015 resulted in a unanimous vote not to remove hydrated lime from the National List.

Questions:
Are adequate safety procedures in place to prohibit fieldworker and applicator exposure to hydrated lime?

Subcommittee vote
Motion to remove hydrated lime based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Dave Mortenson
Seconded by: Jesse Buie
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Liquid Fish Product

Reference: 205.601(j) As plant or soil amendments. (7) Liquid fish products —can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Liquid fish products are used as fertilizers for the production of organic crops. These products contain fundamental nutrients and many trace minerals critical for use in organic farming. Liquid fish fertilizers are used in soil and container productions systems. Liquid fish foliar applications improve crop yields and reduce both insects and diseases.

Liquid Fish Products are made from fish byproducts that are chopped and then enzymatically digested and heated or enzymatically processed without heat (cold-processing) to produce fish hydrolysate. Liquid fish products are then stabilized with an acid such as phosphoric, sulfuric or citric acid to prevent microbial growth. Use of formic acid is prohibited due to phytotoxicity. A third method utilizes fermentation by bacteria that produce lactic acid, which preserves the fish. All methods cannot result in pH below 3.5.

The Canadian Organic Standard allows for the use of liquid fish products. Acids are permitted to lower the pH to 3.5, but no prohibited preservatives can be used. CODEX Alimentarius allows processed animal products from slaughterhouses and fish industries contingent on recognition from a certification body or authority. The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources. The International Federation of Organic Agriculture Movements (IFOAM) permits the use of fish and shell products and food processing of animal origin. Liquid fish is not on the EU Annex I list of approved fertilizers, but the EU does allow fish meals.

Nutrient runoff from excessively or improperly applied fertilizers can cause eutrophication of surface waters, potentially harming fish and other aquatic animals.

Historically, there has been strong support for keeping liquid fish products on the National List and public comment at the October, 2017 NOSB meeting reiterated the strength of that support. Many farmers considered liquid fish products to be essential for many crops, including foliar and other applications. Concerns about the sustainability of source fish, including possible use of wild fish harvested for the sole purpose of producing liquid fertilizers, were raised by the Crops Subcommittee, and extensive discussion during the October, 2017 NOSB meeting focused on production methods and sources of raw fish material for production of fish-based fertilizers. These discussions resulted in a work-agenda request to assess the environmental impact of harvesting wild, native fish for all fertilizer purposes, to protect natural fish populations, and to ensure that liquid fish and other fish-based fertilizer products used in organic production are not harmful to the environment. Information from this review could inform future policy recommendations regarding use of wild fish for organic fertilizers but is beyond the scope of review for this sunset review.

This proposal to remove will be considered by the NOSB at its public meeting. The Crops Subcommittee supports relisting of liquid fish production the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Subcommittee vote

Motion to remove liquid fish products from §205.601(j) as a plant and soil amendment based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/AMotion by: Asa Bradman

Seconded by: Jesse Buie

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

Sulfurous acid

Reference: 205.601(j) As plant or soil amendments. (9) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

Technical Report: 2010 TAP; 2014 TR

Original Petition: 2008 Sulfurous Acid

Past NOSB Actions: 05/2009 NOSB Recommendation; 10/2014 NOSB sunset recommendation

Regulatory Background: Added to National List 7/6/2010 (75 FR 38693); Sunset renewal notice published 06/19/15 (80 FR 35177).

Sunset Date: 6/22/2020

Subcommittee Review

Sulfurous acid is used to quickly acidify irrigation water in areas of the country where soils are alkaline or saline. Application of the acidic irrigation water can help to alleviate nutrient deficiencies created when saline or alkaline conditions tie up essential micronutrients. This in turn can improve crop yields and help to reduce soil degradation from salinity buildup. While similar reactions can eventually be obtained by applying soil sulfur, the reaction time of sulfur in the soil is relatively slow and the effect may take months or years to be realized (2014 TR). The last technical report was completed in 2014 and comments below draw from that report.

Sulfurous acid is created by spraying water through smoke and fumes created by burning elemental sulfur. Several substances are created in this process, including sulfur dioxide, hydrogen sulfide and hydrogen sulfite (bisulfite). The sulfur dioxide dissolved in water is often termed sulfurous acid. However, the sulfurous acid is unstable and almost immediately forms hydrogen sulfite. The hydrogen sulfite is acidic and lowers the pH of the water (2014 technical report). This process is often done on-farm with a device called a sulfur burner and the effluent from the sulfur burner is used to acidify irrigation water.

Sulfurous acid does not require a tolerance or an exemption from tolerance and appears on the EPA non-food inert list. While sulfur dioxide, a potential pollutant, is generated by the burner, that sulfur dioxide is captured in the irrigation water and the release of sulfur dioxide to the atmosphere is minimal. EPA does not regulate this emission. In fact, the sulfur used to burn in these sulfurous acid generators is often sourced from scrubbers cleaning the emissions from oil, gas and coal industries.

Sulfurous acid is a weak acid and does not produce notably toxic effects on fish, aquatic invertebrates or plants, and many bacteria possess sulfite reductase enabling them to metabolize sulfurous acid. In cases where sulfurous acid is used to acidify irrigation water, soils are often low in sulfur and the application of the sulfurous acid can be beneficial.

Most public comments from Spring 2018 were in favor of relisting sulfurous acid. Comments in support noted that this is a very effective treatment for increasing nutrient availability in alkaline soils and that alternatives would be considered an extremely poor substitute. The few commenters supportive of removing this substance listed concerns that this material allows farming on degraded and unsuitable soils and that there could be an effect on soil microorganisms from high concentrations of this material. These comments were refuted by other public commenters, and those other commenters also noted that this is only a very slightly acidifying material and is used in place of applications of large amounts of soil sulfur over many years.

Subcommittee vote
Motion to remove sulfurous acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Ethylene gas

Reference: 205.601(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.
Technical Report: 2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR

Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 10/2001 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Ethylene gas is listed as a growth regulator for organic pineapple production only. It is used to induce uniform flowering in pineapples and is applied 7-15 months after planting. Application can be repeated two to three times after the initial application (TR lines 53-56). It is made from hydrocarbon feedstocks, such as natural gas liquids or crude oil. It is produced almost exclusively from the pyrolysis of hydrocarbons in tubular reactor coils installed in externally fired heaters. Ethylene may also be produced from ethanol in fixed or fluid-bed reaction systems (2007 TAP). The main safety concern in relation to ethylene use has been the explosive nature of the gas in the air. Operators should be well trained and prepared, though the safety concern to workers is limited when correctly used and monitored (2007 TAP).

The most recent Technical Report (TR) for this material was a supplement developed in 2011 which addressed questions of continued need, use according to scale of operation, and new alternatives. The TR found that small-scale operations likely cannot afford the expensive equipment needed for whole plant application of ethylene gas in large fields (TR lines 215-16). Various technologies for applying ethylene were reported, including some limited evidence that smaller-scale producers are successfully adapting ethylene using handheld booms and manual application techniques in East and West Africa. Experiments involving cold treatment were reported in Taiwan, though actual use patterns in the field are unknown (TR lines 191-210). Alternative natural methods to induce flowering have not changed since the initial material review in 1999. These methods include cold stress, smoke, exposure to ripe fruits, and selective tilling of the weeds and cutting back of trees in agroforestry systems (TR lines 73-75).

This material was reviewed in 2015 as part of the 2017 sunset process. The NOSB was concerned about the lack of comments from pineapple producers for the spring meeting, and they included another request to hear from stakeholders in the proposal for the fall meeting. Subsequently, organic pineapple producers, primarily from Costa Rica, presented a large number of both written and oral comments. These comments, along with historic information, previous sunset reviews, and discussions at the fall meeting helped to provide the NOSB with information about this material, how it is used by operations of various sizes, and the significance it plays in crop production. There have been concerns in the past that this material is used only by larger operations. However the Fall 2015 grower comments showed that organic pineapple producers of all sizes use this material. Public testimony stated that the current level of organic pineapple production is dependent on the availability of this material. No new issues of human health or environmental concerns were raised that had not been addressed in previous review cycles.

As part of the Spring 2018 public meeting, the Crops Subcommittee requested additional information regarding the issue of scale and the use of ethylene and alternative technologies. Written and oral testimonies expressed continued support for this material, stating that it is an essential tool for the commercial production of pineapples for the export market. Commenters stated that no viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. Others commented that the material does not fit any OPFA criteria, and it is not essential for the production of the crop but rather is employed for economic reasons.

Subcommittee vote
Motion to remove ethylene gas from §205.601 (k) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Emily Oakley
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Microcrystalline cheesewax

Reference: 205.601(o) As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.
Technical Report: 2018 TR
Petition(s): 2007 Petition; 2008 Petitioner response to questions
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB sunset recommendation
Recent Regulatory Background: Federal Register rule amendment published 02/14/12 (77 FR 8089); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Microcrystalline waxes are a type of wax derived from the refining of heavy petroleum distillates during the petroleum refining process. It is recovered from crude oil through a series of filtration, solidifying, and solvent extraction steps. The by-product must then be de-oiled at a wax refinery, resulting in three components of the cheesewax. Depending on the end use and desired specification, the product may then have its odor removed and color removed (which typically starts as a brown or dark yellow). This is usually done by means of a filtration method or by hydro-treating the wax material. All the solvents in the process are recovered, with none remaining in the final product.

Microcrystalline cheesewax has been approved by the United States Food and Drug Administration (FDA) at 21 CFR § 172.888 as a "synthetic petroleum wax," for use as a "masticatory substance," in chewing gum, a "protective coating," on cheese and raw fruits and vegetables, and as a "defoamer in food." Microcrystalline cheesewax as a petroleum wax is also listed by the FDA at 21 CFR 178.3710 as an allowed "component of nonfood articles in contact with food."

Microcrystalline cheesewax is not listed in the Organic Foods Production Act of 1990, but is currently listed under the National Organic Program (NOP) regulations at 7 CFR 205.601(o) as a synthetic substance allowed as a "production aid," for "use in log grown mushroom production," with the exception that the wax "must be made without either ethylene-propylene co-polymer or synthetic colors."

Microcrystalline wax is used in mushroom production to seal plug holes in Shiitake logs in which mushroom spawn is inserted. It is melted to a liquid state to be placed in the spawn hole as a sealant to hold in the moisture and to physically hold the mushroom spawn in place when placed over the hole in the log in which the spawn has been inserted. The original petition stated that there is no contact with the growing mushrooms at any time during the mushroom growing process.

Microcrystalline cheesewax is melted to a liquid state to be placed in the spawn hole. During the melting process, petrochemical fumes might be released, causing mild respiratory irritation, according to the Materials Safety Data Sheet. The cheesewax meets the FDA requirements for use in non-food articles in contact with food and for use in food (21 CFR 178.3710 and 21 CFR 172.886). Formulations of the microcrystalline cheesewax contains BHT as an antioxidant preservative.

Microcrystalline cheesewax breaks down readily in the environment, is not toxic to soil flora and fauna, and does not dissolve readily in water.

Neither microcrystalline cheesewax, nor its components are listed in any of the international organic standards as a production aid in mushroom production. The Canadian General Standards Board Permitted Substances List, CAN/CGSB-32.311 “Table 6.5 Processing aids” prohibits the use of microcrystalline wax “either alone or in formulations with paraffin wax.”

During the Spring 2018 public comment period, NOSB heard from several commenters who stated that commercial operations were no longer producing Shiitake mushrooms on logs, reducing the need for the microcrystalline cheesewax as inoculation plugs. Others commented that there is a natural soy-based wax available for use now, and that the substance is no longer needed. Nevertheless, most commenters felt that there were smaller Shiitake mushroom growers that are still growing the Shiitake mushrooms on whole logs and are still using the microcrystalline cheesewax as inoculation plugs and supported the continued listing of microcrystalline cheesewax on 205.601(o).

Additional information requested by Subcommittee

1. During the 2008 NOSB recommendation review it was determined that there were no effective approved natural or synthetic materials that could replace microcrystalline cheesewax for plugging Shiitake mushroom log-grown substrates. Is there now an effective natural or approved synthetic replacement for the microcrystalline cheesewax that is derived from petroleum by-products?

2. Should an annotation be added that requires removal of residues of the microcrystalline cheesewax that remain in the environment once the Shitake logs are finished fruiting?

3. Canada and Japan, and perhaps other countries, also produce organic Shitake mushrooms, but do not allow the use of microcrystalline cheesewax in their organic production. Why do these countries not allow the microcrystalline cheesewax and/or what other types of substances are those producers using as a sealant?

Subcommittee vote
Motion to remove microcrystalline cheesewax based on the following criteria in the Organic Foods

Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Alternatives, such as a natural soy-based wax are available to replace this synthetic material. Additionally, many operations are no longer producing Shitake mushrooms on logs, thus this material may no longer be needed.
Motion by: Sue Baird
Seconded by: Emily Oakley
Yes: 2 No: 4 Abstain: 1 Absent: 1 Recuse: 0

Potassium chloride

Reference: 205.602(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
Technical Report: 1995 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 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Potassium is required for health in humans, plants, and microorganisms (TAP pg. 4, 14). Potassium is an essential element for plants as they use it to regulate movement of water and nutrients within the plant, photosynthesis regulation, and enzyme activation. While potassium is found in many soils, it may not exist naturally in a high enough concentration for optimal plant growth, and/or it may be present but in a bound format rendering it unavailable. Potassium is commonly used by growers either alone, as a complex in potassium chloride, or as an ingredient in a fertilizer blend for soil supplementation. Chloride is also an essential element for plants (TAP pg. 12); however, monitoring of chloride use is required to assure soil salinity is managed appropriately. The current annotation in the NOP regulations stipulates chloride monitoring when potassium chloride is used to prevent chloride accumulation in soils.

During the last sunset review in 2015, the NOSB voted unanimously to relist potassium chloride at §205.602(e) with the current annotation requiring origin from a mined source, and that it is applied in a manner to prevent chloride accumulation in the soil.

For the first posting of the sunset review of potassium chloride (in Spring 2018), the NOSB asked the public two questions:

1. Is potassium chloride still required for growers?
2. Are non-chloride potassium products available to organic growers that would eliminate the concern for chloride accumulation in the soil?

Public comment was unanimous in support of continued listing with the current annotation, and there were no other non-chloride types reported by the public. One certifier recommended that the NOSB update the technical report on this substance to more thoroughly consider the use of synthetic dust suppressants or other synthetic additives.

Subcommittee vote

Motion to remove potassium chloride -unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil from 205.602(e), based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A.
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Allyl Isothiocyanate (AITC)
June 19, 2018

Summary of AITC 2016 Petition; 2013 Petition:
Two petitions for allyl isothiocyanate (AITC) have been submitted to the National Organic Program by Isagro USA, Inc. Both petitions propose to add AITC as an allowed synthetic substance in organic crop production (§ 205.601) as a pre-plant fumigant. The original petition, dated December 20, 2013, was received by the NOSB on January 24, 2014. After review and discussion by the Crops Subcommittee, the request to add AITC to the National List at 205.601 was not recommended. The second petition, submitted July 2016, further asserted that AITC offers organic growers the only effective management tool for soil-borne diseases and pathogenic nematodes at levels that are commercially relevant and supports the phytosanitary certification process for organic fruit and vegetable nursery stock production.

Summary of Review:
Based on information from the 2018 technical report (TR), AITC is a naturally occurring compound found in plants such as broccoli, brussel sprouts, mustard, wasabi, and horseradish. AITC, commonly referred to as “oil of mustard” was first registered by the U.S. EPA in 1962 for use in pesticides and rodent control products; however, oil of mustard is a common food ingredient and has been listed on the U.S. Food and Drug Administration’s Generally Regarded As Safe (GRAS) list since 1975 (2018 TR, lines 78-79, 132.

To facilitate review of the petition dated July 2016, the Crops Subcommittee requested a limited scope technical report (TR) to address outstanding issues. These issues were addressed in the TR dated February 12, 2018, as follows:

- Provide a review of allyl isothiocyanate as it pertains to the newly listed additional uses that were not listed in the original petition.
- Review the proposed phytosanitary use for nursery stock and plants which deals with Nursery Stock certification, including potential benefits, all applicable rules and regulations on both a State and Federal level, as well as how that applies to USDA APHIS requirements. Would allyl isothiocyanate work and would it be allowed for this mandatory process as required by law?
  - Clarification: The 2018 petition mentions the use of AITC as a phytosanitary tool for use on organic nursery stock and plants when there is a requirement to meet phytosanitary restrictions. There is currently an exemption that allows treatment of organic nursery stock and plants if that is the only alternative to meet phytosanitary certification processes. This may occur during the intra- and inter-state movement of plant materials (e.g., seed and nursery stock) through inspection and certification programs (e.g., USDA APHIS). Specific soil-borne pathogens and nematodes are targeted pests of the nursery stock registration and certification program and must be treated for presence of such in stock or seeds. Eradication treatments of thermotherapy, fumigation using methyl bromide or Telone II™, other synthetic fumigants, and/or hot water treatments are mandatory. Would this material work, and would it be allowed for this mandatory process, as required by law.
- Provide a comprehensive look at both the short and long-term impacts on soil beneficial life forms compared to existing practices and/or materials being used.

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?

   AITC may be considered synthetic or natural depending on the method utilized for its production. The petitioned substance is produced using chemical synthetic methods (2018 TR lines 337).

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: 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?

   AITC contains a singular sulfur atom; therefore, AITC may be considered a sulfur compound.

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?

   One possible interaction between the petitioned substance and other materials used in organic crop production involves the reaction of AITC with free amino acids, peptides and proteins contained in organic composts and fertilizers. Specifically, electron deficient AITC can react with the electron rich amino groups of the free amino acids alanine and glycine as well as cysteine, lysine and arginine residues of intact proteins. Diminished enzymatic digestibility was documented for some of the resulting protein-AITC adducts; however, it is uncertain how these chemical transformation products might affect the absorption and metabolism of amino acid building blocks in plants (2018 TR lines 563-569) 2018).

2. What is the toxicity and mode of action of the substance and of its breakdown products or any containments, and their persistence and areas of concentration in the environment?

   Overall, as noted in the TR, it can be concluded that the toxicity rating of AITC ranges from toxic to practically non-toxic to the few non-target taxa evaluated in the TR (2018 TR lines 669-670). The risk of toxicity associated with mammalian exposure to AITC is variable depending on the source and concentration of AITC used in toxicity testing. According to US EPA, oil of mustard containing AITC at a concentration of 4.43% is practically non-toxic via the acute oral and inhalation routes of exposure. In addition, oil of mustard is not an acute dermal irritant or sensitizing agent.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance.

Considering its moderately high volatility (3.7 mm Hg at 25°C), high application rates (85–340 lbs/acre), and agricultural use as a soil biofumigant, releases of AITC to the environment are inevitable. AITC is both flammable and potentially toxic to nontarget organisms such as mammals and fish. Aquatic wildlife may be exposed to AITC through spills and/or irrigation runoff. As with conventional fumigants, measures such as the use of plastic tarps on treated fields or application of AITC through a drip system could be taken to further protect humans (bystanders and workers) and nontarget terrestrial organisms from exposure to AITC following soil biofumigation. The rapid breakdown and dissipation of AITC in the environment reduces the probability of contamination of groundwater and surface water due to agricultural applications of the substance (2018 TR lines 523-531).

4. Discuss the effect of the substance on human health.

   The TR specifies that natural sources of AITC contained in natural vegetable oils (e.g., mustard oil) are generally non-toxic to humans via oral exposure. This observation is not surprising considering the high concentrations of AITC (3 mg/kg to 15 g/kg) generally found in popular food items such as kale, broccoli, mustard and horseradish. However, moderate doses of concentrated AITC are considered toxic to mammals based on laboratory studies in animals.

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.

   AITC can have a short-term harmful effect on beneficial soil microorganisms and mutualistic fungal interactions. However, long term soil effects for other fumigation agents is relatively non-existent, as they have not been as widely utilized as methyl bromide and have only received considerable attention since the ban on methyl bromide in 2005.

   In a short-term study (28 days) of the effect of AITC on soil bacterial and fungal communities, the application of AITC significantly decreased soil fungal populations but had negligible impact on soil bacterial numbers. However, AITC did have an influence on certain microbial community composition changes. The results showed increased proportions in bacterial taxa, which include bacteria associated with fungal disease suppression. The increase in these bacteria and decrease in overall fungal populations following application of AITC suggests that the observed efficacy of AITC on fungal suppression was not only due to direct toxicity of AITC to soil fungi, but also to biological interactions and competition with the altered microbial community that existed following fumigation. (2018 TR lines 640-650).

6. Are there any adverse impacts on biodiversity?

   AITC may have an impact on certain fungi that produce mutualistic relationships with plants and prey on insects. Exposure to livestock, birds, freshwater fish, freshwater invertebrates, non-target plants, and non-target insects is not expected based on the application methods proposed and the rapid environmental degradation of AITC (2018 TR lines 605-608, 610-611).

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials.

   Mustard seed meals, mustard green manures (plowed cover crop), and Regalia (OMRI approved material) are biopesticides that are available. SoilGard, a fungal biocontrol material, Seranade, and Bionematicide Melocon are also feasible alternative materials available for use in organic crop production systems.

   Crop rotation and soil nutrient management are alternative practices, as well as cultural practices that enhance crop health. For pest problems, introduction of predators or parasites of a pest species, lures, traps and/or repellants also can be used. For weed control, mulching, flaming, mowing, hand or mechanical weeding are some examples of practices currently in use. Also, the tilling in of mustard plant cover crops to create a green manure is currently being used and is a viable alternative practice.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture?

   No, the substance is not compatible with the system of sustainable agriculture.

Classification Motion:

Motion to classify allyl isothiocyanate (AITC) as synthetic
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add allyl isothiocyanate (AITC) at §205.601
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, August 24, 2018

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Sodium Citrate
June 19, 2018

Summary of Petition:

A petition was received in July 2016 for the use of sodium citrate as an anticoagulant when drying blood into blood meal which is then used as a crop fertility input in organic production. The petition specifically describes the sodium citrate as a processing aid in the production of dried blood meal.

Summary of Review:

Sodium citrate, a salt derivative of citric acid, currently appears on the National List of approved synthetic substances at §205.605(b), allowed as an ingredient in or on processed products labeled as organic or made with organic. There is no restrictive annotation for its use in organic handling. It is produced microbially typically from a molasses fermentation process and then neutralized with sodium hydroxide and crystallized into sodium citrate. It can also be produced microbiologically directly from the culture of a specific strain of yeast.

To date, the NOSB has not routinely been asked to review processing aids used in the production of crop fertility inputs. To our knowledge (according to a spring 2017 OMRI newsletter), sodium citrate is currently being used to produce blood meal used in organic production (i.e., the products are OMRI listed).

It is unclear if listing this material will instigate review and NOSB approval of more crop input processing aids. Would some materials currently in use and present on the National List no longer be allowed due to the presence of non-approved processing aids? In its spring 2017 newsletter, OMRI (a materials review organization which aids organic producers in determining allowed and prohibited materials in organic production) noted that if sodium citrate is approved as an anticoagulant processing aid for blood meal, they may feel compelled to review other anticoagulants. If other synthetic anticoagulants not present on the National List are used, OMRI may decide to not approve those brand name blood meal products as OMRI listed. It is unclear if the approval of sodium citrate as a processing aid in the drying of blood into blood meal as a crop fertility input would result in more processing aids being brought forth or disrupt the availability of other crop inputs due to the use of processing aids that are not present on the National List.

In discussions with the National Organic Program staff, it is still unclear where this material would specifically be listed on the National List, since there is no dedicated section for crop input processing aids and the term *processing aid* is not defined in the context of crop input production. It is also unclear if the use of sodium citrate, a synthetic, as a processing aid in the production of blood meal, would change blood meal from its current status as a nonsynthetic substance to a synthetic one, and therefore blood meal (made using sodium citrate) should be placed on the National List (similar to liquid fish products pH adjusted with synthetic acids). The NOSB Crops Subcommittee is bringing the sodium citrate proposal forward for full NOSB discussion, review, and vote, and will continue to work with the NOP to address the issues listed above.

Specific Uses of the Substance:

Sodium citrate is routinely used to aid in the processing of blood meal to prevent coagulation. Blood will begin to clot soon after slaughter, making the drying of the blood into blood meal difficult to impossible. Keeping the blood chilled and continually agitated are mechanical methods used to slow or prevent the rapid clotting of the blood, but this is impractical in a commercial sense when spray drying liquid blood into blood meal. Canada, Codex, the European Union, Japan and IFOAM allow sodium citrate in use of organic processed foods, but do not specifically approve its use in organic crop production as a crop input manufacturing processing aid.

Approved Legal Uses of the Substance:

Sodium citrate is present on the EPA Safer Chemical Ingredient list (SCIL) and described in the Technical Report as a material of low concern. Sodium citrate is not currently allowed as a synthetic in organic crop production as a stand-alone material, and the Crops Subcommittee is presenting this proposal to limit its use in organic crop production to use as an anticoagulant in the production of blood meal. It is currently allowed as an ingredient in organic foods, typically used as a pH control, buffering agent, and stabilizer. Sodium citrate is present on the National List as an approved synthetic in organic processed foods, with no restrictions.

Action of the Substance:

Sodium citrate acts as a chelation agent that removes the available calcium present in the blood. The naturally present calcium acts to allow the fibrinogen in freshly harvested blood to convert to fibrin which causes clotting or coagulation. Even with the use of this anticoagulant, blood must be dried fairly quickly after harvest. The sodium citrate is added directly to blood as it is collected in the meat slaughtering facility.

Manufacture:

Sodium citrate, the sodium salt derivative of citric acid, is a crystalline white powder with a melting point of >300°C. Its molecular formulae are: anhydrous: $C_6H_5O_7Na_3$; hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5) or $C_6H_5Na_3O_7$ or $C_6H_5O_7$. 3Na. It has a molecular weight of 258.08 grams/mole. A two-dimensional structure of sodium citrate is provided in Figure 1. Previous technical reviews for citric acid and sodium citrate are available on the NOP website (NOP, 2015). Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization. It is most commonly in the anhydrous or dihydrate forms.

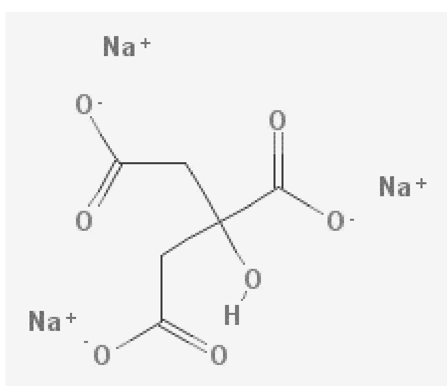

Figure 1 2D Sodium Citrate Structure

(PubChem, 2017)

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.

   Sodium citrate is produced through a chemical process, introducing sodium hydroxide or other synthetics to a naturally fermented citric acid.

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?

   Sodium citrate may fall within the OFPA production aid category. Sodium citrate is not a synthetic inert ingredient of toxicological concern.

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)]**

   The technical report (TR) does not identify any detrimental chemical interactions with other materials used in organic farming systems. It is currently approved for use with no restrictions as an ingredient in organic foods.

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

   The TR states "Sodium citrate is of low acute toxicity to freshwater fish, daphnia, algae and marine species. Similarly, sodium citrate has no obvious toxic potential against protozoans and many species or strains of bacteria including activated sludge micro-organisms (EPA, 1992; OECD, 2001)."

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

   The production of sodium citrate (biological fermentation process) results in waste by-products. The agricultural byproducts can be composted, and the acidic wastewater can be treated through a variety of wastewater treatment systems. No toxic environmental contamination was noted 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)].**
   As petitioned, there are no effects expected on human health, the TR states any remainder of the sodium citrate in the blood meal is expected to become a metabolite of soil bacteria. Organic farmers or consumers would not be in contact with sodium citrate. Workers in processing facilities might experience irritation to the eyes and skin when handling sodium citrate.

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

   The TR did not note any negative effects associated with the low concentration of sodium citrate found in blood meal used as a fertility input in organic production. The many benefits of blood meal as a crop fertilizer were noted.

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

   The TR states citric acid is found naturally in soil and water, and sodium citrate readily degrades when in contact with soil microorganisms. There is low toxicity to aquatic environments, and no negative effects upon terrestrial ecosystems and animals.

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)]**

   The Crops Subcommittee asked for further detail to explore alternatives to the use of this synthetic in the production of blood meal. The TR notes that none of the mechanical methods were practical for spray drying since this process involves spraying a fine, uniform mist and any coagulation interferes with the process. However, there are blood meal products that do not use sodium citrate, but they may not have the same uniformity or other beneficial characteristics of products that are spray dried.

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 discussed this issue in detail and found sodium citrate to be compatible with a system of sustainable agriculture. It is currently approved for use with no restrictions as an ingredient in organic foods. The TR states citric acid is found naturally in soil and water, and sodium citrate readily degrades when in contact with soil microorganisms. The TR did not note any negative effects associated with the low concentration of sodium citrate found in blood meal used as a fertility input in organic production. The many benefits of blood meal as a crop fertilizer were noted and sodium citrate is an important aid in the manufacture of blood meal.

Classification Motion:

Motion to classify sodium citrate as a synthetic substance.
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

National List Motion:

Motion to add sodium citrate to §205.601 with the annotation "For use as an anticoagulant in the production of blood meal."
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOP August 22, 2018

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Natamycin
June 19, 2018

Summary of Petition:

A petition was received in September 2016 to classify natamycin as an allowed nonsynthetic substance in organic crop production. The intention of the petition is to allow natamycin to be used as a post-harvest treatment on various food commodities to control fungal diseases. This product has been approved by the EPA for a wide range of uses where it prevents the germination of many types of fungal spores on mushrooms, pineapples, citrus, pome and stone fruits, cherries, avocados, kiwi, mango and pomegranate. Natamycin is described as a nonsynthetic pesticide produced by a fermentation of a naturally occurring microorganism.

Summary of Review:

The technical review (TR) requested by the Crops Subcommittee detailed the manufacturing process, the application process and use of this material in post-harvest handling. Natamycin is considered a fungistat, since it inhibits the growth of fungus, however, it can also be referred to as a fungicide, which has a broader definition which includes fungistats. Natamycin is used in nonorganic beverages, sausage, cheese and bread products to control the growth of molds and yeasts and is approved by the FDA as a direct food additive.

Natamycin is used in livestock feeds to retard the growth of the fungus that can cause mycotoxins, as well as an additive to broiler chicken water. For livestock health, it is used to suppress a variety of fungal livestock eye infections as well as ringworm, candidosis and nasal aspergillosis.

Natamycin is also used to control fungal eye, skin, mouth and vaginal conditions in humans and is therefore a useful antimicrobial for human health. There is a research study that shows concern that when natamycin is incorporated into food, such as yogurt, resistance to natamycin can occur by *Candida spp.* which have colonized the intestinal tracts of patients following natamycin treatment of fungal infections.

Natamycin is ineffective against bacteria, and regulatory definitions from FDA and USDA would classify natamycin as an antimicrobial instead of an antibiotic. The EPA, however, has a broader definition of antibiotic that would encompass natamycin (TR lines 301-332).

In 2007, natamycin was considered by the NOSB Handling Subcommittee for placement on the National List (NL) at §205.605(b) as an approved synthetic for use on baked goods to delay the growth of mold. The NOSB did not officially classify this material as a nonsynthetic or synthetic, nor did they allow this material to be used in or on organic foods.

While the petition is specifically requesting natamycin be approved for placement on the crops section of the NL for post-harvest use, if the NOSB determines natamycin to be nonsynthetic, it could then be used in a wide range of crops from mushrooms to citrus, and in organic livestock production as well. Nonsynthetic materials that are not agricultural must be listed as approved for organic processed foods on §205.605(a), so this determination as a nonsynthetic would not automatically result in its approval for use in organic handling.

During the subcommittee's review, we reached out to members of the farming, wholesale and retail produce organic community. We were not told that this product is needed from our small sample, and we look forward to hearing more comments from the public. Some natural products retailers do not allow the use of natamycin on cheese or dairy products they sell in their stores. Natamycin would appear as a "mold inhibitor" on the retail label of the product. Since natamycin is being petitioned as a post-harvest handling material, its use would not be made known to the wholesalers, retailers or consumers of the product, since there would not be a requirement, nor a method, to label these fruits, mushrooms etc.

There was concern by the Subcommittee that this material is widely used in human health, and while cases of resistance to natamycin are not currently a human health issue, this material has only been used widely in dairy products for 10 years and less than 5 years in produce.

Specific Uses of the Substance:

The TR states the commercial applications of crop, livestock and food production can be grouped into three basic categories: 1) as an agricultural fungicide, either pre- or post-harvest, 2) as a livestock medication, and 3) as a preservative in processed foods. Natamycin is used for its antifungal properties over a wide range of pH environments and fungi. Natamycin is used most commonly to protect the surfaces of cheese and sausage against fungal development and can be incorporated into other dairy products such as yogurt, sour cream and cottage cheese. It has also been used on salad mixes to control mold. The petitioner is specifically requesting it be allowed for use as a post-harvest handling material for fruits of many types. There are no tolerances or wait periods set after use of natamycin for these fruits, with natamycin first approved for use on fruits in 2016. There are wait periods between use and sale for mushrooms and maximum levels set when incorporated into dairy products.

Approved Legal Uses of the Substance:

Canada allows biological organisms for use as crop production aids. While natamycin is not a biological organism, microbial organisms such as spinosad are permitted under this allowance and the technical review states that since natamycin is a microbial product similar to spinosad, it might be allowed under Canadian Organic Standards. Codex has a similar allowance for microbials in organic production, but only when recognized by the certification body. Natamycin is not specifically recognized as allowed under Codex. The European Union, Japan and IFOAM do not list natamycin as an approved substance on their approved materials lists. As listed above, natamycin is used in post-harvest handling for mushrooms, salad mix and a wide range of fruits as well as in and on dairy products and sausage.

Action of the Substance:

The technical review goes into detail on the action of natamycin. Natamycin interferes with the fungi's normal cell membrane function by specifically blocking ergosterol, which aids fungal cells to transfer nutrients such as glucose and amino acids through their membranes. It is most effective on fungal spores rather than mature tissue. In commercial use, it is typically added to water or wax, the type of wax was not noted in the TR.

Manufacture:

Natamycin is biosynthesized through submerged aerobic fermentation, and then extracted and purified in a post-fermentation broth through the use of solvents, pH adjustment or physical means.

There are a variety of possible other ingredients in formulations where natamycin is the active substance, to aid in its commercial use, they include:

Thickening / bulking agents: xanthan gum[iv], carrageenan[iv], methylcellulose[iv], gum Arabic[iv].
Surfactants: sodium dodecyl sulfate[iv]
Buffers: citric acid[iv], mono[iv]-, di[iv]-, tri-sodium salts of citric acid[iv], mono[iv] and disodium salts of phosphoric acid[iv]

Fillers: lactose[iv] or cellulose[iv]

Carriers: Fumed silica[iv], microcrystalline cellulose powder[iv].

pH adjustors: hydrogen chloride[iv], sulfuric acid[iv], citric acid[iv], lactic acid[iv], sodium hydroxide[iv], potassium hydroxide[iv], ammonium hydroxide[iv].

Solvents: food grade solvent such as ethanol[iv] if for agricultural or food use. Other uses include many other solvents.

Anionic surfactants: polyelectrolyte polymers (such as sodium lignosulfonate[iv]), modified styrene acrylic polymers[N], polyoxyethylene sorbitan trioleates[iv], polyoxyethylene sorbitol hexaoleates[iv], dioctyl sodium sulfosuccinate[iv], sodium salts of naphthalene sulfonates[iii].
Diluents: glycerol[iv], hexylene glycol[iii], dipropylene glycol[iii], polyethylene glycol[iv].
Preservatives: benzoates[N] and potassium sorbate[iv].
Antifoams: silicone based antifoam agents[N], vegetable oils[N], acetylenic glycols[N], and high molecular weight adducts of propylene oxide[N].
Antifreeze: ethylene glycol[iii], 1,2-propylene glycol[iv], 1,3-propylene glycol[N], 1,2-butanediol[N], 1,3-butanediol[iii], 1,4-butanediol[iii], 1,4-pentanediol[N], 3-methyl-1,5-pentanediol[N], 2,3-dimethyl-2,3-butanediol[N], trimethylolpropane[iii], mannitol[iii], sorbitol[iv], glycerol[iv], pentaerythritol[iii], 1,4-cyclohexanedimethanol[N], xylenol[N], bisphenol A[N].

Miscellaneous: the patent application describes applying the product with an additional coating wax.

pH adjustors: hydrogen chloride[iv], benzoic acid[iv], propionic acid[iv], sorbic acid[iv], acetic acid[iv], lactic acid[iv], or sodium hydroxide[iv].
Carriers: fumed silica[iv].
Solvents: C1-C4 alcohols[N], glacial acetic acid[iv].
Surfactants: sodium lauryl sulfate[iv], dioctyl sulfosuccinate[iv], calcium chloride[iv], non-ionic surfactants[N].

Thickening / bulking agents: hydroxypropylmethylcellulose [iv] (HPMC), carrageenan[iv], methylcellulose[iv], xanthan gum[iv], gellan gum[iv], gum Arabic[iv]

Emulsifier: lecithin[iv].

Key: * = Patent application only, not granted; iii = Present on 2004 EPA List 3; iv = Present on 2004 EPA List 4; N = Not able to confirm 2004 EPA list status.

Category 1: Classification

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

   The Technical review states during the biosynthesis, extraction and purification of natamycin, the chemical makeup of the material is not changed from the original substance. The decision tree in NOP Guidance 5033-1 was used to evaluate whether or not this material is synthetic. Details are present in the TR.

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?

    If the NOSB determines natamycin to be nonsynthetic, there is no reason to determine a specific approved category for synthetics. Natamycin is naturally produced by bacteria, it is not listed as an inert by the EPA.

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)]**
Chemical interactions were not known beyond the issues with possible solvents used during manufacture. The TR did not state there was risk of detrimental chemical interactions with other materials used in organic farming systems.

2. **What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]**
The TR states due to its proposed use in post-harvest handling, it is not expected there would be any significant effect on the agro-ecosystem. It would not have any direct effect on soil biological life, earthworms, mites or other macro or micro soil organisms including mycorrhizal fungi, since it is not applied to soil. The EU Food Safety Authority, had some concerns about resistance to natamycin over time, but in ten years of use, none has yet been found. However, there has been some evidence that natamycin resistance can be caused under laboratory conditions.

3. **Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**
The technical review did not find any literature from the EPA, FDA, the National Institute of Environmental Health, the European Environmental Agency or other academic or independent papers addressing the issue of environmental contamination caused by the production, use, misuse or disposal of natamycin. The TR discusses possible effects that might occur through the production and use stream, through manufacture waste water or overuse, but the TR's conclusion states it is unlikely to affect the surrounding environment in a significant way. There could be negative effects on beneficial fungi if applied on non-approved agricultural crops.

4. **Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**
At this time, the EPA determines there is a reasonable certainty that no harm will result from exposure to natamycin residues when used according to product labeling. Since bacteria is the main component of intestinal microflora in the human gut, and natamycin does not have a negative effect on bacteria, some studies have determined minimal to no negative impact when natamycin is ingested. There are other studies that show concern about the potential risk for development of fungal resistance to natamycin, or to other materials in its polyene class of

fungistats, by fungi that are problematic in human health. Natamycin is used by the medical community to treat eye, mucous membrane and skin issues by addressing fungal and yeast problems.

The use of natamycin as an antifungal agent can suppress mycotoxins that contaminate food and could be seen as beneficial to human health through this action.

The product label for natamycin to be used as an agricultural fungicide includes health warnings for the workers indicating that the product is harmful if swallowed and can cause moderate eye irritation as well as other warnings to use protective gear and activities. The TR states these warnings are probably due to the presence of other undisclosed ingredients in the formulation of the brand name products.

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)]**
   Natamycin is being petitioned for use as a post-harvest handling material, and this use would not result in direct contact in any significant way with the agroecosystem. However, if the material is found to be nonsynthetic, it could be used in field situations in the future, if the EPA expands its biopesticide approval to this use.

6. **Are there any adverse impacts on biodiversity? (§205.200)**
   As discussed above, its limited use as a post-harvest handling material, does not result in its use in field or other situations where it may affect biodiversity in the environment. As a fungistat, it could negatively affect beneficial soil fungi if used or disposed of improperly, or if in the future it is approved as a fungicide for field applications. It is unknown if there are any negative effects on various types of wildlife or sensitive ecosystems, although it does not seem likely.

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)]**
   The technical review describes numerous nonsynthetic and approved–for-organic-production synthetic materials, as well as hygienic activities, that can be used to control fungi in both mushroom production and post-harvest handling. Some of these are experimental, others are commonly used. It could be argued that natamycin would add another tool to the toolbox, but the case is not made that it is essential for the production of organic crops.

2. **In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**
   If determined to be a nonsynthetic, natamycin could be a useful tool in controlling fungal problems in a wide variety of human and livestock foods. However, the wide use of this material to address human health issues, brings pause to the Crops Subcommittee, when considering this material for use in or on organic foods. In 2007, the NOSB did not approve this material for use on organic foods, based upon similar concerns. With other alternatives available and in use, the Subcommittee views this material as non-essential. Even if there is a just a small risk that use of this material on organic foods could result in resistant fungi or yeasts that would render natamycin no longer effective in a human or livestock medical condition, the Subcommittee sees this risk as incompatible with a system of sustainable agriculture.

Classification Motion:
Motion to classify natamycin as a nonsynthetic substance.
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

National List Motion:
Motion to add natamycin at §205.602 - nonsynthetic substances prohibited for use in organic crop production
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOP August 22, 2018

National Organic Standards Board
Crops Subcommittee Proposal
Strengthening the Organic Seed Guidance October 2018
August 21, 2018

Introduction and Background

The planting of organic seed/planting stock is required under the USDA organic regulations, unless these items are not commercially available. Organic seed/planting stock use provides organic producers numerous benefits including varietal characteristics specifically bred for organic production systems in their region and soil type as well as building a seed/planting stock industry that is focused upon the needs of organic farmers. Organic seed/planting stock breeders focus on developing varieties to provide high quality crops to meet yield requirements as well as the unique needs of the diverse organic marketplace. Seed/planting stock grown using organically approved inputs and within an organic management system, provide resiliency to organic growers by protecting and expanding genetic resources as well as economic opportunities when adding seed/planting stock production to their farm's cropping options. Increasing the use of organic seed/planting stock sets the stage for a future vibrant domestic and international organic agricultural sector by enhancing a foundational area of organic crop production, seeds/planting stock.

The organic community has repeatedly noted that progress towards full adoption of organically grown seed/planting stock in organic systems is not as rapid as hoped. The NOSB provided recommendations to the NOP in 2005 and 2008 focused upon increasing the use of organic seed. In 2011 and 2013, the NOP has addressed this issue with draft and final guidance. While organic seed availability continues to improve, there has been inconsistent progress in the proportion of organic seed in use by many growers. The NOSB circulated discussion documents and draft proposals in 2016 and 2017 to address the issue. The Board received significant public comment on these documents, which the Crops Subcommittee then incorporated into a final proposal. This current proposal strives to incorporate the points made in previous NOSB recommendations along with the public comment into a practical proposal that the National Organic Program can then use to update the 2013 organic seed guidance document.

The goal of the NOSB would be to achieve full compliance with §205.204(a) "*The producer must use organically grown seeds, seedlings and planting stock".* It is understood that the organic seed industry is not currently robust enough to meet every organic grower's needs, however, there is also some concern that the allowance to not use organic seed if not "commercially available", leads some producers to seek out nonorganic seed due to lower price, unfamiliarity with organic seed varieties, social or cultural pressures and more. The availability of organic planting stock, is growing even slower than the availability of organic seed, and offers a great opportunity to perennial crop breeders, as the market becomes more robust. This proposal seeks to address the barriers to adoption of organic seed/planting stock use and to aid the NOP to set a path to increased organic use in the coming years, through improved guidance on this subject.

A fall 2018 companion proposal, addressing the genetic contamination by GMOs of seed planted on organic land, will address that issue separately. Farmers growing crops for the organic marketplace take on an extra risk if they are unaware of the GMO contamination of the seed they plant, and may grow their crop organically for the season, only to have it rejected by the buyer at harvest due to the percentage of contamination that had been present in the seed they used. The proposal addressing

GMO contamination of seed planted on organic land, proposes a pilot project using transparency based upon specific testing protocols, to provide growers the information necessary to make informed choices for seed they plant on organic land.

This NOSB proposal lists improvements to the practices listed within the current NOP guidance 5029. These practices are requested of both certified entities and their certification agencies, and were developed to result in more uniform compliance to §205.204(a). The implementation of these practices is not anticipated to have negative economic impact on the operations, other than a few additional farm activities and increased documentation that would need to be maintained.

Relevant Areas of the Rule and Guidance

From the NOP Rule:

§205.2 Terms defined

Commercial availability. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Planting stock. Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

§205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

.....

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except,* That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except,* That, organically produced seed must be used for the production of edible sprouts;

Excerpts from the **Guidance on Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production** published March 4, 2013 (NOP 5029).

4. Policy

Producers should develop and follow procedures for procuring organic seeds, annual seedlings, and planting stock and maintain adequate records as evidence of these practices in their organic system plan (OSP).

4.1 Sourcing of Seeds, Annual Seedlings, and Planting Stock

4.1.1 Certified operations must use organic seed, annual seedlings, and planting stock in accordance with the requirements at § 205.204.

4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available.

a. Commercial availability is defined at § 205.2 and refers to the ability to obtain a production input, in this case seed or planting stock, in an appropriate form, quality, or quantity to fulfill an essential function in organic production. For the purposes of this exception, an "equivalent variety" is a variety of the same "type" (e.g. head lettuce types versus leaf lettuce types) or has similar agronomic or marketing characteristics needed to meet site-specific requirements for an operation. These characteristics may include, but are not limited to: number of days until harvest; color, flavor, moisture, chemical, or nutrient profiles of the variety of the harvested crop; vigor or yield of harvested crop; regional adaptation, disease and pest resistance, or the plant's utility in a crop rotation.

b. Price cannot be a consideration for determination of commercial availability.

4.1.3 The following considerations could be acceptable to justify use of non-organic seeds and planting stock as not commercially available. These considerations must be described by the operation in their organic system plan (OSP), pursuant to § 205.201(a)(2), and approved by the certifying agent.

a. Form Considerations: Examples of forms may include, but are not limited to, treated or non-treated seeds or planting stock, use of pelleted seed, or use of bare root nursery stock or container plants.

b. Quality Considerations: Examples may include, but are not limited to, germination rate of the seed; presence of weed seeds in the seed mix; shelf life and stability of the seeds; and disease and pest resistance.

c. Quantity Considerations: Producers may provide evidence that quantities are not available in sufficiently large or small amounts given the scale of the operation.

4.1.4 For certified operations producing edible sprouts, there is no exception to the requirement to use organic seed, as stated at § 205.204(a)(1).

4.1.5 Certified operations may use non-organic annual seedlings to produce an organic crop only when a temporary variance has been granted by the AMS Administrator in accordance with § 205.290(a)(2) due to an extreme weather event or business disruption beyond the control of the producer (§ 205.204(a)(3)).

4.1.6 Use of non-organic planting stock to produce organic crops is subject to commercial availability as per § 205.204(a)(1). If planting stock is from a non-organic source and is used to produce perennial crops, then that *planting stock* may be sold, labeled or represented as organic planting stock after 12 months of organic management (§ 205.204(a)(4)).

4.2 Recordkeeping for Organic Producers

4.2.1 The following records should be maintained by organic producers:

a. A list of all seed and planting stock, indicating any non-organic seeds or stock used, and the justification for their use including lack of equivalent variety, form, quality or quantity considerations. Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.

b. The search and procurement methods used to source organic seed and planting stock varieties, including:

1. Evidence of efforts made to source organic seed, including documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. Sources should include companies that offer organic seeds and planting stock.

2. Records may include, but are not limited to: letters, faxes, email correspondence, and phone logs from seed suppliers and companies; seed catalogs; searches of organic seed databases; receipts; receiving documents, invoices, and inventory control documents.

4.4 Role of Certifying Agents

4.4.1 Certifying agents must verify the procedures that certified operations utilize to obtain and plant organic varieties suitable for their operations as part of their annual review of the OSP.

4.4.2 Certifying agents must review substances and inputs used to treat seeds and planting stock for compliance with the USDA organic regulations.

4.4.3 Certifying agents shall verify the commercial availability requirements on an annual basis, in their review of the OSP, pursuant to § 205.402(a)(1).

4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years.

DISCUSSION

This proposal will discuss the previous proposal's recommendations, the public comments we received, the crops subcommittee response to those comments, and current recommendations.

Proposals ***(all proposed text from the previous recommendation is in bold/italic)****, all new text in* **bold/underline.**

1. To amend the National Organic Regulations §205.204 Organic seed and planting stock practice standard as follows:

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except,* That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except,* That, organically produced seed must be used for the production of edible sprouts;

(i) ***Improvement in sourcing and use of organic seed/planting stock must be demonstrated every year until full compliance with (a) is achieved.***

Public Comment and Subcommittee Response:

There were both positive and negative comments to this proposed rule change. While all commenters agreed with the premise that producers should be increasing their use of organic seed where appropriate, from year to year, there was concern by some that this was too prescriptive to place in the regulations. Issues raised included the possible unintended consequence of narrowing the genetic diversity of seed grown on organic land, which brings its own share of negative consequences from lowered yields, susceptibility to disease, and lowered access to niche markets. Those in favor of this proposal believed this statement was the necessary strong incentive needed to bring organic producers into full compliance with the organic seed and planting stock usage requirement.

Since the use of nonorganic seed is only allowed when the producer can prove the organic seed is not "commercially available", the crops subcommittee feels improvement to the interpretation and enforcement of what meets this allowance is a more appropriate area to address this issue. An important aspect of proving the lack of commercial availability includes a robust search. Operators are not mandated to use lower quality or seeds with unwanted characteristics, but they must search for organic seed that meets their farm's needs, and improvement in that search can be quantified. The guidance below does not require any specific benchmarks, and is sufficiently open ended to allow for farmers to use nonorganic seeds as long as they demonstrate their organic seed search is valid and improving. Therefore, this previous recommendation is being modified with this wording.

CURRENT RECOMMENDATION:

(i) Improvement in searching, sourcing and use of organic seed must be demonstrated every year with the goal of using only organic seed and planting stock.

2. Changes to NOP 5029 Guidance
The Guidance for Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production should be amended as follows:

2a.
5029 -4. Policy
Producers should develop and follow procedures for procuring organic seeds, annual seedlings, and planting stock and maintain adequate records as evidence of these practices in their organic system plan (OSP). Producers must also provide clear documentation regarding the inputs and materials used during crop production (as required at § 205.201(a)(2)). ***Producers must prevent and avoid contamination from excluded methods in seed of at-risk crops (corn, soybeans, canola, alfalfa, beets, chard, cotton, rice, and summer squash).*** Certifying agents must assess procedures and documentation of certified production and handling operations as they source seeds, annual seedlings, and planting stock on an annual basis. Each of these concepts is described in more detail below.

<u>Public Comment and Subcommittee Response:</u>

Another fall 2018 proposal addresses GMO contamination of seed grown on organic land. There were many negative public comments on this previous recommendation, stating that producers cannot be responsible for the genetic contamination of the organic seed they purchase, and all nonorganic seed is required to have documentation that it is not a GMO seed. Therefore, this previous recommendation is being withdrawn from this proposal, with no addition of wording to this section.

4.1 Sourcing of Seeds

2b.
4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available, ***and the conventional replacement variety can be documented as being produced without the use of excluded methods.***

<u>Public Comment and Subcommittee Response:</u>

All certification agency commenters stated this is already being required of their organic operators, and it is unnecessary to add this statement to current guidance. The issue of contamination of organic seed with genetically engineered germplasm, is being addressed in a separate proposal, which will require transparency in the level of genetic contamination by excluded methods on corn, as a pilot project, with the longer term plan to require this transparency of all crops where there is a risk of GMO contamination. The statement "not produced through genetic engineering" is many times made by a seed supplier, but this does not provide information if the seed was inadvertently contaminated and still contains GMO traits in small or even large quantities. Therefore, this previous recommendation is being modified to include this option below.

CURRENT RECOMMENDATION:

4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available. <u>**When there is a risk of excluded method contamination in seed production, the certified operation may ask the seed**</u>

<u>supplier for a non-GMO level of purity assurance, and communicate this information to their organic certification agency.</u>

2c.

<u>*§4.1.2(c)*</u> ***On-farm variety trials of organic seed may be used by producers to evaluate and document equivalency and quality of varieties that are available.. Trials are encouraged and records of results should be kept to show inspectors, but the trials are not mandatory***.

<u>Public Comment and Subcommittee Response:</u>

There was agreement among most commenters that performing trials on organic seed helps an operator determine if they are "equivalent" to the nonorganic seed that they are currently using. Many organic seeds, especially in the commodity crop sector, are different variety numbers, bred by organic seed breeders and sold by organic seed companies. These organic seeds may not be familiar to the organic grower, and operators are typically reticent to plant large acreages of seeds they do not know to be acceptable for their soil type, climate, and growing systems. In addition to the original proposal above, the sentence in bold/italic/underlined is added to the previous proposal, as an improvement. Both producers and certifiers need to understand what characteristics are desired for that farm operation, and if the field trials were performed with sufficient rigor to determine equivalency or not. Many commenters stated the following: the trials are not mandatory", are only guidance not mandated regulatory language, and should be removed. The Subcommittee kept this statement, since it is recommended it be placed in a NOP guidance document and not in the regulation. While most comments pertained to the use of organic seed, the recommendation below covers planting stock as well, and producers planting perennial crops should also be encouraged to trial organic cultivars.

CURRENT RECOMMENDATION:

<u>*§4.1.2(c)*</u> **<u>On-farm variety trials of organic seed/planting stock may be used by producers to evaluate and document organic variety/cultivar equivalency to the nonorganic item in use. Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.</u>**

<u>*§4.1.2(d)*</u> **<u>Documentation of these trials must be available at the annual inspection. This documentation should include which seed characteristics are desired, and be based upon the varietal benefits of the current nonorganic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the nonorganic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.</u>**

2d.

4.1.3 The following considerations could be acceptable to justify use of non-organic seeds.....

> ***d. Contamination from GMO consideration: non-organic seed can be used if organic seed cannot be sourced because of GMO contamination.***

<u>Public Comment and Subcommittee Response:</u>

Many commenters were mute on this discussion, although some did state there was not enough information on GMO contamination to enforce this guidance at the certification level. The fall 2018 proposal on genetic integrity of seed planted on organic land, will require testing of corn as a pilot crop, with the expectation that testing will be expanded to all crops with a commercial GMO presence in the marketplace, sometime in the future. The proposal also requires transparency on the seed tag, detailing the level of purity from genetic contamination. Since the definition of commercial availability does not include any mention of GMO contamination, the proposal recommends this be added to the NOP guidance 5029 in the section cited below, to reflect this allowance. Each operation, depending on their farm's goals and markets, will have different levels of acceptability when assessing GMO contamination. For some crops, it is very difficult to obtain seed with a zero detectable level of contamination.

CURRENT RECOMMENDATION:

> **4.1.3 d. Contamination from GMO consideration: non-organic seed can be used if there is no organic seed available of equivalent variety with the desired level of purity from GMO contamination.**

3. **4.2 Recordkeeping for Organic Producers**

3a.

4.2.1 The following records should be maintained by organic producers:

> a. A list of all seed and planting stock, indicating any non-organic seeds or stock used, and the justification for their use including lack of equivalent variety, form, quality or quantity considerations*. Justification for use of varieties needs to be specific to each variety on the list and which issue (form, quality, quantity, or equivalence) is the reason*. Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.

Public Comment and Subcommittee Response:

Numerous certification agencies and producers provided negative comments about this proposal, stating that it would be a significant burden to track each nonorganic seed and justify its use, especially for diverse vegetable operations,. Many noted the subsequent improvement to section 4.2.1 b, noting that it provides more flexibility and quantifiable methods of tracking the reasons nonorganic seed is being used. Therefore, this statement is being removed from this proposal.

3b.

> b. The search and procurement methods used to source organic seed and planting stock varieties, including:
>
> 1. Evidence of efforts made to source organic seed, including
>
> > *i.* documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. ***Five sources must be contacted for seed of at-risk crops.***

Public Comment and Subcommittee Response:

There were many comments on this section, with some requesting this be extended to all crops, and others concerned that there was not a clear definition of "at-risk" crops. Many supported the increased number of sources to be contacted for organic seeds. With many more organic seeds being offered by a wide range of suppliers locally and nationally, it does not appear to be a burden to require a larger number of suppliers be contacted. Commercial availability is not limited by geographic region, nor by price.

CURRENT RECOMMENDATION:

1. Evidence of efforts made to source **organic seed/planting stock**, including
   i. **At least five documented sources must be contacted for seed/planting stock of all crops when this number of sources is available for an equivalent variety or cultivar.**

3c.

i. Sources should include companies that offer organic seeds and planting stock. ***Such sources should provide evidence of their organic certification (if relevant), ability to source organic seed, and specific varieties sourced every year.***

Public Comment and Subcommittee Discussion

Many certifiers and producers did not approve of this addition, stating it was a burden on producers, and difficult to assess if a specific seed broker is performing a valid seed or planting stock search. However, the wording is being strengthened to make it clear that the search must include companies that carry organic products, to be considered valid. Therefore, this change is recommended.

CURRENT RECOMMENDATION:

***ii.* Sources must include companies that offer organic seeds and planting stock.**

3d.

iii. Failure to demonstrate improvement in sourcing organic seed over time may result in additional seed sources being required or additional steps taken to procure organic seed.

Public Comment and Subcommittee Discussion

Most commenters were in agreement with this statement, as it requires continual improvement over time, and provides flexibility for the certifier to assess when there may be additional requirements based on each operations activities and situation. Therefore, it is included in this proposal as well.

CURRENT RECOMMENDATION:

iii. Failure to demonstrate improvement in sourcing organic seed/planting stock over time may result in additional seed/planting stock sources being required or additional steps taken to procure organic seed/planting stock, by the organic certifier.

3e.

3. If seed sourcing is carried out or mandated by the buyer of a contracted crop, the producer must keep records of the buyer's documentation on attempting to source organic seed as part of the producer's own Organic System Plan. Such documentation must be comparable to that required of a producer who sources their own seed.

Public Comment and Subcommittee Discussion

This statement addresses the issue in which a finished-crop buyer requires or supplies seed/planting stock that is not organic. Since use of organic seed is not part of a handler's organic system plan, it falls on the organic crop producer to verify and document there was a valid organic seed/planting stock search by the entity that supplied or mandated the use of a specific nonorganic variety. Most commenters agreed with this addition, and some noted this was an important issue that needed to be addressed. Therefore, this recommendation, with some modified wording, is present in this proposal.

CURRENT RECOMMENDATION:

3. If seed/planting stock is sourced or mandated by the buyer of a contracted crop, the producer must obtain sourcing information and documentation from the contracted buyer. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan. Such documentation must be comparable to that required of the producer who sources their own seed/planting stock.

4.4 Role of Certifying Agents

4a.

4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years

a. If sufficient progress is not demonstrated a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed.

Public Comment and Subcommittee Discussion

Most commenters felt this was a reasonable request, with certifiers stating they work with their operators to develop solutions that will result in greater use of organic seed and planting stock. No changes to this recommendation.

CURRENT RECOMMENDATION:

a. If sufficient progress is not demonstrated a certifying agent may ask for a corrective action plan including the following; additional research for seed sources, variety trials, or additional steps to procure organic seed.

4b.

b. Non-compliances should be issued for repeated lack of progress in sourcing organic seed over time*.*

Public Comment and Subcommittee Discussion

Most commenters agreed with this sentiment and many certifiers noted they are currently issuing noncompliances if they believe the organic operation is not taking effective action in sourcing organic seed/planting stock. Certifiers obtain information from many operations and have knowledge of what organic seed/planting stock is available and practical in their regions for many types of crop production. This provides the certifiers a unique perspective to determine if a producer is doing a valid search. Many commenters requested more detail in assessing a noncompliance. The recommendation below takes into account these public comments.

CURRENT RECOMMENDATION:

b. Non-compliances should be issued for repeated lack of progress in sourcing and using commercially available organic seed/planting stock over time. Judgement of a noncompliance can include, but is not limited to, the certifier's communication detailing commercially availability organic seed/planting stock and continued non-use by the farmer, the producer's lack of on-farm seed trials for judging equivalency between nonorganic seed and organic seed, and organic seed searches that do not include suppliers who carry organic seed.

4c.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of at-risk crops**.**

Public Comment and Subcommittee Discussion

The vast majority of commenters felt this was an important addition to the policy guidance. Producers who save their own seed, as well as sell seed to others, should include practices that specifically address GMO contamination prevention. There was some comment that the term "at-risk crops" was unclear, and so the wording below provides clarification.

CURRENT RECOMMENDATION:

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops at-risk of GMO contamination.

5. Other items

Public Comment and Subcommittee Discussion

Organic Seed/Planting Stock Database

Commenters supported the development of an organic seed and organic planting stock database, to be managed and maintained by the National Organic Program. Certifiers, suppliers, brokers and operators could all contribute information to this database, and having a link to this on the NOP website would be a service to all sectors of the organic community. The Crops Subcommittee strongly supports the development of this database and encourages the NOP to consider how this might be added to the organic integrity database or be developed separately.

Accredited Organic Certifier and Organic Inspector Training

Many commenters agreed with the previous proposal's assessment that both certification office staff and organic inspectors could benefit from further training on how to assess a valid organic seed/planting stock search. The above organic seed/planting stock database would be a very useful tool for certifiers to track the availability of organic sources and their offerings, as well as providing objective information to their certified operators. In-person and webinar trainings with knowledgeable certification personnel as well as NOP staff, should be developed to provide useful tools and/or checklists to aid in consistent review of a valid organic seed or planting stock search. Certifiers are encouraged to share the practical activities and documentation they require with other certification agencies and inspectors. Training of certification personnel has been recognized as an important aspect of preventing fraud in the organic marketplace, and information on organic varietal sourcing and documentation could be added to the training opportunities being explored for fraud prevention.

Crops Subcommittee Proposal:

To amend the National Organic Regulations §205.204 Organic seed and planting stock practice standard as follows (in bold):

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except,* That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except,* That, organically produced seed must be used for the production of edible sprouts;

(i) Improvement in searching, sourcing, and use of organic seed/planting stock must be demonstrated every year with the goal of achieving full compliance in the use of only organic seed/planting stock.

<u>**To Amend NOP Guidance 5029 – changes in bold**</u>

4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available. **When there is a risk of excluded-method contamination in seed production, the certified operation may ask the seed supplier for a non-GMO level of purity assurance**, **and communicate this information to their organic certification agency.**

§4.1.2(c) On-farm variety trials of organic seed/planting stock may be used by producers to evaluate and document organic variety/cultivar equivalency to the nonorganic item in use. Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.

§4.1.2(d) Documentation of these trials must be available at the annual inspection. This documentation should include which seed characteristics are desired, and be based upon the varietal

benefits of the current nonorganic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the nonorganic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.
§4.1.3 d. Contamination from GMO Consideration: non-organic seed can be used if there is no organic seed available of equivalent variety with the desired level of purity from GMO contamination.

§4.2.1 b

1. Evidence of efforts made to source **organic seed/planting stock**, including
    - *i.* **At least five documented sources must be contacted for seed/planting stock of all crops when this number of sources is available for an equivalent variety or cultivar.**
    - *ii.* **Sources must include companies that offer organic seeds and planting stock.**
    - *iii.* **Failure to demonstrate improvement in sourcing organic seed/planting stock over time may result in additional seed sources being required or additional steps taken to procure organic seed/planting stock, by the organic certifier.**

3. If seed/planting stock is sourced or mandated by the buyer of a contracted crop, the producer must obtain sourcing information and documentation from the contracted buyer. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan. Such documentation must be comparable to that required of the producer who sources their own seed/planting stock.

4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years

a. If sufficient progress is not demonstrated a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed.
b. Non-compliances should be issued for repeated lack of progress in sourcing and using commercially available organic seed/planting stock over time. Judgement of a noncompliance can include, but is not limited to, the certifier's communication detailing commercially availability organic seed/planting stock and continued nonuse by the farmer, the producer's lack of on-farm seed trials for judging equivalency between nonorganic seed and organic seed, and organic seed searches that do not include suppliers who carry organic seed.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops at-risk of GMO contamination.

Motion to accept all additions as described in the proposal section above, to both the National Organic Program Regulation and the National Organic Program Guidance 5029.
Motion by: Harriet Behar
Seconded by: Dave Mortensen
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, August 21, 2018

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Ammonium Citrate and Ammonium Glycinate
August 7, 2018

Summary of Petitions for ammonium citrate and ammonium glycinate:

Alpha Chelates has petitioned for the inclusion of ammonium citrate and ammonium glycinate on the National List at §205.601 (synthetic substances allowed for use in organic crop production). These new petitions follow two petitions in 2016 of **ammonium citrate** and **ammonium glycinate** during which time the NOSB determined in its fall **2016 recommendation**[1] that alternatives exist, including lignin sulfonate (synthetic) and nonsynthetic substances. Also on file for these materials are four petition addendums; the **first addendum** was submitted in response to a request for additional information by the Crops Subcommittee in 2016; the **second addendum** was volunteered by the petitioner in 2016; the **third addendum** was volunteered by the petitioner in 2016. An **addendum to the new petition** was submitted in 2018.

Ammonium citrate and ammonium glycinate are used as chelating agents with inorganic metal micronutrients copper, iron, manganese, or zinc for high pH soils. Chelated micronutrients ("chelates") are used to supply micronutrients that are not readily available to plants in deficient soils. Ammonium citrate and ammonium glycinate are not being petitioned to be applied to crops alone but to serve as chelating agents in the formation of chelates.

During its 2016 review, the Board determined that there was insufficient information in the justification statement regarding the necessity of these materials for organic crop production. Chelates occur naturally in soils, so chelates, *per se*, are not incompatible with a system of sustainable agriculture; however, overreliance on synthetic materials is not compatible with a system of sustainable agriculture. The Subcommittee determined that there were insufficient grounds for adding these substances to the National List as there are alternatives available, and it was not clear that the permitted products already on the market are inadequate to meet farmers' needs.

The most recent re-petitions were submitted on the premise that "the technology concerning chelating agents and micronutrient chelates has been significantly misunderstood by [the] NOSB". Additionally, the new petition refers to the results of a field trial of wheat in high pH soil in Australia in which chelated micronutrients led to an increase in yield over unchelated micronutrients. A significant component of the original and second petitions is a case for clarifying the terms "chelate" and "chelating agent" (or "ligand") in the regulations and guidance. The petitioner requests that the NOP define which bases can be used to neutralize specific acids used to synthesize chelating-agent-salts. Additionally, the petitioner asks for "recognition that the species and strength of acid and base are needed for accurate and reproducible neutralization; hence the suitability for use of 'nature identical' acids and bases". Other clarification and revision appeals are explained in the second petition.

A Technical Report (TR) was not requested as part of the 2016 review; however, TRs have been solicited in response to this second application, both to review the petitioned materials and to investigate the broader issue of nomenclature and technical errors elaborated by the petitioner.

[1] The 2016 recommendation and all 2016 addendum links are to Ammonium Citrate, though an identical recommendation and complementary addendums were submitted for Ammonium Glycinate and can be found on the List of Petitioned Substances.

Questions:

1. Are these materials for which organic farmers have expressed a need? If so, please describe how these materials perform a function that the nonsynthetic and/or synthetic chelating agents already allowed do not.
2. Please provide evidence of the efficacy of these petitioned chelating agents over currently approved chelating agents.
3. Are other changes to the regulations appropriate to clarify which substances are allowed in the manufacture of chelated micronutrients?

Vote in Subcommittee

Motion to accept the ammonium citrate and ammonium glycinate petitioned material discussion document
Motion by: Emily Oakley
Seconded by: Dave Mortensen
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, August 7, 2018

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Calcium Acetate
August 21, 2018

Summary of Petition for Calcium acetate:

Calcium acetate is being petitioned for use as a plant micronutrient for the prevention of calcium deficiencies and as a product to help prevent sunscald. The petitioner notes that because calcium acetate is highly water soluble, it is immediately available for uptake by plants. Other forms of calcium may not become water soluble until exposed to soil microbes and/or acidic conditions. Lime, for instance, may take up to six months to become available for uptake by plants. Products that include calcium acetate coupled with less soluble forms of calcium could have an immediate impact and an "extended release" effect.

Calcium, in addition to being necessary for cell wall formation, also aids in the uptake of other micronutrients, producing healthier plants. Plants with strong cell walls produce fruits and vegetables with a longer shelf life and a greater resistance to pests. A deficit of calcium produces disease in many crops. Examples include hollow heart in potatoes and bitter pit in apples. Some plants, like peanuts and soybeans, produce fewer "pops" or empty spots in shells when grown with adequate calcium.

Calcium products such as gypsum, limestone, dolomite lime, and ground oyster shell flower can take up to six months to become available for uptake by crops. Gypsum and oyster shell flour frequently contain traces of heavy metals. Other calcium products, such as calcium chloride, must be applied in very small amounts when used as a foliar spray to avoid burning a crop. Calcium acetate does not have this issue or limitation. Calcium acetate can also reduce sunlight transmission and may be used over black plastic to reduce heat loading.

Calcium acetate is a calcium salt of acetic acid. It does occur naturally but is most often manufactured. Calcium acetate can be prepared by soaking calcium carbonate (found in eggshells or in common carbonate rocks, such as limestone or marble, or hydrated lime) in vinegar.

Questions:

1) Is another calcium material necessary for organic crop production?
2) Does this material have a unique mode of action that differentiates it from other calcium materials allowed for organic production?
3) Is there a need for a material to prevent sunscald in organic production?

Motion to accept the discussion document on calcium acetate
Motion by: Steve Ela
Seconded by: Eric Schwartz
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, August 21, 2018

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Paper Planting Pots
August 21, 2018

Summary of Petition for Paper Planting Pots

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, it has 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". 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)."*

In February 2018, the NOP notified all certifiers that paper chain transplanting 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 in the product. Further, the current allowance for paper on the National List does not extend to the use associated with paper pots.

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. There have also been synthetic fibers in small quantities in the paper pots, but these fibers are now being replaced by a natural hemp fiber. The petitioner and public comment at the Spring 2018 NOSB meeting stated this system is unique and necessary. The only alternative would be the much slower and more costly method of hand planting individual plants. The system is used for closely spaced crops such as onions, beets, baby salad, etc. The petition states that similar to newspaper, these pots decompose in the soil over time.

The petition states the TR on newspaper addresses the presence of adhesives 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. In addition, the petition states that in the manufacture of the paper, magnesium chloride and urea are used.

The Crops Subcommittee is considering a technical review request covering a variety of manufacturing processes for paper pots as a generic material.

Questions:

1. Is this material needed by organic producers, and why?
2. Are there alternatives to this material?
3. Are there risks to the environment or human health resulting from the use of this material?

Vote in Crops Subcommittee

Motion to accept the paper planting pots petitioned material discussion document
Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair, to transmit to NOSB, August 21, 2018