National Organic Standards Board Meeting
Renaissance Seattle Hotel 515 Madison Street Seattle, WA, 98104-1119
Courtyard Ballroom B Level
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National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Method Determinations April 2019
February 12, 2019

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. The 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. In Fall 2018, the NOSB recommended one technology be added to the list of methods that are not to be excluded in organic production.

Goals of this proposal/document

This proposal addresses three more items on the "To Be Determined" list found in the November 2016 discussion document. Using the NOSB's proposed improved definitions of excluded methods, the NOSB Materials Subcommittee has clarified what type of technologies used to cause transposons should be excluded methods in organic agriculture and what type of activity should not be excluded.

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 or cannot be used under the USDA organic seal.

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 an 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.

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	The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.	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	The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.	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		
Embryo rescue in plants		NO		IFOAM's 2018 position paper on Techniques in Organic Systems considers this technique compatible with organic systems.

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 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 tests or other methods will be developed over time to 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 that may have been used in production.

In the Fall 2018 discussion document, there were descriptions assigned to both cisgenesis and intragenesis. These descriptions are still valid, and in this document we would like to add the following to further clarify these two technologies. There is no further clarification for agroinfiltration proposed.

- Cisgenesis—The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.

- Intragenesis—The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.

The following methods will continue to be researched in future NOSB proposals.

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 be evaluated.
Cell Fusion within Plant Family		*TBD*		Subject of an NOP memo in 2013. 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.
Transposons		*TBD*		Produced from chemicals, ultraviolet radiation, or other synthetic activities considered to be a method of "induced mutagenesis"
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.

Transposons

- Transposons are jumping genes that can occur in nature and are responsible for mutations through mobile genetic elements. Transposon activity can be modified through stress or genetic engineering to increase mutation rates. 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.
- Transposons are responsible for mutations when moving around within a genome. Various forms of environmental stress, such as heat, cold or drought, as well as stress caused by chemicals or exposure to irradiation, can increase the movement of naturally occurring transposons which then results in higher mutation rates.
- Transposons can also be developed in a laboratory using in vitro nucleic acid techniques to then be introduced into plants or animals.
- IFOAM's 2018 position paper on Techniques in Organic Systems considers transposons caused by physical stress to be compatible with organic systems.
- Transposons, when produced from chemicals, ultraviolet radiation, or other synthetic methods, are considered to be a method of "induced mutagenesis". Further research and discussion are needed to determine if induced mutagenesis methods, both those that are random or targeted, should be considered excluded from organic production, or not.

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	1, 3, 4	Developed via use of in vitro nucleic acid techniques

The method below has been determined to **not** be an excluded method based upon the criteria listed above.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons		NO		Developed through environmental stress, such as heat, drought, or cold

The method below needs further review.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons		*TBD*		Produced from chemicals, ultraviolet radiation, or other synthetic activities considered to be a method of "induced mutagenesis"

Future Work on this Topic

The Materials Subcommittee has developed a discussion document for the April 2019 NOSB meeting to encourage public input on embryo transfer in animals and the various methods of induced mutagenesis.

Subcommittee Proposal

The NOSB recommends the NOP add the following to the table of excluded methods, in NOP excluded methods guidance.

1. **Transposons - Developed via use of in vitro nucleic acid techniques.**

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

2. **Transposons - Developed through environmental stress, such as heat, drought or cold**.

3. **Add these two definitions to the excluded methods terminology chart for Cisgenesis and Intragenesis**
   - Cisgenesis—The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.

   - Intragenesis—The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant, and arranged in sense or antisense orientation. In addition, the promoter, spacer and terminator may originate from a sexually compatible gene pool of the recipient plant.

Subcommittee Vote
Motion to accept the proposal on excluded methods determinations April 2019
Motion by: Harriet Behar
Second: Dave Mortensen
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Emily Oakley, Materials Subcommittee Chair, to transmit to NOSB February 13, 2019

National Organic Standards Board
Materials Subcommittee Excluded Methods Discussion Document
Induced Mutagenesis and Embryo Transfer in Livestock
February 12, 2019

SUMMARY

The Materials Subcommittee invites public comment on this discussion document to determine if induced mutagenesis and embryo transfer should be allowed or excluded from organic production. Induced mutagenesis can be accomplished through a variety of activities, with some possibly acceptable and some not. Embryo transfer in livestock, with its accompanying possible use of synthetic hormones and its by-pass of traditional breeding methods, presents its own challenges. The Materials Subcommittee invites the public to answer the questions posed at the end of this discussion document, as well as to present other issues that may not have been considered in the questions listed.

DEFINITIONS AND CRITERIA

Under the National Organic Program organic regulations, methods that employ genetic engineering techniques are excluded from use in organic production. The current regulation defines an excluded method as:

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.

In 2016 the NOSB recommended the following criteria be used to assess emerging technologies and determine if they should be excluded from organic production:

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 recommended the following methods be excluded from use in organic production:

- *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*

BACKGROUND

As the NOSB continues to work through the list of methods "to be determined" as excluded or not for organic production, the determinations become more difficult to categorize. The Materials Subcommittee seeks public comment to aid in understanding the technologies and how they might be determined using our current criteria describing genetic engineering methods.

Induced or Directed Mutagenesis

Mutations that suddenly occur in nature under natural conditions are known as spontaneous mutations. These are typically rare events. Spontaneous mutations result from a biological process, or from mutagenic agents present in the environment (i.e. cosmic rays, heat, starvation) that change the structure of DNA. That mutation can be an atypical recombination, an atypical segregation, a removal of an amino group from an amino acid, or serious damage to the DNA caused by the breaking of covalent bonds that release nucleic acid components guanine or adenine from DNA.

Induced mutations are the result of human interference and can be accomplished through physical agents, such as ultraviolet light, x-rays, heat, irradiation and/or chemical agents (i.e. mustard gas, ethylene amine, and others). Induced mutations can be both random and targeted through a variety of genetic engineering techniques. Epigenetics, where gene expression can be altered rather than an alteration of the genetic code itself, can be the result of induced mutagenesis. The various induced mutagenesis techniques that turn on or off genes or combinations of genes for a desired effect needs to be reviewed. Transposon, or jumping genes in which genes move from one location to another and

cause change to both the new location and the old location, can also be caused by induced mutagenesis. The changes found in spontaneous mutagenesis listed above can also be produced through induced mutagenesis.

Determining whether induced mutagenesis should be considered a genetically engineered plant (genetic engineering is referred to under the NOP regulations as an excluded method), was decided by the Court of Justice of the European Union on 25, July 2018. In short, the ruling determined that induced mutagenesis techniques, which make it possible to alter the genome of a living species without the insertion of foreign DNA, are to be considered genetically modified organisms. The decision did allow individual states within the EU to determine if older methods of mutagenesis, those that have been used conventionally, have a long safety record, and that did not include "in vitro" engineering techniques, might not be considered to be genetic engineering. According to Codex, all gene editing that is based upon invasive nucleic activity is considered genetic engineering or the product of modern biotechnology.

Embryo Transfer in Livestock

Embryo transfer in livestock is the process of removing one or more embryos from the reproductive tract of a donor female and transferring them to one or more recipient females. In order to accomplish this transfer, one or more of the following may occur:

- The embryo may have been produced in a laboratory using in vitro fertilization techniques.
- The embryo may have been produced in a laboratory using somatic cell cloning techniques.
- The donor female may have been treated with GnRH (Gonadotrophin-Releasing Hormone) that results in superovulation, producing numerous donor eggs instead of one or two, and those embryos were harvested from that female.
- The receiving female may have been treated with prostaglandin (brand name: Lutalyse) to synchronize estrus (heat) to improve the implantation success of the donated embryo.
- Collection and insemination of embryos is done through use of stylets or pipettes.
- Evaluation and short-term storage of embryos.
- Micro-manipulation and genetic testing of embryos.
- Freezing of embryos.

Embryo transfer in bovines was developed commercially in the 1970s and 1980s but has been performed experimentally since 1890 on many types of livestock. This technique is performed for a variety of reasons, including:

a. An animal has a biological or physical impediment to natural fertilization, such as scarring on the ovaries, which prevents the eggs from being released and fertilized.
b. The livestock producer seeks to improve their herd by focusing on the eggs and sperm of individuals that have desired characteristics.

Currently, some NOP accredited certifiers are allowing embryo transfer into organic cattle if the receiving animal was not treated with prostaglandin. The donor animal most likely had been treated with GnRH. There is some research detailing the short- and long-term effects of the use of both prostaglandin and GnRH in beef and dairy cows and their off-spring. Use of embryo transfer might be a way to accelerate the inclusion of desired traits into a herd, such as cows that produce A2A2 proteins in their milk or polled livestock (livestock that typically have horns, are born without horns), which lessens the need for the invasive procedure of dehorning on young animals.

DISCUSSION QUESTIONS

Induced or Directed Mutagenesis

1. Using the NOSB recommendation on the criteria to determine a technology as genetic engineering (listed above), please provide information on which technologies that result in induced mutagenesis could be considered an excluded method under organic production and why?
   These would include induced mutagenesis caused by irradiation, x-rays, heat, UV light, and a variety of chemicals.

2. Using the NOSB recommendation on the criteria to determine a technology as genetic engineering, please provide information on which technologies that result in induced mutagenesis could be considered not an excluded method under organic production and why?
   These would include induced mutagenesis caused by irradiation, x-rays, heat UV light, and a variety of chemicals.

3. Should the random or targeted aspects of induced mutagenesis be considered when determining if a technology should be excluded.?

4. How do epigenetic implications affect the determination of whether the method is to be excluded? Are there some types of epigenetic methods that could be allowed or not allowed?

5. Would there be any effects on currently accepted varieties, cultivars, or breeds if induced mutagenesis was determined to be excluded? Be specific.

6. Are there types of induced mutagenesis that are highly beneficial to organic production or highly problematic?

Embryo Transfer in Livestock

1. Should the use of hormones to stimulate egg production be allowed in donor animals?

2. Should the use of hormones to synchronize estrus in animals who will receive the embryo be allowed?

3. Are there concerns for the health of the adult animal or their offspring after the use or repeated use of these hormones?

4. Could the approval of this technology have any unintended consequences, such as the narrowing of the gene pool, due to widespread use of embryos from a narrow pool of egg and sperm donors in organic production?

5. Is embryo transfer a necessary method for organic livestock production?

Subcommittee Vote

Motion to accept the discussion document on induced mutagenesis and embryo transfer in livestock
Motion by: Harriet Behar
Seconded by: Dan Seitz
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, February 13, 2019

National Organic Standards Board
Materials Subcommittee Discussion Document
Marine Materials in Organic Crop Production
February 12, 2019

SUMMARY

At its Fall 2018 board meeting, the NOSB explored a means of addressing the environmental impact of harvesting marine algae[1] for use in organic crop production inputs through a proposed requirement that marine algae under §205.601 (j)(1) aquatic plant extracts and other nonsynthetic uses be certified organic. This discussion document highlights the public comments received, presents the various methods proposed, and puts forth additional discussion questions for stakeholders in anticipation of a fall 2019 proposal.

BACKGROUND

The Organic Foods Production Act National List criteria require, among other things, that materials not be harmful to the environment (7 USC 6517(c)). The NOSB has received extensive public testimony over the past several years regarding overharvesting of many marine algae species and the potential for contamination and harm to ecosystems. Stakeholders have agreed that organic agriculture should not contribute to this problem. The NOSB is exploring the best means of accounting for and minimizing the environmental impact of marine algae used in organic crop production inputs. This discussion document reviews the various methods that have been suggested to achieve that goal in hopes of identifying a proposed change to the standards that will be supported by a diverse organic community.

For detailed information on the relevant areas of the rule, please see the Material Subcommittee's Fall 2018 Discussion Document.

PUBLIC COMMENT[2]

A spectrum of written and oral public comments was received, from support for organic certification, to those stating that marine algae should not be harvested at all for use in organic crop inputs due to negative environmental effects, to those concerned about the feasibility of applying organic certification to a crop input. Despite the range of views, there was broad agreement on the importance of working on this issue.

Authority to Require Certification for an Ingredient in an Organic Crop Input:
Some commenters questioned the authority of the NOSB to require organic certification of a crop input ingredient. One commenter explained that inputs are not listed at §205.100 which outlines what must

[1] For the purposes of this document, the term "marine algae" is used to refer to aquatic plants, marine plants, seaweed, and marine vegetation.
[2] For a summary of public comments of NOSB documents on this topic prior to Fall 2018 and for a review of the 2016 Technical Report, please see the Materials Subcommittee's Fall 2018 Discussion Document. These cover issues of overharvesting, selective harvesting, and cultivation.

be certified. Another said that while they understood the positive intentions of the proposal, they opposed applying §205.207 to crop inputs as they understand that section to apply only to crop outputs.

Some worried about a domino effect that might result in requiring organic certification on a crop input ingredient. One stated:

> Marine materials harvested for use as an agricultural input should not be equated to the definition of a wild crop or an agricultural product when its purpose is not for human or livestock consumption. Requiring the certification of crop production materials that are not intended for human or livestock consumption sets a precedent for all agricultural inputs that are marine (or terrestrial) plant-based.

One commenter expressed the sentiment that "certification of inputs has been found to be outside of the scope of the NOP as established by OFPA". These commenters noted the proposed recommendation would require the certification of "inputs to an input". One commenter thought this would conflict with NOP's guidance that inputs cannot be certified. They asked if certification of the input's formulator would also be required or if it would be deemed sufficient to check the certification of the marine algae ingredient during a Materials Review Organization's review of a brand name product.

These concerns were answered in detail by another commenter:

> …Organic certification under the crop or wild crop standards should be required only of the aquatic plant ingredient within a formulated crop input. Handlers that further process and/or formulate the organic aquatic plants into final crop fertility input products should not be required to be certified.
>
> This approach is similar to livestock feed additives that contain agricultural ingredients, in which the agricultural ingredient must be organic, but the final formulated product is not required to be certified as a processed product. As required by §205.237(a), agricultural ingredients included in the ingredients list for livestock feed additives and supplements must be certified organic. However, there is no requirement that that handlers that use organic agricultural ingredients in the formulation of final feed additive product have to be certified organic.
>
> This approach will avoid complications that might arise from crop fertility inputs being certified organic under NOP, which has historically excluded crop input materials from its scope of certification and enforcement. Crop fertilizers and pesticides are generally considered to be outside of NOP's scope of organic certification because they are not intended for human or livestock consumption, and therefore do not meet NOP's definition of "agricultural product" at §205.2. Furthermore, it would be confusing and unrealistic to expect that formulated crop input products meet organic certification for processed products in terms of permitted ingredients and organic product composition requirements.
>
> Clarification on the requirements for labeling crop inputs that contain organic ingredients will also be needed. NOP regulates the term "organic" as it applies to agricultural products, which has historically only included products intended for livestock or human consumption. Thus, NOP does not have enforcement authority over organic claims on fertilizers, soil amendments, and other crop input materials (i.e., fertilizers that are not certified organic can still be marketed as "organic" and without violating NOP regulations). Certifiers will not be able to use organic claims on crop inputs as a means of verify organic status and must obtain proper organic certification documents for the aquatic plant ingredient to verify organic status.

Several commenters said verifying the organic status of an ingredient is not onerous, and that requiring organic certification of the marine algae ingredient would be similar to the verification of molasses as an organic input. Others explained that §205.207 is already being used to certify marine algae for human food, as livestock feed, and as a crop input ingredient. There are already a number of crop input products on the market that contain a certified organic marine algae ingredient. A manufacturer of organic fertilizers shared support for additional guidance and shared that they use certified organic kelp meal for their products.

Effectiveness of Using Organic Certification to Address Environmental Impact:
There were a broad range of opinions as to whether requiring organic certification is the right means to ensure that the harvest of wild marine algae is not harmful to the environment. Some producers of crop input products using marine algae were satisfied with the status quo, saying that current government standards are sufficient. A manufacturer harvesting marine algae off the coast of Mexico said they are adequately regulated through permits that stipulate the methods and quantities of harvest. Another producer noted that while some government regulations limit harvest rates, no government entities do on-site boat inspections. Government harvest limits and reviews are performed off-site and through paper trail audits, unlike the organic certification process which involves on-boat inspection of harvest locations, among other areas. The producer emphasized that it is not in their interest to over-harvest and in their case, scientists are hired to prepare and implement management plans. Certain producers of rockweed currently certify some of their harvest to the wild crop standard, and one testified that they could expand organic certification to all of their harvest.

A substantial number of residents in Maine expressed reservations about habitat loss, by-catch, frequency of harvest, and re-growth rates with mechanical harvesting of rockweed (*Ascophyllum nodosum*). Some said the term "sustainable harvest" fails to recognize the habitat role of rockweed. A number were affiliated with wildlife refuges and conservation areas, and they asserted that rockweed in particular, cannot meet the criteria for certification under §205.207 because of ecosystem damage caused by large biomass removal. One former wildlife refuge manager said that state and federal officers cannot fully regulate and police mechanized harvest boats. A landowner documented that two different companies harvested rockweed off of his property within 18 months of each other, despite his requests that they not. Some commenters said that organic certification of rockweed pushes harvesters into conservation areas and offered first-hand experiences observing rockweed harvested repeatedly from preserves. Some commenters from Maine requested that rockweed be listed as a prohibited natural on §605.602.

A number of commenters stated that trying to use organic certification would be inadequate to resolve the environmental impact of harvesting. A commenter stated:

> Currently, the standards are not detailed enough to meet the needs of the seaweed populations, let alone protecting the ecological community from which they are taken. It may be necessary for the NOSB to develop recommendations for new regulations concerning the wild harvest of marine plant species for use in organic to best ensure that they meet the needs of seaweed populations and the surrounding benthic and trophic communities from which they are taken.
>
> At this time, we are concerned that certifiers that certify seaweed harvest as organic lack the expertise to make the judgement that harvesting is not negatively impacting the ecosystem. If they are using standards of the local states, these fall short, as they were crafted by the industry

using heavy lobbying. Therefore, even organic seaweed may still be harvested in a way that alters the ecological balance to an unacceptable degree.

One commenter who supported the reasoning of looking to organic certification as a means of addressing the environmental impact of marine algae harvesting, noted that they agreed:

> with the subcommittee's logic of using existing organic certification tools as a means of verifying sustainable production practices. Organic is the strongest and most regulated food system in the world, so it is logical to use our existing standards and verification processes to ensure that crop materials are produced and harvested in a manner that would not be harmful to the environment. Although it is unprecedented for the NOP standards to require organic status of crop input materials, it is not without precedent in other international organic standards. For example, the Canadian Organic Standards require organic status of some crop inputs, such as molasses (shall be organic), alfalfa meal and pellets (shall be organic if commercially available) and oilseed meals (shall be organic if commercially available).
>
> Therefore, in short, it is feasible to require and achieve organic certification of aquatic plants under the existing NOP regulations. Additional complexities lie in the details of whether organic certification is feasible as a solution for achieving the subcommittee's intended sustainability goals, and if so, whether it is feasible for the organic industry to build up sufficient organic supply to accommodate the needs of organic producers.

Additionally, the commenter pointed out that both the crops certification scope and the wild crops certification scope prohibit the destruction of the environment. §205.200 requires that crop producers "maintain or improve the natural resources of the operation" while §205.207(b) requires that wild crops be "harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop".

<u>Alternatives to Organic Certification to Address Environmental Impact</u>:

It is important to emphasize that despite the diversity of opinions, there was near unanimous support for addressing the environmental impact of marine algae harvesting. This varied from general statements supportive of the concept of sustainable harvesting to specific suggestions for alternative means of verification. In addition to expressed support for requiring organic certification of marine algae ingredients used in organic crop inputs, other actionable positions were: 1) limited or no harvest of marine algae for organic crop inputs, 2) exploring existing third-party standards for "sustainable" harvesting, and 3) annotations to material listings within the National List of Allowed and Prohibited Substances.

1) *Limited or no harvest of marine algae for organic crop inputs* – Some commenters asserted that there is more to be gained from saving than exploiting this resource, and there are populations that are endangered or in decline that cannot be sustainably harvested. Some asked why farmers are using marine algae as a fertilizer and encouraged seeking alternatives that could replace it. Some suggested looking at invasive aquatic plant species as an alternative. Others explained that freshwater algae do not contain the same properties. One commenter suggested that it is more appropriate for organic farmers to source nutrients from waste streams rather than harvesting an input from a wild, native ecosystem. A few recommended allowing only farmed marine algae, particularly farmed kelp, for crop inputs.

Others noted that organic crop inputs containing marine algae are widely used by growers and include dried, liquid, and whole, unprocessed formulations. Some coastal growers use marine algae as a mulch. One commenter described that:

> It is not uncommon for organic farmers in New England to acquire seaweed from local municipalities that collect it from public beaches after storms. This "everybody wins" situation would not seem to present significant risk to adjacent aquatic ecosystems. Moreover, it seems unlikely that a municipality would bother with organic certification in order to ensure that organic farmers would be able to use the seaweed.

2) *Exploring existing third-party standards for "sustainable" harvesting* – Quite a few commenters suggested looking to third party sustainability standards to "explore the opportunity of integrating aspects of other standards or references into the NOP regulations or guidance". This could result in "identifying certain other standards as equivalent to NOP for the purposes of ensuring sustainable harvest of aquatic plants for use in crop inputs". An annotation could allow for "multiple options of third-party verifications, including organic". One commenter recommended that "a better alternative to organic certification for aquatic plant input materials may be phasing in a requirement that NOSB should consider establishing a goal of marine materials be sourced from third-party verified and/or certified sustainable fisheries in 10 years".

As one public commenter noted, however, the term "sustainable harvest" has different meanings across stakeholder groups. For example, some third-party standards focus on vegetative regrowth, but "because of the many roles that marine algae play in the ecosystem, standards should not be based on the level of disturbance that can sustain a harvest (recovery of biomass), but on recovery of ecosystem function and structure".

3) *Annotations to material listings within the National List of Allowed and Prohibited Substances* – Rather than requiring that marine algae ingredients in crop inputs be certified organic, one commenter recommended adopting the language at §205.207 and annotating the relevant listings. As such, annotations would be made under §205.601 (j)(1) for synthetic inputs and under §205.602 for nonsynthetic inputs:

> Marine algae should be listed on §205.602, prohibited nonsynthetic crop inputs, with the annotation, "unless 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 harvest and 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 population of the species".

Another commenter supported "the development of guidelines for seaweed harvested for fertilizer production, similar to compost, where certifiers verify that the product is made according to the NOP rules" and suggested that "this could be managed with the development of an annotation for seaweed under §205.601 (j)(1)".

<u>Need for Guidance</u>

Any requirement for organic certification of marine algae input ingredients would have to be accompanied by NOP guidance on how to apply the standards to a marine environment. It was observed that the wild crop standards do not define what is meant by "not destructive to the environment". Suggestions included strengthening the interpretation of §205.207 through guidance developed with marine biology experts. Others noted that a certifier's ability to determine if a harvest is destructive to the environment depends on his/her knowledge of marine ecology. One harvester and manufacturer of rockweed products for livestock feed and soil conditioners believes that the current

standards "leave too much room for individual interpretation by certifying agents that are not necessarily qualified to assess the health of localized or coastwide marine environments". Several commenters illustrated that contaminants in the ocean are more mobile, presenting unique challenges to certifying that the crop hasn't come in contact with prohibited substances. Some specific suggestions included requiring documentation of the locations, inputs, and methods of harvest. Guidance should make clear that conservation areas should not be harvested.

A commenter provided the following specific examples of how to expand guidance through "Marine Algae Harvest Guidance":

> Documentation should occur before and after each marine algae harvest for all biodiversity: the seaweed itself, the bycatch from the harvest, and the wildlife that use seaweed as perches for hunting and cover from predators. For the seaweed, documentation of the three-dimensional structure in the seaweed bed (clump density, clump height, clump biomass, and branching) should be conducted. For bycatch, the harvester simply should record how much they had. For wildlife, documentation should include a survey of birds and marine mammals using the seaweed.

In looking to other standards, one commenter suggested a "working group could determine whether existing […] standards align 100% with the national organic standards, and if not, which elements may need to be added or modified in order to ensure ocean-sources inputs meet NOP standards". Recommendations could then be about "how to integrate [other] standards, plus any additional elements, into NOP standards, guidance, or instruction".

Another commenter noted that "the health of vertebrate wildlife (birds and fish species) also depends on seaweed beds". They suggest guidance should elucidate how wildlife is maintained when marine algae bed harvesting occurs. They recommend "an independent estimate of bird and other wildlife use of seaweed beds before and after harvest in each harvest area" in order to "verify that wildlife is being "maintained" in the harvest area". Additionally, they recommend field staff with marine biology training perform the certification of marine algae.

Feedback on the Discussion Document Questions

The Fall 2018 discussion document sought input on four questions. Extensive comments were received on the first question regarding the feasibility of requiring all seaweed harvested for use in organic crop production to be certified to the wild crop standards, and these are discussed above. There were limited responses on the question to certifiers currently certifying marine materials to the wild crop standard asking how they verify that biodiversity is conserved and how wildlife are maintained in the harvest areas, with the exception of one certifier who provided extensive information, including a link to their process for Certifying Sea Vegetables (an excerpt of which can be found in the Appendix). Mixed comments were reported as to the difficulty of listing species on a label, with some saying it would be challenging and others saying it is possible and already being done. There was widespread support to develop a working group for additional guidance on wild cropped and farmed marine algae and to clarify the definition and measurement of "not destructive to the environment". There seemed to be limited potential to replace marine algae with freshwater materials for crop production inputs due to the particular properties of marine species.

Other Comments

A number of commenters advised a phase-in period to allow adequate time for input producers to come into compliance for any requirement of organic certification or third-party standards. A commenter remarked that the rule requiring that livestock be fed organic kelp allowed for a twelve-month phase-in,

and a phase-in for any rule requiring organic certification of marine algae should be at least as long. Another suggested examining commercial availability to ascertain an appropriate phase-in period.

DISCUSSION

The goal of this project is to find the most effective and realistic means of addressing a complicated issue. No single solution will be satisfactory to all, nor will it be able to resolve all areas of conflict. Despite the different opinions, there is consensus on the importance of ensuring that marine algae harvesting "maintains or improves the environment". The NOSB aims to bring a proposal forward in the Fall of 2019 with a recommendation for meeting the environmental impact criteria.

Questions of Jurisdiction:

As noted in the previous section, there were some concerns 1) that it would be difficult for certifiers to verify organic claims for marine algae in crop inputs in the absence of NOP purview over fertilizer products and 2) about precedent setting.

Marine algae are currently treated as an agricultural "crop" for livestock feed and human consumption, and in each instance they are being certified to the wild crop or crops standard. Indeed, in some cases the same boat may harvest the same species of marine algae for both certified organic livestock feed and for non-certified crop inputs. As a point of clarification, any NOSB recommendation would only require that the marine algae *ingredient* be certified organic, not the entire crop input or product. Labels would list the certified organic marine algae ingredient(s). Certifiers and Material Review Organizations would look for the marine algae ingredient's organic certificate to accompany a product and could also use the Organic Integrity Database to verify production. Certifiers would perform the verification of agricultural ingredients in fertilizers the same way they already do for agricultural ingredients in livestock feed additives.

Several stakeholders cautioned that requiring organic certification of marine algae ingredients in organic crop inputs could lead to a similar requirement in other crop input materials. To be clear, that would not be the intention nor the focus of any proposal to require organic certification of marine algae ingredients; nor is the objective to remove tools or inputs from farmers. Opting for organic certification would use an existing standard and verification process to meet the requirement that already exists, namely that materials not be harmful to the environment.

Environmental implications form part of the NOSB's criteria when examining new petitioned synthetic materials for potential inclusion on the National List and when reviewing the continued listing of materials during the sunset process. Indeed, the issue of environmental impact in marine algae harvesting came to the NOSB's attention during the 2015 sunset review process.

The proposed requirement of organic certification for marine algae ingredients is a means of addressing conflicts over the environmental impact of harvesting these species, but it does not necessarily follow that organic certification would be the right mechanism to account for environmental impact in other crop inputs.

The environmental impact of natural materials used in organic production receives comparatively little consideration simply because they do not undergo the same review process as synthetic materials. Yet the regulations specifically allow for the prohibition of natural materials "if the use of such substances would be harmful to human health or the environment" (7 USC 6517(c)). From this we understand that

natural inputs should also minimize environmental impact. Natural input materials should not be exempt from deliberations of environmental impact simply because they do not go through a petitioned material and subsequent sunset review process.

There are few crop input ingredients that are themselves living organisms harvested directly from wild native ecosystems. The question posed by the NOSB of petitioned materials--are there any adverse impacts on biodiversity--arguably assumes a unique accountability when those input materials themselves (in this case, marine algae) form part of the biodiversity of a wild native ecosystem.

Identifying the Right Tool to Address Environmental Impact:
The status quo does not provide a means of verifying that marine algae inputs are not harmful to the environment. Can either the crop or wild crop organic standards adequately define, measure, and verify that through guidance? Should all or part of a third-party verification standard be adopted through an annotation? Should an annotation be developed that stipulates how marine algae should be harvested to meet the wild crop standard but without the requirement of certification?

Throughout the NOSB's discussion documents on this issue, numerous commenters have suggested that there may be some species, regions, and/or harvest methods for which a limited or prohibited harvest should be recommended. While this could inform future NOSB work, that is not within the capacity of this current discussion document and proposal effort. Additionally, a small number of commenters said that marine algae harvests are "sustainable" without further action. In the absence of a universally agreed upon definition, measurement, and enforcement of sustainable harvest in marine algae, making claims related to the term are difficult to support.

There are several independent non-profit organizations with third party certification services and ecolabels that certify "sustainable seaweed". Much of the focus has historically been on fisheries[3], though recent efforts have launched marine algae certification programs. The first two listed below certify both farmed and wild harvested marine algae, while the third certifies only farmed marine algae. Excerpts from these standards can be found in the Appendix.
1. The **Marine Stewardship Council** (MSC) has traditionally focused on standards for seafood products; however in 2017, MSC and the Aquaculture Stewardship Council (ASC) launched "a joint standard for environmentally sustainable and socially responsible seaweed production" under the ASC-MSC Seaweed Standard. These standards contain 31 performance indicators under five principles: sustainable wild populations; environmental impact; effective management; social responsibility; community relations and interactions.

> Sustainable wild populations: Seaweed harvesting and farming must be conducted in a manner that does not lead to depletion of the exploited wild populations. For depleted populations, harvesting operations must be conducted in a manner that demonstrably leads to their recovery. Where appropriate, stock status, harvest strategy, and the genetic impact of the assessment site on the wild stock are also assessed.
>
> Environmental impacts: Seaweed harvesting and farming activities must allow for the maintenance of the structure, productivity, function, and diversity of the ecosystem (including

[3] For example, see The Monterey Bay Aquarium's Seafood Watch list of recommended Eco-Certifications for specific farmed and wild fish. These include ASC, Naturland, Global Aquaculture Alliance Best Aquaculture Practices, Canada Organic, MSC, and FishWise. For example, **FishWise**'s vision is promoting "the health and recovery of ocean ecosystems by providing innovative market-based tools to the seafood industry, supporting sustainability through environmentally and socially responsible business practices".

habitat and associated dependent and ecologically related species) on which the activity depends. Seaweed operations must also adhere to criteria related to habitat, ecosystem structure and function, species status, species management, waste management and pollution control, energy efficiency, disease and pest management practices, and introduced species management.[4]

2. **Friend of the Sea** launched a sustainable marine algae harvesting and farming certification program in 2016 that reviews an operation's: "management system; legal compliance; biomass and Environmental Impact Assessment; water monitoring; air emissions monitoring; waste management; chemicals and hazardous substances; energy management; social accountability; and traceability".
3. The **Maine Seaweed Exchange** has a Seaweed Farmer Certification for farmed marine algae.

At least three international certification bodies provide specific marine algae standards. Others, like Japan, set standards for farmed marine algae[5]. Excerpts from these standards can be found in the Appendix.

1. **The Soil Association** Organic Seaweed Standards cover both farmed and wild harvested marine algae (see page 8 for the standards on wild harvested marine algae).
2. The **European Commission** Regulation 710/2009 sets "conditions for the aquatic production environment and impacts on other species".
3. **Canadian Organic Standards** has standards set out in its "Organic production systems : aquaculture - general principles, management standards and permitted substances lists".

The suggestion that the NOSB require certification to an existing third-party certification system raises questions of jurisdiction. The challenge of adopting a third-party standard rather than simply adapting from it is that they cover the social and economic tiers of "sustainability", such as working conditions and wages, which are beyond NOP purview. For the purposes of organic production, "sustainable" harvest in marine environments addresses environmental impact. Additionally, any third party would need to be both impartial and expert in ocean sustainability. Concern has been raised by some in the conservation community that existing third-party standards don't take an ecosystem-wide perspective.

There were several suggestions for adopting annotations at §605.601 (j)(1) and §605.602. These included 1) adapting and/or elaborating the wild crop standard wording at §605.207 and 2) looking to the various third-party standards to identify and adopt sustainability benchmarks. Any annotation wording would need to be feasible for Material Review Organizations (MROs) to assess. The challenge arises in making an annotation enforceable and verifiable without accompanying certification. Who would perform on-site/on-boat inspections of each harvester's operation to measure and substantiate that their harvest and management procedures met the annotation criteria without a certification process?

Opting for organic crop certification employs a tool already at our disposal for verification. As one NOSB member noted in the Fall 2018 board meeting discussion, the only way to ensure compliance with environmental standards is regulatory action.

[4] The Aquaculture Stewardship Council. "The ASC-MSC Seaweed Standard". Accessed on January 25, 2019. https://www.asc-aqua.org/wp-content/uploads/2017/06/BC2146_ASC-MSC_A4_6pp_ARTWORK_LRES.pdf.
[5] See: JONA Organic Standards, "Section 8 Organic Macroalgae Standards", pg. 40 http://www.jona-japan.org/form/JONA_Standards.pdf.

The Fall 2018 discussion document included a proposal to require that marine algae ingredients in organic crop production inputs be certified organic to the wild crop standard under §205.207. Based on public comments, that language has been modified to the following (proposed language changes are underlined):

§205.601 (j) As plant or soil amendments.

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

and

§205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

(j) Marine algae -- unless certified organic.

Note that the term "marine algae" in any annotation would be clearly defined to avoid confusion about the differences with the more general term used in §205.601 (j)(1), "aquatic plants". Moreover, it was proposed by commenters that organic certification could occur under either the wild crop or crops standard.

The Role of Guidance:

Regardless of the recommended action, guidance is necessary. Guidance could borrow from multiple standards to improve organic certification or for an annotation. The excerpts from the Appendix: Other Certifier and Third-Party Marine Algae Standards can provide a starting reference. The Materials Subcommittee's Fall 2018 Discussion Document offered some guidance evaluation questions and parameters obtained from public comments.

In the case of requiring organic certification, guidance is needed to explain what is meant by "not destructive to the environment and will sustain the growth and production of the wild crop" (§605.207 (b)) and "maintain or improve the natural resources of the operation" (§205.200). With an annotation not tied to certification, guidance would be required to define and provide measurement tools for environmentally "sustainable" harvesting.

Some said certifiers don't typically have the skills needed to certify marine algae to the wild crop standard. There are certifiers already doing this; however, there is undoubtedly a need for additional guidance and explanation as to how to apply the standards to a marine environment. Certifiers should be qualified through adequate training and education.

CONCLUSION

While this is a new way of looking at a wild harvested crop input, that does not mean it is outside of the scope or purview of the NOSB. Organic agriculture is about more than simply limiting the use of synthetic ingredients. Farmers and consumers rely on the NOSB and the NOP to affirm the environmental integrity of organic production, including inputs used. Although finding a middle ground is always challenging, failing to do so will not resolve this issue. There are strong reasons for using the existing instrument of organic certification for marine algae ingredients; nevertheless, the NOSB is interested in obtaining further suggestions from stakeholders.

DISCUSSION QUESTIONS

1. If you are not in support of requiring organic certification, what approach do you support? Please describe the method for defining, measuring, and most importantly, enforcing, that the harvest would not be destructive to the environment under an alternative approach.

2. Some existing wild harvest marine algae standards from other certifiers and third-party entities are listed in the Appendix. Please comment on strengths in these standards that could be adapted for NOP guidance. Please identify areas of weakness or areas that are not covered.

3. What existing certification or private standards to support marine algae harvest sustainability have not been included in this document or the Appendix that can help inform the NOSB's understanding of the current work being done?

4. How many crop input products approved for use in organic production currently contain certified organic marine algae ingredients?

5. Are there any crop input products utilizing or developing farmed marine algae?

6. Are there enough certifiers able to offer certification services to meet the needs of the crop fertilizer markets if organic certification were required? If organic certification were required of marine algae ingredients, what would be an appropriate phase-in time to allow markets to meet the demand?

7. The NOSB hopes to convene an expert panel at the Fall 2019 board meeting to include a marine algae harvester for crop inputs, scientist, conservationist, and certifier, among others. What are some questions that could be posed to help identify the issues and solutions?

Vote in Subcommittee

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

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, February 13, 2019

Appendix of Excerpts from Other Certifier and Third-Party Marine Algae Standards:

Note: This is not intended to be an exhaustive list and is meant to provide examples and references to some existing marine algae certification standards.

This Appendix includes:

A. Soil Association organic seaweed standards Version 1.0 – January 2016
B. European Commission Regulation (EC) No 710/2009 of 5 August 2009
C. Canadian General Standards Board: Organic production systems Aquaculture – General principles, management standards and permitted substances lists
D. The ASC-MSC Seaweed Standard
E. Friend of the Sea Certification Criteria Checklist for Seaweed Products: Seaweed Harvesting and Farming
F. MOFGA Sea Vegetable Supplement

A. Soil Association organic seaweed standards Version 1.0 – January 2016[6]

SP c. Sustainable harvesting of wild seaweed
1. You must harvest wild seaweed without significant impact on the aquatic environment.
2. You must put in place measures that ensure seaweed regeneration, taking into account:
    a. harvesting technique
    b. minimum sizes
    c. minimum ages
    d. reproductive cycles or
    e. size of remaining seaweed.
3. You must keep records that demonstrate:
    a. the history of harvesting activity for each species in named beds
    b. that the seaweed harvested is wild seaweed and that it is harvested according to these standards
    c. that where you harvest seaweed from a shared or common harvest area, the total harvest complies with these standards.
4. Your records of harvest estimates and sources of potential pollution must provide evidence that you are managing the harvesting areas sustainably with no long-term impact.

B. European Commission Regulation (EC) No 710/2009 of 5 August 2009[7]

CHAPTER 1a
Seaweed production

Article 6a
Scope

[6] Soil Association. "Soil Association organic seaweed standards Version 1.0 – January 2016". Accessed on January 25, 2019. https://www.soilassociation.org/media/5250/sa-seaweed-standards.pdf.
[7] European Commission. "Commission Regulation (EC) No 710/2009 of 5 August 2009 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production".

This Chapter lays down detailed production rules for the collection and farming of seaweed. It applies *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

Article 6b

Suitability of aquatic medium and sustainable management plan

1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorized for organic production, or pollutants that would compromise the organic nature of the products.
2. Organic and non-organic production units shall be separated adequately. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Member State authorities may designate locations or areas which they consider to be unsuitable for organic aquaculture or seaweed harvesting and may also set up minimum separation distances between organic and non-organic production units.

Where minimum separation distances are set Member States shall provide this information to operators, other Member States and the Commission.

3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control body or control authority. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC [(21)]. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.

The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimize negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and re-cycle materials and shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources.
6. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

Article 6c

Sustainable harvesting of wild seaweed

1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with Regulation (EC) No 834/2007.
2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

4. With respect to Article 73b(2)(b) and (c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

C. Canadian General Standards Board: Organic production systems Aquaculture – General principles, management standards and permitted substances lists[8]

7.2 Wild crops

7.2.1 An organic wild crop shall be harvested from a clearly defined area or production unit in accordance with this standard. Documented evidence that prohibited substances have not been used for at least 36 months before the harvest of an organic crop shall be available.

7.2.2 The operator shall prepare an organic plan (see 4.1, 4.2 and 4.3) that includes:

a) a detailed description of production areas and harvest methods. If wild crops are harvested from a shared or common area, records shall be available to demonstrate that the total harvest complies with this standard;

b) management practices that preserve wild species and avoid disturbance of the environment; and

c) a record-keeping system that meets the requirements of 4.4.

7.2.3 Harvesting shall be carried out in such a way that the amounts harvested do not cause significant impact on the state of the environment. Measures shall be taken to ensure that crops can regenerate. Examples of such measures include harvest techniques and tools, minimum sizes, ages, reproductive cycles or size of remaining crops. Evidence of sustainable management and of no long-term impact on the harvesting areas shall be provided.

7.2.4 The production zone for wild crops shall be situated in locations where water is not subject to contamination by products or substances not authorized for organic production, or pollutants that would compromise the organic nature of the production.

D. The ASC-MSC Seaweed Standard[9]

Certified seaweed operations must be well-managed, environmentally sustainable and socially responsible.

If you decide to begin the audit process, an accredited third-party conformity assessment body (CAB) will provide an assessment team to independently score your farm or wild harvest operation to some or all of the 31 performance indicators (PIs) that make up the ASC-MSC Seaweed Standard.

[8] Canadian General Standards Board- Standards Council of Canada. "Organic production systems Aquaculture – General principles, management standards and permitted substances lists", pg. 23. CAN/CGSB-32.312-2018. Accessed on January 25, 2019. http://publications.gc.ca/collections/collection_2018/ongc-cgsb/P29-32-312-2018-eng.pdf.

[9] The Aquaculture Stewardship Council. "Get certified! Your guide to the ASC-MSC Seaweed Standard audit process", pg. 8. Accessed on January 25, 2019. https://www.asc-aqua.org/wp-content/uploads/2017/11/Get-Certified-Guide-Seaweed.pdf.

The number of PIs scored depends on the type of seaweed production system that you use. Your CAB will explain exactly which of the PIs will be scored for your operation.

Table 1: List of performance indicators

Principle 1 Sustainable wild populations
PI 1.1 Stock status
PI 1.2 Harvest strategy
PI 1.3 Genetic impact on wild stock

Principle 2 Environmental Impacts
PI 2.1 Habitat
PI 2.2 Ecosystem structure and function
PI 2.3 ETP species
PI 2.4 Other species
PI 2.5 Waste management and pollution control
PI 2.6 Pest(s) and disease(s) and management
PI 2.7 Energy efficiency
PI 2.8 Translocations
PI 2.9 Introduction of alien species

Principle 3 Effective management
PI 3.1 Legal and/or customary framework
P1 3.2 Decision-making processes
P1 3.3 Compliance and enforcement

Principle 4 Social responsibility
PI 4.1 Child labour
PI 4.2 Forced, bonded or compulsory labour
PI 4.3 Discrimination
PI 4.4 Health, safety and insurance
PI 4.5 Fair and decent wages
PI 4.6 Freedom of association and collective bargaining
PI 4.7 Disciplinary practices
PI 4.8 Working hours
PI 4.9 Environmental and social training

Principle 5 Community relations and interaction
PI 5.1 Community impacts
PI 5.2 Conflict resolution
PI 5.3 Rights of indigenous groups
PI 5.4 Visibility, positioning and orientation of farms or water-based
PI 5.5 Identification and recovery of substantial gear
PI 5.6 Noise, light and odour
PI 5.7 Decommissioning of abandoned production units

E. Friend of the Sea Certification Criteria Checklist for Seaweed Products: Seaweed Harvesting and Farming [10]

3 - Biomass and Environmental Impact Assessment

3.1 In case of seaweed harvesting activity, an assessment of the status of the seaweed and its biomass by appropriate research institutes or other recognized institutions unconnected to any harvesting and/or processing industries must be undertaken and it must conclude that the seaweed is not overexploited nor endangered. [The auditor must make reference to the biomass studies (title, date, author).]
3.2 This requirement applies to all harvesting operations and to those farming operations producing more than 20 tonnes per year. An EIA or equivalent assessment of the harvesting or farming activity has been carried out with a positive outcome by the presiding authority or by other recognized independent institute or laboratory. [The auditor must check whether an independent environmental impact assessment or equivalent was carried out. The auditor must specify the title, date, author and significant conclusions of the inspected EIA or equivalent document. *In case the Organisation is not compliant for 3.1, it must alternatively be compliant to 3.2 and sub requirements.]
3.3 In case of non-compliance with 3.2, farming activities producing more than 20 tonnes per year must alternatively be compliant with the following requirements:

3.3.1 sea-based systems must not imply removal of rocks, corals or other obstructions leading to damage to the coastal ecosystem;

3.3.2 sea-based systems must not imply removal of competitive grasses or predators leading to damage to the coastal ecosystem;

3.3.3 large scale sea-based farms must not influence coastal water movement in a detrimental way. Protection from erosion or other positive impacts would not constitute a non-compliance with this requirement;

3.3.4 any multiuser conflict must have been solved positive and allow other users access to the sea and to the shore.

3.3.5 a careful assessment of potential impacts must precede the introduction of any non-native species.

3.3.6 removal of mangroves for farming purposes is prohibited. In case removal has occurred, a reforestation program must fully compensate the mangroves degradation occurred and caused by the seaweed farming activity.

3.3.7 carrying capacity must have been independently evaluated, considering in particular the potential impact of nutrients removal. [The auditor must acquire documented information and evidence (text, photos, official documents to be annexed to the audit report) of the environmental conditions of the ecosystem prior to the installation and assess whether the site has led to a negative impact on the ecosystem.]
3.4 In case of farming operations of less than 20 tonnes each per year, but more than 20 tonnes on a regional or national level, a regional or national level independent assessment must prove compliance with requirements 3.3 and sub. The study cannot be older than 5 years. [The auditor must make reference to the regional or national level assessment. The auditor must run sample onsite checks at small scale producers and produce / report evidence of compliance.]

[10] Friend of the Sea. "Certification Criteria Checklist For Seaweed Products: Seaweed Harvesting and Farming (Latest update: 19/03/2014)" pgs. 7-9. Accessed on January 25, 2019. http://www.friendofthesea.org/public/news/en%20-%20checklist%20fos%20seaweed%2019032014.pdf.

F. MOFGA Sea Vegetable Supplement[11]

Part 2. WILD CRAFTED SEA VEGETABLES – Wild Crafted sea vegetables are sea vegetables harvested from natural growing areas along ocean coastline. Wild crafted sea vegetables must meet the wild crafting requirements of the NOP rule.

Wild Crafted Sea Vegetable Variety	Harvest Method	Site Locations (harvest area) (Please include each site on the Harvest Area Form.)*

*Include maps and a Landowner Affidavit, if applicable for each site. On each harvest area map designate harvest areas, boundaries, buffer zones, and sources of possible contaminants and prohibited materials.

Part 3. GROWING AREA DESCRIPTION: Cultured and/or Wild Crafted Sea Vegetables

3.1. Describe the natural environment of the harvest area. List any rare or endangered terrestrial or aquatic plants or animals that occur in the harvest area. Lists of rare or endangered plants and animals are available from MNAP or MDIFW.

3.2. Describe methods used to prevent negative impact to the harvest area and monitoring procedures used to verify lack of impact on the aquatic ecosystem, water quality and biodiversity.

3.3. How do your harvest practices ensure the health, sustained growth, and long-term viability of the wild crop(s)?

3.4. Approximately what percentage of the wild crop is harvested at each harvest? Are you aware of other harvesters working the same area?

3.5. List harvester training provided including frequency of trainings and the procedures used to ensure your collectors harvest crops in accordance with answers provided above.

3.6. What procedures are in place to prevent contamination from adjoining land/water use or other sources of contamination?

3.7. Describe your record keeping system for wild crop area management, monitoring, harvest and sales.

[11] MOFGA Certification Services LLC. "Sea Vegetable Supplement" pgs. 3-4. Accessed on January 25, 2019. https://mofgacertification.org/wp-content/uploads/Crop_2019_SeaVegetableSupplement.pdf.

National Organic Standards Board
Materials Subcommittee Discussion Document
Genetic Integrity Transparency of Seed Grown on Organic Land
February 12, 2019

I INTRODUCTION

The USDA National Organic Program (NOP) regulations do not allow the use of materials developed using "excluded methods" in certified organic production. The USDA defines "excluded methods" as organisms, including seed, bacteria, insects, animals, and vaccines, that have been produced through genetic engineering (GE). According to the most recent National Agricultural Statistics Survey (NASS), at least 94% of soybeans, 92% of corn, 94% of cotton, 75% of Hawaiian papaya, 98% of sugar beets, and 90% of canola are genetically engineered. This discussion document and any future proposal will address field corn seed planted on organic land.

II BACKGROUND

The National Organic Standards Board (NOSB), in separate recommendations in 2016, 2017 and 2018, defined terms used when describing gene altering technologies and the subset of those methods deemed to be excluded methods. The list of those excluded methods are as follows:

- 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 and non-organic seed (when the organic seed is not commercially available in the form, variety, or quantity required). Some, but not all, certification agencies perform GE testing on a farmer client's harvested crop; what is proposed here is an

additional step-- testing the seed the farmer plants in order to reduce the likelihood of a contaminated harvested crop.

To meet the current certification standard, farmers are required to provide documentation that the seed they plant was not produced using excluded methods. This standard is met in one of two ways. Certified organic seed breeding companies must verify excluded methods were not used in the production of certified organic seed. For non-organic seed, a non-GE affidavit is required if the crop has a genetically engineered equivalent in the marketplace. Affidavits typically state "to the best of the seed supplier's knowledge, the seed was not produced using excluded methods"; however, the affidavit does not address the issue of contamination of the seed lot with seed having been produced using excluded methods. The *intentional* use of seed produced by an excluded method is prohibited. Non-GE affidavits have been accepted as proof by organic certifiers that the seed is acceptable in organic systems.

A future proposal will address the "front end" of the food system, that is, the seed farmers plant. We argue that if farmers don't know what they are starting with, it puts them in a compromised position when they sell their crop; after all, they are committed to producing GE-free grains, fruits, and vegetables. The organic marketplace or the "back end" of the food system on the other hand, has developed a fairly robust testing protocol for organic foods intended for human consumption as well as livestock feeds. Depending on the market being served, various tolerance levels of genetic contamination must be met in order to sell into that market. Knowing the purity of the seed farmers plant on the "front end" is critically important for several reasons. The level of contamination at the beginning of the season will not decline and can only worsen by cross-pollination and post-harvest seed handling. 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 and proposal documents addressing the issue of clarity around genetic purity of the seed supply in 2013, 2014, 2015, 2016, 2017, and 2018. The strong response from the public in the form of many comments clearly demonstrates the importance of this issue for organic farmers, processors, and consumers.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

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 genetically engineered organisms. That memo clearly states that the use of genetically engineered organisms is prohibited and goes on to address questions that have been raised concerning the use of these organisms and how to minimize their presence in organic production and handling. The memo emphasizes that organic certification is a process-based standard, explaining the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

IV RESPONSE TO PUBLIC COMMENT

The organic seed industry, various NGOs, and certifiers felt more information should be gathered on the effect a proposal that provides transparency of the genetic integrity of seed planted on organic land would have on the availability of seed traits, the increase in cost of seed, and the paperwork burden to provide and collect the information needed. To allow the private sector to gather this information, the Materials Subcommittee has decided to not bring forward a proposal but to instead gather more information from stakeholders through this discussion document. We plan to bring a proposal forward for public discussion and an NOSB vote at the fall 2019 in-person NOSB meeting.

Public comment over the years, from 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. A future proposal will not include tolerance levels that could prohibit the planting of seed that exceeds any specific tolerance.

In the Fall of 2018 public commenters requested that the NOSB review the various licenses, utility patents, contracts, or other legal instruments that could limit producers from testing hybrid corn seeds for the presence of GE. In discussion with numerous seed suppliers, testing laboratories, and others involved in oversight of GE, it became clear that there are no current restrictions that would prevent a farmer from taking a sample of hybrid corn seed (a non-GMO variety) and having it tested for the presence of GE. There are agreements that seed breeders might encounter when purchasing the foundation seed for building their own hybrid varieties that could restrict them from testing that seed for the presence of GE. However, this proposal only requires testing of the seed that would be planted by an organic producer who has no legal impediments to this testing.

Another concern was that GE testing might restrict the availability of germplasm or seed traits needed by organic farmers. The Materials Subcommittee views this is a significant concern and looks forward to hearing back from the organic community about its validity. The nationwide availability of field corn seed that meets private agency non-GMO requirements widens the pool of seed available to organic farmers that seek low to no levels of GMO contamination beyond available organic varieties that may not have the traits they seek.

In addition, comments were made that it would be an unnecessary burden to require farmers to retain seed samples of corn seed they plant on organic land, and therefore a subsequent proposal will recommend, but would not mandate, the saving of samples by farmers.

The type of testing will be narrowed to all commercially available GE traits that can be found by testing and not all GE traits developed for field corn. The various responsibilities of organic seed suppliers, nonorganic seed suppliers, organic farmers, and organic certification agencies will be clearly identified by

entity and activity in a future proposal.

A future proposal will include the gathering of information for a database. This information would include whether or not the seed was organic, the level of purity of that seed, and the state/province and country where it was grown. The seed supplier, variety number/name, and farmer who planted it would remain anonymous and only be known to the farmer and certifier. The Materials Subcommittee is in discussion with the NOP to determine if the NOP can contract out this work to an outside entity or if they prefer to collect and summarize this information within the USDA.

V DISCUSSION QUESTIONS

1. Would the testing and knowledge of GE contamination of seed grown on organic land lead to less available corn seed varieties that contain traits or regional adaptability sought by organic farmers?

    a. Please describe if there is a risk that nonorganic seed suppliers would not sell seed to organic farmers if the seed supplier is aware the seed could be tested for GE contamination.
    b. Please describe if there is a risk that an organic farmer would choose to leave organic production or have a significant loss due to their choice to not plant corn seed if they were knowledgeable of the level of purity from GE contamination. Note, the level of purity from GE contamination is not proposed to affect the certified organic status of the seed or crop.
    c. If there are any other negative consequences that might come from the testing and knowledge of GE contamination presence in seed planted on organic land, please be specific on what these might be.

2. Can organic seed growers and their certifiers provide information on how many entities are testing seed for the presence of GE contamination? If they are not testing, what are the reasons?

3. Can nonorganic seed growers and/or farmers and their certifiers provide information on how many entities are testing seed for the presence of GE contamination? If they are not testing, what are the reasons?

4. Should there be a sentence added to a proposal addressing a possible future legal impediment to testing seed for GE traits? Would requiring documentation from the seed seller to the certifier stating that it is illegal for the farmer to test that seed corn, hence exempting that farmer from testing the seed, be a solution?

5. Can you provide feedback on how to gather the “level of purity from GE contamination” information from the certification agencies, and which entity should receive and summarize that information for the public?

VI Subcommittee vote
Motion to accept the “Genetic Integrity Transparency of Seed Grown on Organic Land” discussion document
Motion by: Harriet Behar
Seconded by: Lisa De Lima
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, February 14, 2019

National Organic Standards Board
Materials Subcommittee Discussion Document
Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling
February 21, 2019

I SUMMARY

Sanitizers and disinfectants are used in all areas of organic crop/livestock production and food processing. These materials are present on the National List of Allowed and Prohibited Substances (National List) at Sections 206.601, 205.603, and 205.605 of the USDA organic regulations. Based upon this work agenda item, the NOSB Materials Subcommittee will assist the NOSB Crops, Livestock, and Handling Subcommittees to generate consistent reviews when addressing the possible placement of sanitation materials on the National List that have direct contact with organic crops, livestock, and foods.

II INTRODUCTION

For a number of years, there has been public comment and discussion asking the NOSB to develop a system to assess sanitizers for essentiality as well as evaluate them under the OFPA and NOP regulatory criteria for inclusion on the National List. Commenters, including advocacy organizations, certifiers, and handlers, referred to this as a "comprehensive review of sanitation materials". The NOP and NOSB agree that a technical review and reference materials used by the NOSB, need to focus on the current regulatory requirements for materials review, as well as providing practical evaluation guidelines for this unique set of materials. The NOSB evaluates materials for inclusion on the National List when the materials are newly petitioned, as well as when listed materials come up for their sunset review.

One of the aspects the NOSB reviews when assessing a material for inclusion on the National List is essentiality to organic production. In determining if a material is currently essential to organic production, the NOSB considers the availability of either approved synthetic or natural alternatives to the current or proposed National List material. Materials used to clean or sanitize may have a wide range of actions and effectiveness in many situations, or they may be narrowly targeted for specific needs or circumstances. Since NOSB membership rotates, and with it the expertise and knowledge about sanitizer use, it is important to have a reference document for current and future members to use when evaluating these materials. Reference materials and evaluation guidelines will promote consistency

Background information on how to assess these materials by category, as well as a list of viable alternatives, would be useful information for both the NOSB and organic producers. There is universal support among NOSB members to provide materials to organic producers in order to meet food safety requirements. Our goal is not to limit these tools. This review could help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.

To support the NOSB in their review of such materials (new petitions and sunset reviews), the NOSB has requested a technical review to provide information on the essentiality and appropriateness for these types of materials in a variety of situations. The Materials Subcommittee acknowledges that any changes to the National List is beyond the scope of any technical review; such changes can only be pursued by the National List petition process.

III BACKGROUND

A technical review has been requested to provide the following information:

- References and information to develop a framework and questions for review of sanitation and disinfection materials in all areas of crop/livestock production or during food handling. The framework/methodology could be used as guide for both sanitizer/disinfectant petitioners to address in their petition and for the NOSB and associated subcommittees to consider when they are in the material sunset review process.

- A broad scope of questions to consider for such material reviews. This could include mode of action in various environmental conditions (i.e. hot/cold; wet/dry), target microorganisms (i.e. bacterial, fungal, viral), other regulatory considerations (e.g. Food Safety Modernization Act requirements), and other questions/considerations that would provide the subcommittees with scientific information to make informed decisions.

- A consideration of how other international organic regulatory organizations address this unique area of materials review for possible improvement to the NOP's National List.

  This document can be used as reference for current and future NOSB members, as well as the public, to enable consistent reviews of these materials and provide a comprehensive toolbox of food safety options for organic producers.

- **Evaluation criteria** could include:

    1. Level of toxicity on human health in its manufacture, use, and disposal
    2. Consideration of how the materials meet the current requirements to be on the Safer's Choice list of sanitizers
    3. Corrosive nature
    4. Presence of harmful odors
    5. Length of time residue remains after application
    6. Compatibility or incompatibility with other chemicals
    7. Persistence and effect on the environment in its manufacture, use, and disposal
    8. Ancillary ingredients found in commercial formulations, especially those of toxicological concern
    9. Use of nanotechnology in its manufacture and/or presence in final product
    10. Susceptibility of resistance by its target organism when material is used over time
    11. Ease of application and use
    12. Whether the product is broad spectrum or narrow spectrum
    13. Its effectiveness on gram-positive/gram-negative bacteria, fungi, algae, viruses, and other pathogens.
    14. Its effectiveness in various environmental situations, i.e. cold/hot, wet/dry
    15. Is it required to be used under federal or state statutes in specific situations?
    16. For what specific type of use is it commercially approved: crops, livestock, handling?

The technical review could aid the NOSB by categorizing these materials by use so there can be a comparison of materials by function, which will help in determining which are unique. As new products are petitioned, manufacturers can identify where their products should be classified.

Materials classified by their active ingredients:

A. Chlorine compounds (both calcium and sodium hypochlorite)
B. Bromide
C. Alcohols: Ethanol, isopropanol
D. Peroxide and peroxyacid compounds
E. Hydrogen peroxide
F. Acid anionic compounds (sulfuric, hydrochloric)
G. Ionic compounds (trisodium phosphate, sodium bisulfate)
H. Fatty acid compounds (glycerin)
I. Acetic, citric, lactic, phosphoric, carboxylic, and other acids
J. Quaternary ammonium compounds
K. Iodophor compounds
L. Soap-based compounds
M. Ozone, ethylene oxide, hydrochlorofluorocarbons, chlorine dioxide, and other gas-based sanitizers
N. UV light, infrared light
O. Essential oils: natural or synthetic compounds based upon their chemical makeup
P. Microorganism-based products (example brand names: Bio-Save, Nexy)
Q. pH adjusters or surfactants used in concert with the above materials
R. Silver and other elements

IV RELEVANT AREAS OF THE STATUTE, RULE, and RELATED DOCUMENTS

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

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

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

(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;

(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;

(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;

(5) The substance is listed as generally recognized as safe (GRAS) by 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; and

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

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

Organic Foods Production Act (U.S.C. 6518)

(m) Evaluation- In evaluating substances for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider-

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

(2) 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;

(3) the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance;

(4) the effect of the substance on human health;

(5) the effects of the substance 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;

(6) the alternatives to using the substance in terms of practices or other available materials; and

(7) its compatibility with a system of sustainable agriculture.

V DISCUSSION QUESTIONS

Please answer the questions below to assist the Board in creating a framework to help future NOSB members evaluate sanitizers both on the National List and those newly petitioned.

1. Should the "evaluation criteria" list noted above be modified, consolidated, or shortened; are there additional items needed**?**
2. Should the "materials classified by their active ingredients" noted above be modified, consolidated, or shortened; are there additional items needed?
3. Do you have additional suggestions for the development of this framework?

SUBCOMMITTEE VOTE

Motion to accept the "Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling**"** Discussion Document
Motion by: Harriet Behar
Seconded by: Dan Seitz
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, February 21, 2019

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Oversight Improvements to Deter Fraud Discussion Document
February 21, 2019

I. INTRODUCTION

Organic products have been one of the fastest growing sectors in agriculture for decades. In 2017 organic sales in the U.S. were nearly $50 billion. The most recent figures for 2017 show growth of 6.4% for organic food products versus 1.1% growth for nonorganic food products. The strong demand for organic products, coupled with limited supply in some supply chains, has led to documented occurrences of both domestic and import fraud in the use of the organic label. The organic community, trade, regulatory agencies and Congress have all taken note of these activities and have moved forward with stronger enforcement, and the development of new tools to build a stronger system for protecting organic integrity.

II. BACKGROUND

On August 10, 2017, the USDA issued a memo to the NOSB about the oversight of imported organic products. In this memo, the USDA outlined a number of actions taken by the NOP to deter fraudulent shipments. Additionally, the memo expressed the AMS's priority to explore additional measure that would strengthen the global organic control system. AMS specifically requested the NOSB "provide recommendations on improving the oversight and control procedures that are used by AMS, certifiers, and operations to verify organic claims for imported organic products."

To support this work AMS convened a panel at the Fall 2017 NOSB meeting. This panel was comprised of representatives from several Federal agencies including the Agricultural Marketing Service (AMS), , Animal Plant Health Inspection Service (APHIS), and Customs and Border Protection (CBP) to discuss the federal perspective and tools used in relation to imports of agricultural products. The NOP also provided suggestions on areas of work. At the spring 2018 NOSB meeting, the Board convened a panel representing various entities involved in certification and the organic supply chain, to delve deeper into possible solutions for deterring fraud and protecting organic integrity.

III. DISCUSSION

To continue the work of the NOSB in providing guidance to the NOP, this discussion document summarizes the input we have received from the public, representing certifiers as well as all links in the supply chain from the farm through processing, distribution, and retail. We welcome additional public comment about priorities, and where best to focus funds and enforcement activities that will result in the most positive outcome, and will build a better system for full compliance. The following areas received public support, but could be further refined through public input in order to develop a stronger organic certification system that is both reactive when fraud is suspected and proactive to deter as well as identify fraud. The items below are not listed in terms of priority.

1. Explore working with Congress to provide the NOP with "stop sale" authority.

2. Organic certification agencies should develop a stronger system of collaboration and transparency when investigating fraud.

3. Close the loophole which allows uncertified handlers to both buy/sell organic products, as well as to physically take possession.
    a. Handlers who take possession of organic products in unsealed containers, where they could sort, consolidate, relabel or otherwise compromise the contents or container label, must be certified. This would include warehouses, transfer areas, repack operations, retail consolidation locations among others.
    b. Handlers who do not take physical possession, but instead buy/sell or broker product, must be certified. This would include exporters, traders, importers, brokers and others.
    c. Handlers who manage private labels that have an organic claim, which they then sell into the marketplace, must be certified.

4. In addition to the education of inspectors and internal certification personnel, information on the requirements of organic certification should be developed specifically targeted to handlers to improve their sourcing, processing, and sales of organic products. A goal of this education would be to harmonize, where possible, the procedures used in the trade that track organic compliance. Better understanding of NOP organic crop production is also needed. For example, washing off prohibited pesticide residue does not result in a NOP compliant product.

5. Certification agencies should improve upon the Handler Organic System Plan, by increasing the focus on the *system* that verifies the ingredients, processing, transfer and storage are compliant with organic regulations. Is the system robust enough to address risk to the supply chain for that specific type of business? Are there multiple sources of ingredients? Are they domestic or imported sources?

6. Does every organically sold product, have clear correlation between the information on the certificate, the shipping documentation, and the physical product with the source, certifier, and company name, beyond just the lot number?
    a. At times, in order to maintain a proprietary source a supplier may not wish to have their sources disclosed to their buyer. How can this be addressed?

7. When known, all certifiers provide acreage and possible yields of organically grown commodities for tracking in the Organic Integrity Database. Are there confidentiality issues that need to be addressed? How do we track this information for foreign organic commodities certified under equivalency or recognition agreements?

8. Implement the use of transaction or import certificates for all imported product and track in a database the source, volume, and type of commodity imported.

9. The organic industry could setup an alert system, where buyers who reject a product due to concern of the validity of organic certification, could present this information so other buyers could do their own review before purchase and/or processing or resale.

10. If the supply chain has been identified in the trade as having risk of fraud, does the supplier or certifier perform pesticide residue testing? Is there clear documentation that all transportation and warehousing has been verified as protecting organic integrity by preventing commingling with nonorganic product or contamination by prohibited substances? Maintain a database of positive pesticide residue tests (similar to the EU).

11. In determining areas of risk, does the supplier or certifier take into account:
    a. The distance between the production of the item and the ultimate consumer.
    b. The social pressures found along the supply chain, that might discourage oversight of high-status individuals or companies.
    c. The market demand coupled with short supply of the commodity.
    d. The economic pressures found along the supply chain that might encourage the sale of nonorganic products as organic.
    e. Are samples retained along the supply chain; and if so, is pesticide residue testing being done? Are the pesticide residue results transparent?
    f. The number of intermediaries and or borders crossed between raw supplier and final buyer.
    g. The number of legal entities in the marketplace owned by one supplier that moves product internally as well as externally, making it difficult to track which entity has possession as the product moves through the supply chain.
    h. There is a very large volume of organic product being bought and sold.
    i. The handler manages both organic and nonorganic.
    j. Approach risk assessment and oversight by providing higher scrutiny to the 20% of operations that would affect 80% of the commodities traded.

12. The National Organic Program could improve its oversight through the following activities:
    a. Dedicate staff to oversee the tracking of organic grain being imported from overseas though tools such as “Vesseltracker”.
    b. Improve the regulations by requiring all handlers, both those that take physical possession and those that do not, to become certified organic and provide oversight of organic inspection.
    c. Work with certifiers and the trade for the development of an “approved supplier” list for businesses that import organic into the United States. The European Union has a system like this in place.
        1. Each entity could be assigned a unique number or code, that would then be used by their sub-entities, private labels or other identification in the marketplace, to more easily track which companies are part of a larger parent company, even though they have a different name.
    d. Dedicate funds to aid in spot checking commodities for pesticide residues, in high risk operations. Certifiers could handle the risk assessment, sample collection and testing, and get reimbursed by the NOP for the cost of the testing. This could be tried as a pilot project first, with a limitation on the samples taken.
    e. Review blockchain technology and geotagging as two systems that could enhance and provide redundancy to the current certificate and documentation system which have shown vulnerability to counterfeit or scams by sophisticated operations.
    f. Strengthen requirements for certifier attendance at NOP trainings, and verify during accreditation audits that appropriate staff have been advised of the information obtained at those trainings.

IV REQUEST FOR PUBLIC COMMENT

1. Are there additional activities missing from the list above that would result in better oversight and enforcement of the organic regulations?

2. Are there specific items above that are impractical or difficult to implement and why?

3. Please provide your thoughts on how these items should be prioritized. E.g. by importance? By ease of implementation?

V Subcommittee vote

Motion to accept this discussion document on oversight improvements to deter fraud
Motion by: Harriet Behar
Seconded by: Lisa de Lima
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Sue Baird, Subcommittee Chair to transmit to NOSB, February 21, 2019

National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Oxalic Acid
February 5, 2019

Summary of Petition for Oxalic Acid Dihydrate:

A petition for oxalic acid was received in October 2017 requesting 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). In 2010, the National Organic Standards Board made a recommendation on Organic Apiculture that included oxalic acid for use for control of varroa mites in honeybee hives. The recommendation was not implemented by the USDA.

Currently there are two materials on the National List that are used as pesticides to control varroa mites in honeybee hives. The National List states the following:

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).

At the NOSB October 2018 meeting, the NOSB recommended to remove sucrose octanoate esters (SOEs) from the National List. SOEs are not available for use by beekeepers, since they are no longer EPA registered. In addition, SOEs are ineffective for varroa mite control. 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.

A petitioned material discussion document was presented at the October 2018 NOSB meeting in St. Paul, to begin gathering public comment on this material. These questions were asked:

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 is used for mite control. Why are the other materials/methods insufficient for varroa mite control in organic production?

There were no substantive comments presented, other than three organizations stating there should be organic apiculture standards in place before materials are placed on the National List for this unique agricultural system. Apiculture standards were recommended by the NOSB, but the NOP has not implemented this recommendation. Organic apiculture products such as honey, beeswax, and more are only certified by a few of the accredited certifiers under the NOP.

Summary of Review:

In October 2018, a Technical Evaluation Report was received by the NOSB. Oxalic acid dihydrate (CAS number 6153-56-6 and 144-62-7) is petitioned as an alternative treatment to formic acid for varroa mites. Three EPA-approved application methods would be allowed under this petition: by solution to package bees, by solution to beehives, and by vapor treatment to beehives. Oxalic acid is naturally occurring in plants, fungi, bacteria and animals, as well as honey. Vegetables such as beet leaves,

spinach, chard, and rhubarb contain oxalic acid. It also can be produced in the human body through the metabolism of glyoxylic acid or ascorbic acid.

This material can be used in rotation with, or instead of, formic acid. Current research indicates that the amount of oxalic acid typically applied to the honeybee hive is not toxic to the bees, and is sufficient to kill varroa mites.

This material has been used for many years by hobby beekeepers, who developed methods for dispensing oxalic acid as a vapor into their hives. Recently, a more commercial method of delivery was developed to include use as a spray on bees, or trickled as a liquid into the hive, making its use available to a wider audience of beekeepers. Oxalic acid can be in direct contact with bees, at the approved levels, as well as with components of the hive in order to provide effective varroa mite control. Application in the hive is done when there is no brood present. Detailed methods of application are noted in the TR.

At the time the TR was written and received, it was noted that oxalic acid for parasite control in beehives was not allowed in all states. The Livestock Subcommittee requested further information, and it was clarified that state-level registration had not been completed.

The Subcommittee discussed whether apiculture materials should be reviewed and approved only after there are NOP apiculture standards. It was noted that the NOP currently allows for organic honeybee products to be sold with the USDA organic seal, and honeybee products are certified organic by numerous NOP accredited certifiers. All Livestock Subcommittee members support the implementation of the 2010 NOSB recommendation for organic apiculture standards.

Specific Uses of the Substance:

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 have been a problem for beekeepers and the use of a sugar/oxalic acid syrup spray is a useful method to address this issue. Varroa mites, an invasive pest, are one of the many production problems affecting the livelihood of beekeepers.

Numerous chemical varroa mite treatments have been used over the years in nonorganic operations. Many of these treatments are no longer effective due to the development of resistance by the varroa mite. Formic acid has been used for many years in honey bee hives, with no varroa mite resistance. It is considered unlikely that resistance will occur. Similar to formic acid, it is unlikely that varroa mites will develop resistance to oxalic acid.

Approved Legal Uses of the Substance:

Oxalic acid has been used against varroa mites since the early 1980s. Oxalic acid is allowed under the Canadian Organic Standards as follows:

- CAN/CGSB-32.310-2015 Clause 6.6.10: *"The use of veterinary medicinal substances shall comply with the following: (a) if no alternative treatments or management practices exist, veterinary biologics, including vaccines, parasiticides or the therapeutic use of synthetic medications may*

be administered, provided that 408 *such medications are permitted by this standard and Table 5.3 of CAN/CGSB-32.311 or are required by law."*

- CAN/CGSB 32.311-2015 Table 5.3: Healthcare products and productions aids as follows: "*Oxalic acid: For mite control in honeybee colonies"*

The EU regulation has this annotation:

- EC No 889/2008: Chapter 2 (Livestock production): Section 4 (Disease prevention and veterinary treatment), Article 25 (Specific rules on disease prevention and veterinary treatment in beekeeping): *"6. Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with Varroa destructor."*

It is allowed under Codex Alimentarius and well as IFOAM standards. Japan does not have apiculture standards and oxalic acid is not present on their list of approved materials. As of the writing of this proposal, oxalic acid is currently registered for use in beehives by the EPA in all but one state, California.

Action of the Substance:

The mode of action of this substance is not clearly understood, but it appears to be attributed to its acidity (pH near 0.9). Oxalic acid will cross the exoskeleton of the mites in a few hours of application and cause death. Oxalic acid vapor can enter the mite through the soft pads of its feet, enter the mite's blood stream and kill it. When mites parasitize and suck on the bee, it can kill the mite through this method as well. There is no clear research to determine if one or all of these are the main modes of action.

Manufacture:

Oxalic acid is a dicarboxylic acid, which is in a crystalline form when solid, but loses this structure when dissolved in water. Commercial oxalic acid is produced through a variety of chemical reactions that include oxidation of carbohydrates or alkenes as well as synthesis from carbon monoxide and water. Oxalic acid crystals are produced through precipitation of the crystals from the mother liquor. Oxalic acid can also be produced through microbial fermentation of products such as citric acid, but these are not the typical method for commercial production.

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.

   Oxalic acid dihydrate is produced through a chemical process as described above under "manufacture".

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?

Oxalic acid is a livestock parasiticide.

Category 2: Adverse Impacts

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

   There are no issues with chemical interactions when using other materials used in organic farming systems. The use is limited to direct contact on honeybees either in packages or in the hive. Both oxalic and formic acid can be toxic to honeybees, if used above the recommended rates.

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)]**

   Oxalic acid is naturally occurring in the environment, has low persistence and no potential for accumulation in the food chain. It readily biodegrades both under anaerobic and aerobic conditions. Oxalic acid will not volatilize at room temperature nor concentrate in aquatic organisms and breaks down readily in surface waters and soil surfaces. It degrades into carbon dioxide and water. Oxalic acid is a naturally occurring component of honey. Research has shown no increase of oxalic acid in honey, beeswax or bees after an oxalic acid treatment.

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

   There are no concerns of environmental contamination during manufacture or disposal. The amount used for honeybees is fairly small and does not add to concentrations of greenhouse gases in the atmosphere, and would not have widespread negative impact due to its biodegradability. Misuse of higher-than-recommended concentrations of oxalic acid could result in killing honeybees.

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

   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 or polishing metal. Trade magazines have noted that a pad containing oxalic acid may be developed, similar to formic acid currently used in honey bee hives. This method of dispersal offers a safer alternative than handling the oxalic acid crystals as a liquid or vapor.

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 potential for varroa mite resistance is very low, and has not occurred with formic acid, which has been used more pervasively and for a longer time period than oxalic acid. Having two acids that can be used in rotation is a good strategy to lessen the potential for resistance. There is some concern that oxalic acid could build up on the brood wax in a hive, and cause some damage to developing bees. It appears small amounts can persist in wax for up to six months. This material biodegrades readily on the soil surface and if used properly, will not be in contact with soil.

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

   Since oxalic acid is naturally occurring in the environment and this use is limited to the physical location where bees are congregated, hives and cages, there does not appear to be any negative effects on biodiversity. This material effects only the targeted pest, varroa mites.

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)]**

   Formic acid is currently on the National List as approved for external parasite control for honeybees. Thymol, the natural essential oil (vs. the synthetic form), is also used to control varroa mite in organic operations. Menthol has been used to control tracheal mites, but there is no specific literature detailing menthol's single use effectiveness against varroa. Peppermint and eucalyptus essential oils are exempted from EPA registration and along with menthol, are the ingredients in a widely used product to control varroa mite, Api Life Var, produced in Italy. Hop beta acids are also EPA registered for use to control varroa mites, but since it volatilizes readily, numerous applications are needed for effective treatment. Neem oil has been found effective, but resulted in a significant loss of honey bee brood, there are no EPA registered neem-based formulations for varroa mite. Acetic, citric, costic and lactic acids have been studied, with little to some effectiveness found. Coating honeybees with powdered sugar has also been used, since the bees then groom themselves and the mites drop off. This needs multiple applications. Physical methods of varroa mite management are also used by many beekeepers including the use of screened bottom boards which allow mites to fall through and then they cannot then crawl back up into the hive. Drone comb traps are also used. Drone cells are more attractive to mites, and they tend to use these cells more readily. Removal of the drone comb throughout the brood season, before the larvae hatch, can significantly lower the numbers of varroa mite in a hive. Use of an acid vapor or spray, drone comb and screened bottom boards are typically used together, to improve the effectiveness over the use of just one or two of these activities.

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

   Since oxalic acid is naturally occurring in the environment as well as in honey, and its use has little to no negative environmental impact, its use is not considered damaging to the ecosystem. In the past decade or so, beekeepers have been dealing with numerous

environmental and invasive pest problems, significantly lessening the populations of honeybees around the world. Oxalic acid is another useful tool in the toolbox to be used in rotation with formic and natural essential oils to lessen the destruction caused by varroa mites. Physical activities contribute to varroa mite control as well and are part of an overall integrated pest management system. Honeybees are well known as an important pollinator of many of our foods, and providing another environmentally benign tool to beekeepers will be useful to the small, but growing number of organic beekeepers. The main negative aspect of this material is the need for safety precautions. Humans handling this acid should protect their skin and respiratory systems by using protective equipment.

Classification Motion:

Motion to classify oxalic acid dihydrate as a synthetic substance
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add oxalic acid dihydrate to §205.603(b) "as topical treatment, external parasiticide or local anesthetic as applicable" with the annotation "For use as a pesticide solely for apiculture."
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 5 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Approved by Scott Rice, Livestock Subcommittee Chair, to transmit to NOP February 5, 2019

National Organic Standards Board
Livestock Subcommittee Discussion Document
Use of Excluded Method Vaccines in Organic Livestock Production
February 19, 2019

Introduction and Background

The Livestock Subcommittee requested that the "use of vaccines in organic livestock production made through excluded methods" be placed on the NOSB's work agenda, and this request was approved on November 6, 2018. There are two areas in the organic regulations that address use of vaccines; one on the National List (NL) of allowed and prohibited substances, and in the section that details excluded methods. Through public comment and direct interaction with certifiers and organic producers, it became apparent that there are inconsistencies between certifiers in what vaccines are allowed to be used. Some certifiers do not allow the use of excluded method vaccines, relying on the NOP regulation at §206.105 (e) which only allows use of this type of vaccine if it has gone through NOSB review and NOP placement on the National List. Other certifiers allow any type of vaccine to be used, and may or may not inquire if the vaccine has been produced through excluded methods or not. These certifiers rely on the presence of vaccines on the National List at §205.603(a)(4) without any restriction or clarifying annotation.

This issue was reviewed by the NOSB in August 2014, with a "Findings and Recommendation in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods". Challenges that prevented immediate attention to this issue included: having an updated definition of excluded methods that determines if new technologies were to be excluded methods for organic, having a clear understanding if there were non-excluded method vaccine equivalents to excluded method derived vaccines and how to provide for use of excluded method vaccines if there was an emergency when only an excluded method vaccine could address the problem in a timely way.

In August 2017, the NOSB Materials Subcommittee passed a recommendation that addresses how to determine if specific technologies should be considered excluded or not, with descriptions, terminology and a listing of excluded, not excluded and yet-to-be-determined methods. The NOSB is using this recommendation to review new technologies as they develop. The August 2014 NOSB recommendation lists commonly used vaccines that are known to have been made through excluded method technology. With these issues clarified, the current NOSB is ready to address this issue and provide consistency and certainty for organic livestock producers.

The Subcommittee recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal's production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, 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. The possibility of a livestock health emergency is real, and the NOSB is addressing it now in order to have a solution in place before a crisis might occur.

Relevant Areas of the Rule and Guidance
From the NOP Rule:

§205.2 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.

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.

§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)

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.
The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

The preamble to the National Organic Program final rule (FR Vol. 65, No. 246, page 80554 or page 14 of the pdf) states:

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted

this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

Excerpt from NOP Memo to NOSB dated September 30, 2010

> The NOP's understanding is that excluded methods are prohibited under Section §205.105(e) *except for* vaccines. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under §205.603(a)(4) under "Biologics-Vaccines". The NOSB has not reviewed vaccines in accordance with §205.600(a). The listing under §205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).
>
> The NOP recommends that the NOSB review GMO vaccines under the provisions of §205.600(a). The NOP suggests that the Board request a technical review for biologics-vaccines, including the status of genetically modified vaccines and an assessment of the economic impact of using commercial availability criteria for non-genetically modified vaccines. After the Board completes the evaluation according to the OFPA criteria, it may submit a recommendation to the NOP to add GMO vaccines to the National List of Allowed and Prohibited Substances.

Discussion

The Livestock Subcommittee strongly supports the use of vaccines as an essential component of maintaining animal health and promoting animal welfare. Currently, §205.105(e) requires excluded method vaccines be reviewed and placed on the National List before use. This approach is impractical for a variety of reasons:

- There are new individual vaccines continually being developed; the NOSB will have difficulty reviewing these in a timely manner.
- Putting each of the excluded method vaccines on the NL is a lengthy process (2+ years) and puts organic livestock at risk in emergency situations when that vaccine may be needed immediately.
- Some excluded method vaccines may be patented and there may be confidential information that will not allow NOSB standard review of the material.
- Both the European Union and Canadian organic standards do not differentiate between the use of excluded method vaccines or standard vaccines, putting US organic livestock producers at a disadvantage when addressing animal disease.
- Some certifiers observe this restriction, and do not currently allow any excluded method vaccines, while others ignore this restriction and allow excluded method vaccines or do not determine if a vaccine is made from an excluded method or not. This inconsistency causes problems for some producers and may lead to "certifier-shopping". Any time we can correct an inconsistency, we increase the trust of the organic certification system for both producers and consumers.

The Livestock Subcommittee, and we believe the full NOSB, is committed to not endorsing the blanket use of excluded method technologies. We seek to find a pragmatic way to stand against pervasive use

of excluded methods in organic agriculture and foods, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. Here are some considerations if there is an allowance of excluded method vaccines "as a class" with no restriction.

- This is what is currently done in Europe and Canada.
- Less documentation needed by operators and certifiers.
- Allows for use of needed vaccines in an emergency with no restrictions.
- New excluded method technologies might provide additional animal health effects beyond just control of a specific disease, having a carte blanche approach might have unintended consequences beyond our intention of preventing animal illness.
- Might open the door to more use of excluded methods in organic.

As a third option, the regulatory change could require that vaccines from excluded methods only be used when there are no commercially available vaccines produced without excluded methods. This option, somewhat of a compromise between the two options above, has its own set of issues.

- We need a clear definition of "commercial availability" when searching for vaccines made without excluded method technology and what documentation is sufficient to prove this search.
- Operators and certifiers are accustomed to "commercial availability" since it applies to use of organic seed and agricultural products found on §205.606.
- Would allow for quick use of an excluded vaccine in an emergency, when no other option is available.
- Encourages market availability of vaccines not made with excluded methods by providing buyers for these vaccines and showing a need for their continued manufacture.
- Might be difficult to clearly identify all vaccines are from excluded methods and which are not. We have a current list of widely used vaccines, but there may be others used regionally or sporadically that we do not have clear information.

Questions for the public

The Livestock Subcommittee sees three possible regulatory solutions and asks the public to provide feedback.:

1. Follow the requirements of §205.105 (e) and start reviewing known excluded method vaccines for individual placement on the National List.

2. Approve all vaccines produced through excluded methods as a "class" of vaccines and place this class of vaccines on 205.603(a)(4).

3. Change §205.105 (e) to read as follows:

   (e) Excluded methods, except for vaccines: Provided, That, there are no commercially available vaccines that are not produced through excluded methods to prevent that specific animal disease or health problem.

In addition, please provide information on the following:

4. What type of documentation would be used to prove non-commercial availability of vaccines produced without excluded methods?

5. When reviewing vaccines under commercial availability, are there special issues that should be considered?

Vote in Subcommittee

Motion to accept the “Use of Excluded Method Vaccines in Organic Livestock Production” discussion document
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB February 19, 2019

Sunset 2021
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2019

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

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2019 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2019 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 4, 2019, as explained in the meeting notice published in the Federal Register.

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

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

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

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

(1) not harmful to human health or the environment;

(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic livestock production.

For Comments That Do Not Support Substances under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with livestock production.

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

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

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

Written public comments will be accepted through April 4, 2019, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2021
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2019

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

Atropine
Hydrogen peroxide
Iodine (§205.603(a))
Iodine (§205.603(b))
Magnesium sulfate
Parasiticides: Fenbendazole
Parasiticides: Moxidectin
Peroxyacetic/Peracetic acid
Xylazine
DL-Methionine
Trace minerals
Vitamins

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Atropine

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:**

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 Technical Report
Petition(s): 2002 Petition
Past NOSB Actions: 05/2003 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Atropine is an anti-cholinergic derived from *atropa belladonna* (deadly nightshade) roots; it is isolated via various synthetic extraction processes. It is a highly controlled substance, administered under orders of a veterinarian; its primary use is as an antidote for organophosphate poisoning, which most commonly occurs through ingestion of pesticides. The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI). According to the 2019 TR, atropine is itself toxic, with the risk of toxicity dependent on the relative ability of various species to metabolize atropine (cattle and pigs are the agriculturally most sensitive to atropine toxicity).

Range of uses. According to the 2019 TR: "Within the context of livestock veterinary applications, atropine has been used in a variety of ways...a treatment for organophosphate poisoning by reversibly blocking acetylcholine receptors; a preanesthetic for veterinary surgical procedures due to its ability to reduce secretions and relax muscles; a bradycardia treatment to raise heart rates following anesthesia in surgical procedures; a veterinary ophthalmological treatment as it relaxes ocular muscles, relieves pain, dilates pupils, and affects iris permeability for glaucoma treatments…."

International allowance for use. According to the 2019 TR, atropine is listed on the Canadian General Standards Board Permitted Substances List. However, it is not listed for use under:

- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods;
- European Economic Community (EEC) Council Regulations;
- Japan Agricultural Standard (JAS) for Organic Production; or
- International Federation of Organic Agriculture Movements (IFOAM).

Environmental contamination. According to the 2019 TR, "Due to the limited application of atropine (for veterinary medicine, approved for use only when used or ordered by a veterinarian), and the small quantities administered (milligrams), atropine is unlikely to be a source of environmental contamination…." The 2019 TR also states that "There are no reported studies on the persistence or

concentration of atropine (neither D-hyoscyamine nor L-hyoscyamine), or the metabolized products tropine and tropic acid, although tropine has been identified as 'readily biodegradable' …. Tropine has also been identified as toxic to aquatic invertebrates, including *Daphnia magna* (water fleas) at concentrations of 54.7 mg/L…."

Effect on human health. According to the 2019 TR, "Atropine is most commonly administered intravenously, although it may also be applied via ingestion, or ocular absorption (applied directly to the eye) …. Intravenous administration of the substance using proper medical protocols (e.g., gloves, premeasured doses) makes inadvertent human absorption unlikely. Due to the neurophysiological profile of atropine, its absorption also poses toxicological concerns. Atropine intoxication is associated with symptoms including abdominal pain, confusion and disorientation, hallucinations, urinary retention, hypothermia and tachycardia …. Atropine toxicity can be lethal in humans, however, the level of toxicity and its relationship to fatal outcomes is not well defined."

Natural (non-synthetic) alternatives. According to the 2019 TR, "Atropine is recognized as the most efficient treatment option for organophosphate poisoning within both human and veterinary medicine…." The TR also states that "Magnesium sulfate ($MgSO_4$) is approved for use in organic livestock production at 7 CFR 205.603, and is being studied as a potential alternative or additional treatment to atropine administration for organophosphate treatment protocols…." However, this substance "has seen little clinical applications, and more studies are required to evaluate its effectiveness compared to traditional atropine and atropine oxime combination treatments…."

Additional information requested by the Subcommittee:

1. For what veterinary medical purposes, if any, is this substance currently being used in organic production?
2. How widely used and essential is this substance by organic producers?
3. Are there alternative substances, whether natural or synthetic, considered preferable for use in organic production? If so, what are these substances?

Hydrogen peroxide

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (15) Hydrogen peroxide.**
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Hydrogen peroxide is used as a readily available disinfectant and broad-spectrum germicide. It is an important cleaning agent for use on contact surfaces, such as equipment, calf pails, bottles, and utensils. The material is used to clean wounds and was first registered with the EPA in 1977.

Manufacture:

Hydrogen peroxide is a very simple molecule with a formula of H_2O_2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

International Acceptance:

The 2015 TR notes that a subset of the international organizations surveyed have provided guidance on the application of hydrogen peroxide for disinfection and plant disease control in organic crop production.

> Canadian General Standards Board: allows numerous uses of hydrogen peroxide in organic production. Section 5.3: “Health care and production aids for livestock production” lists pharmaceutical grade hydrogen peroxide for external use as a disinfectant, and food-grade hydrogen peroxide for internal use (e.g., livestock drinking water). Hydrogen peroxide is also listed in Section 7.3: “Food-grade cleaners, disinfectants and sanitizers” that are allowed without mandatory removal of residues, and 7.4: “Cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production” (CAN, 2011).
>
> European Union: According to Annex VII of EU regulation 889/2008, hydrogen peroxide is allowed for cleaning and disinfection of buildings and installations for animal production. Specifically, hydrogen peroxide can be used to satisfy Article 23 (4), which states that “housing, pens, equipment and utensils shall be properly and disinfected to prevent cross-contamination and the buildup of disease carrying organisms.” Hydrogen peroxide is also permitted for use in the production of gelatin under Section B of Annex VIII: and substances for use in production of processed organic food (EC, 2008).

International Federation of Organic Agriculture Movements (IFOAM): Hydrogen peroxide is permitted under Appendix 4 – Table 2 of the IFOAM Norms as an equipment cleanser and disinfectants. In addition, Appendix 5 lists hydrogen peroxide as an approved substance for pest and disease control and disinfection in livestock housing and equipment (IFOAM, 2014). The Norms make not mention of hydrogen peroxide for plant disease control and prevention.

UK Soil Association: Standards permit the use of hydrogen peroxide only as a cleaning product for livestock housing areas. No conditions are provided allowing the use of hydrogen peroxide for plant disease control and prevention (Soil Association, 2014).

Environmental Issues (could include human health issues):
Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

Discussion:
Hydrogen peroxide is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995 (Crops), the technical review of October 2015, the unanimous NOSB 2017 support of this material, and no new scientific or meritorious information.

Additional information from Subcommittee:
Is this synthetic material a necessary input in organic livestock production?

Iodine—§205.603(a)

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (16) Iodine.**
Technical Report: 1994 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre-milking and post milking.

Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor, and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus anti-microbial teat dips used in pre and post milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

Additional information requested from Subcommittee:

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so, what might be substituted?

2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?

3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Iodine—§205.603(b)

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. **(3) Iodine.**

Technical Report: 1994 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 3/15/2022

Background from Subcommittee:

Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre-milking and post milking.

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Additional information requested from Subcommittee:

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so, what might be substituted?

2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?

3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Magnesium sulfate

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. **(19) Magnesium sulfate.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:
Specific Uses:
Magnesium sulfate has a number of veterinary uses. It acts as an anticonvulsant, laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically, in swine, magnesium sulfate is administered to treat malignant hypothermia.

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed.

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium. If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously.

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle‘s use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium.

Magnesium sulfate, or Epsom salt, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation.

Additional information requested from Subcommittee:
Is this material essential for organic livestock production?

Parasiticides, Fenbendazole

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**.** (23) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
(i) Fenbendazole (CAS #43210-67-9)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.
Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 TR

Petition(s): 03/2007 Fenbendazole

Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 recommendation – annotation change
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 (82 FR 14420); Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: pending

Background from subcommittee:
In veterinary medicine the term parasiticide refers to anthelmintic drugs. Anthelmintics are medications capable of causing the evacuation of parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]). The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state does not include the routine use of parasiticides. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed flocks. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected and without treatment parasite infestation can lead to disease and potentially death (Stockdale, 2008).

A petition for inclusion of fenbendazole on the National List was received by the NOP, March 23, 2007. Fenbendazole was added to the National List effective May 12, 2012. A technical review was completed in 2015 to review fenbendazole, ivermectin, and moxidectin as one group. The technical review documented that parasiticide resistance management has become an important issue in animal health and that increased use of anthelmintics in livestock production may lead to subsequent selection and

increased parasiticide resistance (Xu et al., 1998; James et al., 2009). As a result, if resistance to one drug occurs, then other drugs with the same mode of action or binding site will also be ineffective.

Fenbendazole and moxidectin are the only anthelmintics approved for use in organic livestock production. Fenbendazole works very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β-tubulin and ion channel proteins targeted by these anthelmintics. This allows the worms in subsequent generations to avoid drug binding and enables drug resistance. Fenbendazole acts selectively by binding to nematode β-tubulin. Binding β-tubulin disrupts the nematode digestive system and prevents egg formation, while potentiating the GLUCL channel causes spastic paralysis.

Fenbendazole is sold as Panacur and Safe Guard. The orally administered product contains polysorbate 80, simethicone emulsion 30%, benzyl alcohol and purified water. Fenbendazole paste contains the excipients carbome homopolymer type B (Allyl pentaerythritol crosslinked), propylene glycol, glycerin, sorbitol, sodium hydroxide, water, methylparaben and propylparaben.

Risks with the use of Fenbendazole:

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). All FDA livestock approved parasiticides are synthetically produced substances shown by experimental and clinical studies to be safe for application to food animals. The excipients are usually United States Pharmacopoeia (USP) grade chemicals and also subject to FDA approval.

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

The fate of fenbendazole in manure and manured soils has been studied under laboratory and field conditions. After a 102- day incubation period, 80% of fenbendazole remains. The latter was accompanied by 4% of the corresponding metabolite fenbendazole-sulfoxide. Fenbendazole-sulfoxide remains in clay soil samples after 54 days (Kreuzig et al., 2007). Fenbendazole toxicity was demonstrated in pigeons and doves, leading the authors of the study to suggestion a toxic etiology for fenbendazole in birds of the order Columbiformes treatment (Howard et al., 2002).

International Status:

Review of the International Organic Standards- The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production- all shows a commonality: Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. The International Federation of Organic Agriculture Movements (IFOAM) has additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Additional information requested by Subcommittee:

1). Do livestock producers still have a necessity for the usage of fenbendazole for emergency treatment of parasites when good pasture management techniques are being used?

Parasiticides, Moxidectin

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**.** (23) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock **(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.**
Technical Report: 2003 TAP (Moxidectin); 2015 TR
Petition(s): Moxidectin
Past NOSB Actions: 05/2004 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 NOSB recommendation - annotation change
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: pending

Background from Subcommittee:
In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites. Anthelmintics are medications capable of causing the evacuation of parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]). The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state that does not include the routine use of parasiticides. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed flocks. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected, and without treatment, parasite infestation can lead to disease and potentially death (Stockdale, 2008).

Moxidectin, a derivative of nemadectin is a chemically modified Streptomyces cyanogriseus fermentation product (Asato and France, 1990). The NOSB recommended adding moxidectin to the National List in 2004 with the restriction that it only be allowed for use to control internal parasites, but in the proposed rule published on July 17, 2006 USDA announced its decision that moxidectin would not be proposed for inclusion on the National List because of its macrolide antibiotic classification, which was inconsistent with NOP policy prohibiting the use of antibiotics in organic livestock production.

Based upon the evidence received through public comments on the July 17, 2006 proposed rule, the NOP verified the information supplied by commenters and, subsequently, concurred that moxidectin, though categorized as a macrolide antibiotic, does not function as such when used as a parasiticide. In a final rule (72 FR 70479) published in the Federal Register on December 12, 2007, USDA announced that moxidectin would be added to the National List through a future rulemaking action, and in 2011 NOP proposed to add moxidectin. The Final Rule in 2012 added moxidectin to National List for the first time.

The NOSB received a technical review (TR) in 2015 for Moxidectin, along with Fenbendazole and Ivermectin. The TR documented that parasiticide resistance management had become an important issue in animal health and that increased use of anthelmintics in livestock production may lead to subsequent selection and increased parasiticide resistance. As a result, if resistance to one drug occurs, then other drugs with the same mode of action or binding site will also be ineffective. Fenbendazole, ivermectin and moxidectin individually work very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β-tubulin and ion channel proteins targeted by these anthelmintics, allowing worms in subsequent generations to avoid drug binding and enables drug resistance. Moxidectin, the only milblemycin approved for use in organic livestock production, selectively binds to nematode β-tubulin and potentiating the glutamate-gated chloride (GLUCL) channel. Binding β-tubulin disrupts the nematode digestive system and prevents egg formation, while potentiating the GLUCL channel causes spastic paralysis.

Risks with the use of Moxidectin:
The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). Moxidectin is an FDA-approved livestock parasiticide that is a synthetically produced substance which has been shown by experimental and clinical studies to be safe for application to food animals.

Moxidectin is excreted in feces but is both microbially and photo-degraded in dung pats in the soil. It is the least toxic to dung beetles of the macrocyclic lactone anthelmintics. Moxidectin peaks in 2 days in feces after treatment and decreases to less than 10 ppb by 37 days after treatment. The half-life for degradation of moxidectin in the environment may be up to 130 days.

International Status:
Review of the International Organic Standards- The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production- all shows a commonality: Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. The International Federation of Organic Agriculture Movements (IFOAM) has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Additional information requested by Subcommittee:

1). Do livestock producers still have a necessity for moxidectin for emergency treatment of parasites when good pasture management techniques are being used?

Peroxyacetic/peracetic acid

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. **(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.**

Technical Report: 2000 TAP ; 2016 TR

Petition(s): 2008 Petition

Past NOSB Actions: 11/2000 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 3/15/2022

Background from subcommittee:

Specific Use:

According to TR line 88, peracetic acid is listed for use in organic livestock production for sanitizing facility and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment and hard surfaces. TR line 99 states, peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment.

Beginning at TR line 288: The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture:

Solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid."

International Acceptance:

The March 2016 TR outlines the following guidelines from international organizations regarding the use of peracetic acid as a disinfectant, sanitizer and medical treatment.

Canada: Peracetic acid does not appear in paragraph 5.3 (Health Care Products and Production Aids) of the CAN/CGSB-32.311-2015 Permitted Substances List. It is, however, listed at paragraph 7.3 as a food-grade cleaner, disinfectant and sanitizer permitted with a mandatory removal event, with the following annotation: "On food and plants: peracetic acid may be used in wash or rinse water. Peracetic acid may also be used on food contact surfaces." This allowance is consistent with the NOP regulations at 7 CFR 205.603.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (GL 32-1999): The Codex Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) do not mention any permitted sanitizers. Peracetic acid also does not appear on Annex 2 (Permitted Substances for the Production of Organic Foods) in the guidelines.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008:
Peracetic acid is a permitted product for cleaning and disinfection of buildings and installations for animal production (EC No 889/2008 - Annex VII - Products for cleaning and disinfection referred to in Article 23). Peracetic acid and peroctanoic acid are permitted materials for cleaning and disinfection of equipment and facilities in the presence as well as in the absence of aquaculture animals (EC No 889/2008 - Annex VII point 2.2).

Japan Agricultural Standard (JAS) for Organic Production: The Japanese Agricultural Standard for Organic Livestock Products, Table 4, lists "Agents for cleaning or disinfecting of housing for livestock." Included on this list are "Hydrogen Peroxide Solution" and "Cleaning agents and disinfectants for milking equipment, rooms and buildings." Peracetic acid is not
specifically mentioned.

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM norms permit use of peracetic acid for cleaning equipment and disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), and for disinfection of livestock housing and equipment (IFOAM

Environmental Issues:
Peracetic acid is considered to be an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain.

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain.

Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(a)pyrene and methylnaphthalene in lake sediments through oxidation of the parent compound.

Discussion:
The National Organic Standards Board (NOSB) previously reviewed peracetic acid as a disinfectant, sanitizer, and medical treatment in accordance with 7 Code of Federal Regulation (CFR) § 205.603(a). Recently, peracetic acid also has been used to clean stalls and to disinfect livestock, particularly dairy cattle. Acetic acid and hydrogen peroxide both have a longer history of use in livestock production than commercial preparations of peracetic acid, but the substance has, in effect, been used by farmers who combine vinegar and peroxide in a cleaning solution.
Peracetic acid is recommended for relisting based on the available 2000 technical advisory panel (TAP), the technical review of March 2016, the unanimous NOSB 2017 support of this material, and no new scientific or meritorious information.

The NOSB has reviewed few materials for use in barns, stalls, stables and milking parlors, leaving relatively few options for producers.

Additional information from Subcommittee:
Is peracetic acid still necessary for organic livestock production?

Xylazine

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (30) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:**

(i) Use by or on the lawful written order of a licensed veterinarian, and;

(ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 Technical Report
Petition(s): 2002 Petition
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: pending

Background from subcommittee:
Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine.

Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures. Xylazine is commonly used in conjunction with tolazoline, which is a reversal agent for sedatives such as xylazine.

International allowance:

- **Canadian General Standards Board Permitted Substances List**
  Xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list in Table 5.3 “health care products and production aids,” as a “sedative.”

Tolazoline (most commonly used as a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list.

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

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**
  Neither xylazine nor tolazoline are listed in the EEC EC No. 834/2007 or 889/2008.

- **Japan Agricultural Standard (JAS) for Organic Production**
  Neither xylazine nor tolazoline are listed in the JAS for Organic Production.

- **International Federation of Organic Agriculture Movements (IFOAM)**
  Neither xylazine nor tolazoline are listed in IFOAM.

Persistence/concentration of xylazine or its by-products in the environment.
According to the 2019 TR: Environmental studies on xylazine…highlight the possible persistence of the substance and its accumulation in soil systems as well as its role as an aquatic pollutant (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017). Reports of xylazine environmental contamination on the Iberian Peninsula may be linked with xylazine manufacturing, resulting in high contributions to water pollution in Iberian river systems (Fabrega et al. 2013, Pugajeva et al. 2017). The leaching ability of xylazine and its reported slow degradation in aquatic systems make wastewater pollution a concern in cases of improper use or disposal (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017).

Effects on human health. According to the 2019 TR:

> Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrythmias, which has resulted in its lack of approval for human medical applications (Green et al. 1981, EMEA 1999, Reyes et al. 2012). Due to the lack of approval for use in human medical applications, information on the mode of action and toxicity of xylazine is limited.
>
> Reported cases of xylazine in humans have shown physiological effects like those seen in veterinary applications (Samanta et al. 1990, JECFA 1998a). Upon absorption of xylazine, patients were difficult to rouse and showed signs of confusion (indicative of central nervous system and neuropathic depression) and expressed symptoms of bradycardia, hypotension (respiratory depression), and hyperglycemia (Gallanosa et al. 1981, Spoerke et al. 1986, Samanta et al. 1990)…. With regard to human carcinogenicity, no studies of direct effects have been published; however, the IARC has designated the xylazine metabolite xylidine as potentially carcinogenic to humans based on studies with laboratory animals (NTP 1990, IARC 1993, JECFA 1998a).
>
> The lethal dosage of xylazine in humans is not well known and appears to vary dramatically between individuals (Spoerke et al. 1986, Ruiz-Colon et al. 2014). Fatal doses of xylazine recorded have been as low as 40 mg, while other individuals have survived exposure to levels as high as 2400 mg (Spoerke et al. 1986, Ruiz-Colon et al. 2014).

Natural (non-synthetic) alternatives. According to the 2019 TR, "No natural alternatives are common for either [xylazine or tolazoline] (i.e., a sedative alternative for xylazine or a xylazine-reversal agent as a

tolazoline alternative). Moreover, while there are several synthetic alternatives for both substances, no other synthetic alternatives have been approved by the USDA for use in organic agricultural production."

Additional information requested by the Subcommittee:

1. For what veterinary medical purposes, if any, is this substance currently being used in organic production?

2. How widely used and essential is this substance by organic producers?

3. Are there alternative substances, whether natural or synthetic, that are considered preferable for use in organic production? If so, what are these substances?

DL-Methionine

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(d) As feed additives. (1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.
Technical Report: 2001 TAP; 2011 TR
Petition(s): 2005 Methionine; 2007 Methionine; 2009 Methionine; 2011 Methionine
Past NOSB Actions: 10/2001 NOSB recommendation; 03/2005 NOSB recommendation; 2008 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation through October 2012; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012; 04/2010 sunset recommendation; 08/2014 Organic poultry feed proposal; 04/2015 NOSB Formal recommendation; 10/2015 sunset recommendation;
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: pending

Background from subcommittee:
Use: Methionine is an essential amino acid for poultry since it cannot be produced biologically by the birds and is necessary for proper cell development for the growing chicks and for proper feathering. The USDA organic standards, which require all agricultural ingredients for livestock come from an organic source, as well as the prohibition of feeding poultry or mammalian by-products to organic poultry or mammals, narrow the options for natural sources of methionine.

Manufacture:
Methionine is a sulfur-containing amino acid. The 2011 technical review lists these various methods of manufacture:

L-methionine may be isolated from naturally-occurring sources, produced from genetically-engineered organisms, or synthesized through many processes. While methionine has been produced by fermentation in the laboratory, racemic mixtures of D- and L-methionine (i.e., DL-methionine) are usually produced entirely by chemical methods (Araki and Ozeki, 1991). Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:

- *Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);*
- *Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);*
- *Use of the Strecker synthesis method with α-methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or*
- *Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998). In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and L-enantiomers (Ajinomoto Corporation, 2012) or by acetylation of synthetic DL-methionine and subsequent enzymatic selective deacetylation of the N-acetylated L-methionine (Usuda and Kurahashi, 2010). Because much of the DL-methionine supply is synthesized using chemical methods, the L methionine produced from it is also synthetic. While nonsynthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005).*

International:
The European Union does not allow synthetic methionine in livestock feed. EU regulations do allow for some use of nonorganic non-GMO agricultural ingredients when organic forms are not available, and these ingredients (e.g., nonorganic corn gluten meal) could provide natural methionine. In 2015, there was non-organic corn gluten meal available in the United States, and a recent review of the NOP organic integrity database noted 12 sources or organic corn gluten meal, with one located in the U.S. and the others in China. Canadian standards allow the use of DL-methionine with no restrictions. However, there is a notation in the current list of allowed materials under the Canadian Organic Standard, that this use of synthetic methionine will be under review in the near future.

Background from Subcommittee:
A petition to allow use of this synthetic amino acid in organic poultry rations was presented to the NOSB in 1999. In 2001, a Technical Advisory Panel analyzed the use of the synthetic DL-methionine and determined that feed supplementation with this material is compatible with an organic system of agriculture, since it is essential to maintain the health of the birds. Synthetic amino acids are not specifically listed as a category of approved synthetics in the Organic Food Production Act.

For almost two decades this material has been present on the National List of approved synthetics, resulting in many written and oral public comments both for and against its allowance in organic poultry production. Those against its allowance state synthetic methionine in the poultry ration enables high concentrations of organic birds to be raised in confinement, with minimal access to the outdoors. In addition, they state that birds who have access to vegetation and bugs on a healthy organic pasture can obtain methionine from these sources and do not suffer negative health effects when there is insufficient methionine (natural or synthetic) in their ration.

Those in favor of synthetic methionine have stated that natural sources of methionine are difficult to provide in sufficient quantities. Crops, such as soybeans, are a source of methionine, but when sufficient soybean meal is fed to meet methionine levels, other levels of amino acids become too high which results in a poorly balanced ration. Excess protein in the ration causes a significant rise in the ammonia levels from manure in the chicken houses, resulting in a lower quality of life for the birds.

Natural sources of methionine have a variety of issues. There are no organic sources of fish meal, crab meal or blood meal. Black soldier larvae would need to be fed in very large quantities, making it impractical since there are no sources producing enough dried larvae to feed the current flocks of organic poultry in the U.S. Algae is another promising area, but has not been developed to determine its acceptability. Items such as whey powder, nonfat dry milk and potato proteins have been tried, but were not fully digestible by the birds. These items and more have been researched by the Methionine Task Force, an ad-hoc citizen group that has provided information to the NOSB over the years, whose members consist of organic poultry operations and animal nutrition specialists.

A final rule published on December 27, 2018, and effective on January 28, 2019, incorporated the NOSB recommendation of April 2015 to adjust the amount of methionine in the feed ration to meet the demands of the birds at different stages of life, while still limiting the total amount of methionine that can be fed over the lifetime of the birds. This change allowed for a specific amount of methionine over the life of the bird rather than how much would be allowed per ton of feed prepared for the organic flock. Typically, a higher percentage of methionine is needed in the ration when the birds are young and growing. Organic poultry producers, through public comment, stated the previous annotation requiring a specific amount of methionine in each ration led to poor immune system development, poor feathering, feather pecking and cannibalism in their flocks. The new annotation, noted above, effective January 28, 2019, will be the listing that the NOSB will vote upon in Fall 2019. The previous annotation was as follows:
Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(d) As feed additives. (1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

In addition to the 2015 NOSB recommendation to modify the annotation for DL-Methionine, the following resolution was passed unanimously by the Livestock Subcommittee.

Resolution: The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

Additional information requested by Subcommittee:

1. What types of ingredients have been tested in feed ration trials with the goal of developing acceptable sources of natural methionine, and what were the results?

2. Are there new options being trialed to find natural and/or organic agricultural sources of methionine that meet the needs of organic poultry?

3. Has there been any research to determine if pastured poultry that has access to growing vegetation, have less of a need for synthetic methionine than poultry that does not have access to living plants, bugs and biologically active soils?

Trace minerals

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(d) As feed additives. **(2) Trace minerals, used for enrichment or fortification when FDA approved.**
Technical Report: 2013 TR Aquatic Trace Minerals; 2019 TR (pending) to be available at https://www.ams.usda.gov/rules-regulations/organic/national-list/m
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 09/2014 aquatic trace minerals subcommittee proposal; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:
Use:
Trace mineral elements, whether naturally occurring in the diet or provided in supplements, are important for the maintenance, growth, and reproduction in the healthy production of beef cattle, swine, and poultry. In beef cattle production, minerals needed in larger amounts include calcium, phosphorus, magnesium, potassium, sodium, chlorine, and sulfur, while iron, zinc, manganese, copper, cobalt, and selenium are needed only in trace amounts (2013 TR Line 178). Forages and grains are good sources of calcium and phosphorus, respectively. However, the bioavailability of minerals in forage may vary depending on the mineral content of the soil and the level of pasture fertilization. Mineral premixes are therefore widely used for livestock feed fortification to ensure the adequate intake of minerals (Hale, 2001). Likewise, poultry and swine production uses dietary supplementation of trace mineral compounds (Richards, 2010). (TR lines 173-180). The NOP has issued a guidance document for the use of minerals in livestock feed, which spells out in more detail which minerals are covered under this listing. It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock Subcommittee acknowledges this listing also includes macro minerals.

Manufacture:
Because this is a broad categorical listing, manufacture varies. According to the 2013 TR, individual mineral compounds are produced on an industrial scale through chemical synthesis and extraction from either natural or reclaimed sources. Selection of the manufacturing processes typically depends on the available technology, cost of raw materials/chemical feedstocks, availability of mineral containing reclaimed materials, market prices and size, cost of implementing extraction versus chemical synthetic processes and, to a lesser extent, the overall environmental impact of the production method. For a representative sample of common production methods, please refer to the 2013 TR, lines 563 to 631.

International:
Canadian General Standards Board

As included in the 2013 TR, according to the Canadian General Standards Board General Principles and Management Standards (CAN/CGSB-32.310-2006), organic operators may not use "feed and feed additives, including amino acids and feed supplements that contain substances not in accordance with CAN/CGSB-32.311, Organic Production Systems - Permitted Substances Lists" (CAN, 2011a). Minerals are included in the definition of feed additives and therefore subject to regulation. However, the Permitted Substances List (CAN/CGSB 32.311-2006) allows the use of synthetic minerals under certain circumstances: "minerals, trace minerals, elements" may be used for enrichment or fortification of livestock feed, and synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Under no circumstances should minerals be used to stimulate growth or production (CAN, 2011b).

Codex Alimentarius

The specific criteria for feedstuffs and nutritional elements section of the standards set forth by the Codex Alimentarius Commission (2012) pertaining to livestock production states that "feedstuffs of mineral origin, trace minerals, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used" (Codex Alimentarius Commission, 2012).

European Union

The European Economic Community (EEC) Council Regulations, EC No. 834/2007 and 889/2008, state that "feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production." Specifically, the following trace elemental compounds are allowed as nutritional additives in the organic production of livestock under Annex VI:

- Iron – Ferrous (II) carbonate, ferrous (II) sulfate, monohydrate and/or heptahydrate, ferric (III) oxide; Iodine – Calcium iodate (anhydrous and hexahydrate), sodium iodide;
- Cobalt – Cobaltous (II) sulfate monohydrate and/or heptahydrate, basic cobaltous (II) carbonate monohydrate;
- Copper – Copper (II) oxide, basic copper (II) carbonate monohydrate, copper (II) sulfate pentahydrate;
- Manganese – Manganous (II) carbonate, manganous oxide and manganic oxide; manganous (II) sulfate mono and/or tetrahydrate;
- Zinc – Zinc carbonate, zinc oxide, zinc sulfate mono and/or heptahydrate;
- Molybdenum – Ammonium molybdate, sodium molybdate;
- Selenium – Sodium selenate, sodium selenite.

Japan Ministry of Agriculture, Forestry and Fisheries (MAFF)

The Japan Ministry of Agriculture, Forestry, and Fisheries Standard for Organic Feed do not specify the allowed or prohibited status of trace minerals in organic livestock or aquatic animal feed. However, the standard permits natural feed additives:

> Feed additives (except for those produced by using antibiotic and recombinant DNA technology), which are natural substances or those derived from natural substances without being chemically treated. In case of a difficulty to obtain feed additives listed in 8, the use of

similar agents to the described food additives are permitted only for supplementing nutrition and effective components in feeds.

This statement suggests that synthetic minerals may be allowed if naturally derived substitutes are not available (JMAFF, 2005).

International Federation of Organic Agricultural Movements (IFOAM)

Within their norms, the International Federation of Organic Agricultural Movements (IFOAM) allows vitamins, trace elements and supplements from natural sources in animal feed. An exception to this rule states that "synthetic vitamins, minerals and supplements may be used when natural sources are not available in sufficient quantity and quality" (IFOAM, 2012).

Ancillary substances:

See the questions below.

Human Health and Environment:

According to the 2013 TR, at excessive levels of exposure, many of the trace minerals have the potential for toxicity toward humans, aquatic animals, and terrestrial animals. As a result, the U.S. EPA has established maximum contaminant levels for some minerals due to human toxicity concerns (U.S. EPA, 2012). The TR provides further detail regarding toxic effects related to excessive amounts of selected trace mineral elements, lines 704-713.

Discussion:

The NOSB has continually received comments from the organic community supporting the continued use of trace minerals, noting their essentiality to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Additional information from Subcommittee:

1) Are trace minerals still essential to the production of organic livestock?

2) Can trace minerals be produced from agricultural sources that have been produced through excluded methods?

3) Are there ancillary substances used in the production of trace minerals?

Vitamins

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(d) As feed additives. **(3) Vitamins, used for enrichment or fortification when FDA approved.**

Technical Report: 2015 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) ; Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
The National Organic Program (NOP) final rule currently allows the use of vitamins in organic livestock production under 7 CFR 205.603, Synthetic Substances Allowed for Use in Organic Livestock Production for enrichment or fortification when FDA approved. The U.S. Food and Drug Administration (FDA) enforces provisions of the Federal Food, Drug and According to the FFDCA, any substance that is added or expected to directly or indirectly become a component of animal food must be used according to the relevant food additive regulation unless the substance is generally recognized as safe (GRAS) under 21 CFR parts 582 and 584 for that use pattern (FDA, 2014a). In addition, substances listed as FDA-approved food additives (21 CFR parts 570, 571, and 573) may also be incorporated into animal feeds.

In organic livestock production, vitamins are combined in feed rations of grains, beans, oilseeds, and other meals with minerals, amino acids, and vitamins (Pond et al., 1995). Depending on the raw nutrients available to the animal, individual vitamins or a premix of multiple vitamins may be added to feed rations (Sewell, 1993.)

The National Organic Program (NOP) final rule currently allows the use of vitamins, as feed additives, in organic livestock production under 7 CFR §205.603(d)(3) in amounts needed for adequate nutrition and health maintenance (7 CFR §205.237). Further, the USDA organic regulations require producers to meet certain standards for livestock health care practices. As part of this requirement, livestock feed rations must meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants) (7 CFR 205.238(a)(2)).

There are 15 essential vitamins currently allowed for use in organic livestock production for fortification and enrichment: Vitamin A (vitamin A acetate), Vitamin B1 (thiamine hydrochloride), Vitamin B2 (riboflavin), Vitamin B3 (niacin, nicotinic acid), Vitamin B5 (calcium pantothenate), Vitamin B6 (pyridoxine hydrochloride), Vitamin B7 (biotin), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Choline chloride, Vitamin D3 (cholecalciferol), Vitamin E (α-Tocopherol acetate), and Inositol.

The scope of vitamin compounds is reflective of vitamins defined as “required nutrients” by the National Research Council’s (NRC’s) Nutrient Requirements of cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well- being of all animals, including livestock. In particular, most vitamins aid in the metabolism of proteins, carbohydrates, and fats while some vitamin compounds have important antioxidant properties. Common signs of vitamin deficiency include anorexia, poor growth, reduced feeding efficiency and, in some cases, mortality.

Individual vitamin compounds are produced on an industrial scale by chemical synthesis or partial synthesis, fermentation and/or by extraction from natural material sources. Selection of the manufacturing processes typically depends on available technology, cost of raw materials/chemical feedstocks, market prices and size, cost of implementing fermentation versus chemical processes (synthesis or extraction) and, to a lesser extent, the overall environmental impact of the production method.

While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production (Festel, 2005). Fermentation is an enzymatic process whereby microorganisms convert natural carbon-based nutrients (e.g., glucose, molasses, etc.) to desired compounds. Many recently developed fermentation methods for manufacturing vitamins utilize genetically engineered microorganisms, generating concerns over the use of these vitamin sources in organic food production (Roseboro, 2008). As of 2015, when the last technical review (TR) was received, fermentation production using genetic modification was commonly being used in production of vitamins A, B2, B5, B6, C, E, B12.

Accordingly, NOP published Guidance 5030 "Guidance Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed", which instructs certifiers to be diligent in reviewing vitamins for the presence of excluded methods. Specific to excluded methods in vitamins, NOP wrote: "The USDA organic regulations also prohibit use of excluded methods at §205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods."
https://www.ams.usda.gov/sites/default/files/media/5030.pdf

OMRI acknowledged that vitamins may be produced using excluded methods in their Generic List, and which contains a Decision Tree For Evaluation of GMO Inputs in Organic Livestock Production on page 85. http://www.omri.org/sites/default/files/app_materials/OMRI-GML-Stan-2013small_0.pdf

Environmental Impact:
No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Accidental release of chemical reagents during the production process, however, may lead to ecological impairment. Specifically, strong acids and bases are used in the synthetic or extraction process of vitamin compounds. Improper use or disposal of these chemicals during the production of vitamins could affect both the pH and chemical composition of the soil, potentially resulting in physiological effects on soil organisms.

Aquatic ecosystems are particularly sensitive to the introduction of nutrients from nearby agricultural operations. Releasing excessive amount of agricultural materials—including phosphate and nitrate fertilizers, feed materials and manure—to waterways can encourage the growth of algae (algal bloom) and other aquatic plants and ultimately oxygen depletion in the affected water zone (Wu, 1995; NAS, 1969).

Heath Impacts:
In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for human consumption at levels typically ingested through the diet and dietary supplements taken according to label directions. Supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans; hence, the agricultural use pattern for vitamins under review should not adversely impact human health.

International:
The Canadian National Standards Board, the Codex Alimentarius Commission, the EU and the Japanese organic standards all prohibit the use of synthetic vitamins when natural sources are available. If natural sources are not available, synthetic forms of vitamins are allowed. The United Kingdom Soil Association adds an additional stipulation that the producer must demonstrate nutritional deficiency of the animals' feed.

Additional information from Subcommittee:

1) What documentation is required by the certifiers and material review organizations to verify that vitamins that have been produced without genetic modification?

2) Since production methods, such as rotational grazing or reducing the numbers of grazing animals, has been shown to reduce the demand for vitamin supplements, should there be less need for supplying ruminant livestock feeds with synthetic vitamins?

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Silver Dihydrogen Citrate
February 5, 2019

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 considered the petition at its Fall 2018 meeting but voted to send it back to subcommittee for further review after receiving substantial public comment. The NOSB is bringing this forward again for full Board review at its Spring 2019 meeting.

Summary of Review:
Based on the information provided in the TR and by the petitioner, SDC appears to be of low risk to the environment and to human health both in its use and disposal. However, public comments received as part of the Fall 2018 NOSB meeting disputed some of these assertations. Several groups cited research documenting microbial resistance to silver ions as well as that silver- and antibiotic-resistant genes are frequently transmitted together. Public comments at the Fall 2018 NOSB meeting quoted data that SDC is of low risk to the environment if it is disposed of through a managed water treatment system. However, disposal through other treatment systems, such as septic systems, could be problematic. One commenter cited the EPA registration for Silver dihydrogen citrate which states, "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters… do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority." If approved, SDC could be used by all types of handling and postharvest handling operations, including those that are not connected to municipal waste water systems and do not have an on-site wastewater treatment facility. Examples of such uses are activities that commonly occur on-farm or at consolidation points located in rural areas: hydro-cooling, washing, flotation, sorting, packing, etc. The Subcommittee still has concerns around the use of this material in potential field applications - this could potentially be mitigated by an annotation disallowing its use based on the available wastewater treatment facilities for the effluent.

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. Several industry comments were received for the Fall 2018 NOSB meeting asserting that this material would be useful as part of a pathogen risk reduction strategy. Other commenters were concerned that approving the use of silver ions in organic production could lead to pathogen resistance in humans and reduce the effectiveness of a human medical treatment, similar to the argument against antibiotic use in organic agriculture. However, this is also a concern relevant to most sanitizers included on the national list, including chlorhexidine and chlorine compounds (which have been shown to in some studies accelerate antibiotic

resistant bacteria). The Subcommittee did not find the use of this material in medical applications as violative of the OFPA criteria.

The NOSB has received 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. An annotation was included in the Fall 2018 NOSB proposal to limit particle sizes to greater than 300nm. However, the petitioner provided comments that the silver occurs in ionic form and thus cannot be categorized as a particle size and that this annotation is not pertinent to this product. The Subcommittee has unresolved concerns about whether or not this substance meets the previous NOSB recommendations on nano-particles and therefore the Subcommittee questions if this material is compatible with a system of organic production.

There is conflicting information about the use of sodium lauryl sulfate in this substance. The petitioner claims the sodium lauryl sulfate is used as a stabilizer. However, a public commenter cited the patent documents that look at the use of sodium lauryl sulfate as a detergent to increase efficacy. If sodium lauryl sulfate is used as a detergent in a no-rinse application this substance should also be petitioned separately to the national list.

The NOSB finds merits for this material, particularly around the need for alternative sanitizers in organic processing and its relative minimal potential human health impacts. However, concerns linger around its potential impact on the environment, its compatibility with organic production given the concerns around nano-particles and concerns around the use of sodium lauryl sulfate in formulation. At this time the Subcommittee is not recommending this material for inclusion on the National List. If the noted concerns above can be mitigated or addressed, then the above material could be re-petitioned for reconsideration.

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). However, since this product could be used on fruits and vegetables, there is the possibility that its use either as a first step in field sanitization or during on-farm harvesting could result in environmental release other than through wastewater treatment 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 technical report (TR) 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 TR 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 TR 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 TR 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. However, the fate of the silver component when used in facilities without on-site water treatment is unclear (public comment, Fall 2018 NOSB meeting).

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. Once again, it is unknown what the fate of silver is in facilities that do not have a wastewater treatment system, but instead rely on septic or other disposal systems. The petitioner notes that SDC might be used in early processing stages and these stages could potentially occur on farm during harvesting or prior to transport to a packing facility.

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 TR 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. Exposure 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 there is "no anticipated effects on soil organisms, crops, or livestock." As noted in Question 3, this product could be used early in the harvesting/processing process and use of this product in facilities not connected with waste water treatment systems could cause environmental contamination and degradation.

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 sanitation practices and use of SDC as follows:
   When processing agricultural products, biocides like SDC are paramount in ensuring the safety of consumers. 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, although several public commenters during the Fall 2018 NOSB meeting cited research showing potential bacterial resistance to silver ions

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 increases 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 are 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 substance against the food safety benefits, considering the alternatives. Overall the environmental and human health risks seem low, although there are questions about the disposal of the material in facilities that do not include wastewater treatment systems and the potential for silver ion resistant bacteria. With a growing level of resistance to current antibacterial agents on this list, SDC appears to offer unique and necessary food safety attributes, but there are questions as to exposure of workers to the material as well as reducing the efficacy of silver in the treatment of human health concerns. Comments received from packers of organic and non-organic leafy-green products stated the need for this substance to reliably meet sanitation levels. Additionally, they

commented the increased safety and preference by sanitation workforce for this material over alternatives on the national list.

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)

   Human health concerns appear to be minimal according to the petitioner and the TR. However, several public commenters provided research to the contrary. The environmental risk of SDC disposal or release is unclear.

Category 5: Additional criteria for agricultural 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 **form** 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 **quality** 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 **quantity** 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)

The NOSB finds merit for this material, particularly around the need for alternative sanitizers in organic processing and its relative minimal potential human health impacts. However, concerns linger around its potential impact on the environment, its compatibility with organic production given the concerns around nano-particles and concerns around the use of sodium lauryl sulfate in formulation. At this time the Subcommittee is not recommending this material for inclusion on the National List. If the noted concerns above can be mitigated or addressed, then the above material could be re-petitioned for reconsideration.

Classification Motion:

Motion to classify silver dihydrogen citrate as synthetic
Motion by: Tom Chapman
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add silver dihydrogen citrate at §205.605(b)
Motion by: Tom Chapman
Seconded by: Lisa de Lima
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Pullulan
November 20, 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 made with 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 U.S. 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 halal product. Otherwise, to continue producing vegetarian organic compliant products manufacturers would have to surrender their organic certification. According to the petition, the 2018 forecast for pullulan capsules is approximately 2.5 billion capsules, and a conservative estimate of $10 per 30 count bottle would represent an economic value of over $825 million.

Summary of Review:
Based on information provided in the TR and petition, pullulan appears to be of low risk to the environment and human health both in its use and disposal. There are no alternative materials that would allow the continued production of certified "made with organic" vegetarian encapsulated dietary supplements. The Handling Subcommittee recommends adding pullulan to the National List.

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. Nothing was found in the NOSB meeting minutes that would clarify why no recommendation was ever made. In April of 2018 the Handling Subcommittee found the petition for pullulan to be sufficient and requested a technical report (TR). While the technical report was in development, the HS put forward a Petitioned Material Discussion Document with the intent of gathering public comment and allowing for discussion by the full Board at the Fall 2018 NOSB meeting. A number of certifiers and manufacturers wrote in support of classifying pullulan

as a non-agricultural substance and placing it on the National List. The Accredited Certifiers Association also wrote in support and noted that their working group on pullulan found it a challenge to evaluate using the decision tree NOP 5033. However, they did agree that the most appropriate classification was non-agricultural, with most agreeing that classification happens at step 3 of the decision tree. Capsugel, the manufacturer of pullulan capsules commented that they are working on an organic version of their pullulan capsule. They estimated that as many as 115 of their customers would be impacted if pullulan was not listed. They currently have more than 460 customers globally who purchase their pullulan product and the U.S. represents approximately half of all sales.

The TR states that pullulan is not included in any international standards: Canada, CODEX, EEC, or Japan. This is because, unlike in the U.S, international standards don't consider dietary supplement capsules to be an ingredient.

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 first step of the decision tree asks if the substance is a mineral or bacterial culture. No, its best described as a microbial metabolite that is isolated from culture medium or fermentation broth. Since the answer is no, proceed to Step 2.

   The second step asks if the substance is a microorganism or enzyme. No, it's a product of a microorganism. Since the answer is no, proceed to Step 3.

   The third step asks if the substance is a crop or livestock product or derived from crops or livestock. No, it's derived from a microorganism using a crop material as the substrate. Since the answer is no, this results in a nonagricultural classification.

   Additionally, according to the TR (lines 291-294): If one considers that pullulan is derived from the microorganism that produces it, rather than from the agricultural substrates used to cultivate the microorganism, the conclusion is that pullulan is nonagricultural. Historic NOSB decisions on similar carbohydrate polymer substances (gums) currently on the National List are consistent with classification of pullulan as a nonagricultural substance.

   b. If the substance is **Non-agricultural**, 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:

   According to the TR (lines 227 – 253) the petitioned pullulan is produced using steps 1-7 below. The process doesn't modify the extracted pullulan and no solvent residues persist in the finished material. Once pullulan is created/produced in the fermentation process (Step 1), it does not

undergo any further chemical change during either of the manufacturing processes described above. If chemically changed, the substance would no longer be considered pullulan per the JECFA monograph (JECFA 2011) or Food Chemical Codex (U.S. Pharmacopeia 2010). Additionally, the TR stated that no sources were found that indicate the existence of a chemically synthesized form.

The petitioned pullulan is produced using the following steps.

1. Fermentation of saccharide substrate by a microorganism creates pullulan.
2. Microfiltration separates microorganism cells and cellular debris from the aqueous medium containing water-soluble pullulan.
3. Heat-sterilization inactivates the heat-labile enzyme pullulanase, a co-product of the fermentation which causes the degradation of pullulan. This step also ensures the microbiological safety of the pullulan solution.
4. Deionization using insoluble ion exchange resins removes electrolytes and other nutrients, such as minerals, from the pullulan solution, thereby purifying it.
5. Intermediate concentration (water evaporation) increases the pullulan concentration in the solution.
6. Decolorization with activated carbon binds the black pigment melanin produced by the microorganism during the fermentation.
7. Filtration removes the activated carbon and adsorbed melanin.
8. Drying removes the water and yields a solid material.

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)]

   Pullulan is not being petitioned to be used in organic crop production. Additionally, according to the TR it is completely biodegradable (TR lines 420-431)

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)]

   Pullulan is completely biodegradable (Farris et al. 2014). It may be digested directly to glucose by the consumer, fermented by the intestinal flora, or broken down by microflora digesting human waste in a sewage treatment plant. In all cases, the carbon, oxygen, and hydrogen that constitute pullulan are converted to carbon dioxide, water, and sometimes hydrogen gas (produced in the colon).

Each byproduct of the production of pullulan is either biodegradable (the carbohydrate and nitrogen in the cell debris from the microorganism), recyclable (the ion exchange resin), biologically available (the mineral elements), or soil-compatible (activated charcoal). Thus, no harm to the environment or biodiversity is expected from the manufacture or use of pullulan as petitioned (TR lines 420-431).

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

   Pullulan is completely biodegradable (Farris et al. 2014). It may be digested directly to glucose by the consumer, fermented by the intestinal flora, or broken down by microflora digesting human waste in a sewage treatment plant. In all cases, the carbon, oxygen, and hydrogen that constitute pullulan are converted to carbon dioxide, water, and sometimes hydrogen gas (produced in the colon).

   Each byproduct of the production of pullulan is either biodegradable (the carbohydrate and nitrogen in the cell debris from the microorganism), recyclable (the ion exchange resin), biologically available (the mineral elements), or soil-compatible (activated charcoal). Thus, no harm to the environment or biodiversity is expected from the manufacture or use of pullulan as petitioned (TR lines 420-431)

   Additionally, according to the petition, pullulan can be used as a base material in novel flocculants developed to remove contaminants in waste waters (Chimici & Constantin, 2001).

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

   According to the TR evaluation questions #7 & #10, the only adverse effect on human health is flatus as a result of undigested carbohydrates entering the colon. This affect was found at high amounts of pullulan (10-50 grams), compared to the 63 milligrams found in medium sized vegetarian capsules. Pullulan can be considered a “resistant starch” that acts as a source of 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)]

   Pullulan is not being petitioned to be used in organic crop production. Additionally, according to the TR it is completely biodegradable (TR lines 420-431)

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

   No adverse impacts were raised in the TR. No harm to the environment or biodiversity is expected from the manufacture or use of pullulan.

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 NOP compliant vegetarian options available. Organic pullulan is currently not commercially available in the United States. Capsugel, the owner of US patents covering pullulan capsules, is in the process of developing organic pullulan.

The only alternative practice for supplements manufacturers would be to use gelatin capsules. Gelatin is listed on 205.606 of the National List, but its use would be problematic for consumers looking for a vegetarian, kosher or halal product.

Hydroxypropyl methylcellulose (HPMC) based capsules are commonly used as a vegetarian alternative to gelatin capsules. However, HPMC was petitioned to the National List in September 2002 and was not recommended by the Board for inclusion on the National List. The material was classified as synthetic and found not to be compatible with organic production.

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)]

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

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): **NA**

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

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?

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?

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?

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;

    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?

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)

Classification Motion:

Motion to classify pullulan as nonagricultural, nonsynthetic
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add pullulan as petitioned, at §205.605(a)
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Asa Bradman, Subcommittee Chair, to transmit to NOSB, February 24, 2019

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Collagen Gel
February 21, 2019

Summary of Petition 2018:
https://www.ams.usda.gov/sites/default/files/media/CollagenGelPetition.pdf

A petition has been submitted by Devro, Inc. to add collagen gel at 7 CFR 205.606, nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." The NOP defines an agricultural product as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock…".
The petitioned use is to produce sausage using a co-extrusion system. In these systems, collagen gel enrobes the sausage meat like a casing as the meat is extruded and holds the form of the meat product.

Summary of Review:
Based on the review of the petition and the 2019 Technical Report (https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf), collagen is a naturally occurring and abundant animal protein that is isolated from livestock and maritime (fish) sources. Collagen gel is derived from animal skins with some processing. The Handling Subcommittee had extensive discussions about whether the processing to produce collagen gel constituted a change to the chemical structure and might be considered non-agricultural. The Subcommittee ultimately concluded that the material is agricultural and eligible for listing at §205.606.

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. Cellulose is currently approved for use as a synthetic substance "in regenerative casings [extruded collagen casing that is dried prior to use], as an anti-caking agent (non-chlorine bleached) and filtering aid," and for processed products labeled "organic" or "made with organic," at 7 CFR 205.605.

Collagen gel can be used in organic sausage production using a co-extrusion system. Typical products using this ingredient include cooked and smoked sausages. In these coextrusion 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. Collagen casings and gels are GRAS (Generally Recognized as Safe) for use in sausages and meat products.

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon 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.

The Handling Subcommittee voted to classify the material as agricultural and list the material under 205.606.

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:

   Collagen gels are derived from the corium layer of skins from cows, pigs, chickens and/ or turkeys and also maritime sources. The isolation process includes the partial hydrolysis of the protein, typically achieved with acid or base treatment, homogenization, and further denaturation with acid before final extrusion to form manufactured casings or coextrusion for direct application to extruded sausage batter.

   The Handling Subcommittee had extensive discussions about whether processing steps to produce collagen gel constituted a change to the source protein chemical structure and might be considered non-agricultural. Because protein denaturation results from the disruption of non-covalent bonds that maintain the three-dimensional structure of the original protein, but leaves the peptide bonds intact, the Subcommittee ultimately concluded that the material has not been chemically changed and is thus agricultural.

   In summary, based on the NOP 5033-2 decision tree, the material is derived from an animal; the substance is not a microorganism or enzyme, and not a product of a microorganism or an enzyme; the substance has not been processed to the extent that its chemical structure has been changed, and therefore is classified as agricultural.

3. For **Handling** 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?

   As noted above, the Handling Subcommittee had extensive discussions about whether processing steps to produce collagen gel constituted a change to the chemical structure and might be considered non-agricultural. Because protein denaturation results from the disruption of non-covalent bonds that maintain the three-dimensional structure of the original protein, but leaves the peptide bonds intact, the Subcommittee ultimately concluded that the material has not been chemically changed and is thus agricultural

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?

   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 containments, and their persistence and areas of concentration in the environment?

   There is no known toxicity of collagen gel. It is an edible product produced from animal skins.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance.

   There is little probability of environmental contamination during manufacture, use, misuse, or disposal of collagen gel. Because the proposed petition is for nonorganically produced collagen gel, the material may be sourced from conventionally raised animals that have been fed GMO grain treated with pesticides as well as other materials not allowed in organic husbandry, such as antibiotic use.

4. Discuss the effect of the substance on human health.

   Collagen gel is a food product with no known health effects.

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.

   Collagen gel is unlikely to have any effects on biological and chemical interactions in the agroecosystem, including physiological effects on soil organisms.

6. Are there any adverse impacts on biodiversity?

   Conventional production of animals used as source material for collagen gel may employ agricultural practices that adversely impact biodiversity. However, additional processing of these resources into collagen gel for organic sausage production will not add additional burdens on the environment.

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)]

   Current options (casings, from processed intestines) will not function in this type of co-extrusion sausage production system. Nonorganically produced casings are allowed in sausages labeled as "organic" or "made with organic".

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?

   An organic form of collagen gel would be expected to perform similarly to nonorganic forms. Availability of organic collagen gel is a limiting factor.

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 form of available nonorganic versus organic animal source material for collagen gel is not relevant to the petitioned request for this material.

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?

   The quality of available nonorganic versus organic animal source material for collagen gel is not relevant to the petitioned request for this material.

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?

   According to the petitioner, collagen gel could theoretically be formed using skins from certified organic sources were they readily available in mass quantity and an identity preservation system in place. However, the quantity of organically raised animals required to satisfy the market demand may not exist. Organic options for collagen gel for meat production were not found based on internet searches and review of the USDA integrity database. Allowing the use of collagen gel could increase the market for organic meat and improve the potential for there to be sufficient organically raised animals to provide collagen gel source material. Under §205.606, future availability of organic collagen gel source materials are encouraged.

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;

      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 on the impact of 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?

      None.

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)

   Yes, the substance increases opportunities to produce organic sausages and meat products that are not possible using existing production aids, and in particular allows production of single-

species products that can meet the needs and preferences of different consumer populations, thereby expanding opportunities and markets to produce organically certified livestock. Collagen gel is used in similar fashion to casings, already listed under §205.606(b).

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional 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. Because source material for production of collagen is usually produced from nonorganically raised livestock, there may be environmental and human health impacts from materials used to produce nonorganic grain and livestock. However, it is a co-product of the animal production industry, thereby providing a raw material that otherwise has less value, and helps support markets for organically produce meats.

In summary, listing of collagen gel could help build a bigger market for organically produced meat and is consistent with current regulations allowing up to 5% of nonorganic materials in processed food products labeled as "organic" or 30% in products labeled as "made with organic". Listing of collagen gel is also consistent with the current listing of gelatin and casings as nonorganically produced animal products. Under §205.606, future availability of organic collagen gel source materials are encouraged.

Classification Motion:

Motion to classify Collagen gel as agricultural.
Motion by: Asa Bradman
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 1 Absent: 1 Recuse: 0

National List Motion:

Motion to add collagen gel as petitioned at §205.606.
Motion by: Asa Bradman
Seconded by: Tom Chapman
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Asa Bradman, Subcommittee Chair, to transmit to NOSB, February 24, 2019

Sunset 2021
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 2019

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

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2019 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2019 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 4, 2019, as explained in the meeting notice published in the Federal Register.

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

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

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

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

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

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

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

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

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

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

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

Written public comments will be accepted through April 4, 2019, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2021
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 2019

Note: With the exception of Activated Charcoal, L-Malic Acid, Microorganisms, Peracetic Acid/Peroxyacetic Acid, and Sodium Acid Pyrophosphate, 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)).''

§205.605(a) *Nonsynthetics allowed:*

Acid, Citric
Acid, Lactic
Calcium chloride
Dairy cultures
Enzymes
L-Malic acid
Magnesium sulfate
Microorganisms
Perlite
Potassium iodide
Yeast

§205.605(b) *Synthetics allowed:*

Acid, Alginic
Activated charcoal
Ascorbic acid
Calcium citrate
Ferrous sulfate
Hydrogen peroxide
Nutrient vitamins and minerals
Peracetic acid
Potassium citrate
Potassium phosphate
Sodium acid pyrophosphate
Sodium citrate
Tocopherols

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

Celery powder
Fish oil
Gelatin
Orange pulp, dried
Seaweed, Pacific kombu
Wakame seaweed (*Undaria pinnatifida*)

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Acids – Citric

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Citric acid is widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. It is also an ingredient in dietary supplements and a nutrient, sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), raising agent, and emulsifying salt for many other products. It is also used to improve baking properties of flours, and as a stabilizer, and to inhibit color and flavor deterioration in fruits. Roughly 75% of all citric acid commercially produced is used by the food industry including baby food, breakfast cereals, frozen desserts, frozen entrees and certified organic personal care products. The remainder is used in cleaning agents, or in the cosmetics and pharmaceutical industries.

Manufacture:
First isolated from lemons, it was extracted from lemons and limes until 1919 when production shifted to fermentation (a biological process by which sugars are metabolized to acids, gases, and/or alcohol). Today, the mold *Aspergillus niger* is cultured with low pH values and high levels of sugars and mineral salts to economically produce high yields through fermentation. Various chemical synthesis of citric acid appeared but none have reached the economics derived from the fermentation process. The fermentation process has been refined over the years to produce high levels of citric acid instead of high levels of the by-product oxalic acid. Some public commenters expressed a concern that the fermentation process involves the use of synthetic chemical reactions that were not considered in the original 1995 classification.

International Acceptance:
Citric acid is an allowed ingredient in all international organic standards reviewed in the 2015 TR. The only noted annotation is that Japan Agriculture Standards allow citric acid but only as a pH adjuster for processed fruits and processed vegetables.

Environmental Issues:
Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will

degrade to produce non-toxic and non-persistent environmental products. The last time EPA evaluated citric acid was 1992 at which time they found it posed no environmental risk.

Discussion:
Citric acid has been approved for organic use under 205.605 if the citric acid used is produced by microbial fermentation of carbohydrate substances (non-synthetic). The NOSB in its initial request for public comment in 2017 did not ask for any specific information from stakeholders. While there were no specific questions asked of the public, the subcommittee did receive several comments from various stakeholders.
Citric acid has GRAS status (Generally Recognized as Safe) by the FDA. Citric acid has many uses in food production. It has a history of safe use in organic foods dating back to 1995. Natural citric acid may be isolated from organically grown fruit but has not been commercially available in the quantities that would be required to service the organic sector. Alternate acids are not more natural and do not give the same flavor profile. It is used as a pH adjuster for organic fruit processing and spreads. There are no other alternatives to date that can replace citric acid.
While there were some public concerns from the 2015 sunset review about the relisting of this material, the majority of public comments from the 2015 sunset review stated that it is necessary in the organic industry for proper pH control in many foods. There are currently no allowed alternatives available to citric acid.
This material satisfies the OFPA Evaluation criteria.
Several commenters were in favor of relisting, stating citric acid is a naturally occurring substance but classified as a synthetic due to chemical processing through fermentation. One commenter suggested malic acid may work for lowering pH instead of citric acid but there are no studies that determine feasibility and the effect on product profiles. Comments from cut-fruit manufacturers stated no other alternatives provide the same shelf life extension as the fruit treated with citric acid.

Additional information requested by Subcommittee:
1. Are there any commercially available sources of citric acid derived from organically grown crops?

Acids – Lactic

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting Transcript 2015 pp. 263). The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008). Other uses include mixing with sodium, potassium, and distilled water to form intravenous fluids commonly used after blood loss. It is sometimes used in the pharmaceutical industry to adjust acidity. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material with no restrictions on use.

Common uses include, but are not limited to:

1. In sugar confectionery, it is used in a continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and NOSB Mesentericur groups of bacteria.
6. Lactic acid can be used as a meat carcass “wash” or in meat products to reduce microbial contamination.
7. It is used in jams, jellies, and frozen fruit desserts.
8. In dairy products such as cottage cheese, the addition of lactic acid is preferred by some manufacturers to fermentation.
9. Used in imitation dairy products such as non-dairy cheese and non-dairy yogurt powder.
10. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.
11. Buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
12. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
13. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
14. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.
15. Lactic acid is used for flavor development and the control of microorganisms in soy cheese.

Manufacture:

First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid. A secondary manufacturing

process involves chemical synthesis of adding hydrogen cyanide to acetaldehyde, an organic chemical compound found in coffee, bread, ripe fruit, coal, or crude oil. This process only exists today in Japan. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation.

International Acceptance:

Lactic acid is permitted under all five major organic standards (US, EU, Canada, Japan Agriculture, and IFOAM). Canada classifies it as non-organic "for fermented vegetable products or in sausage". CODEX permits its use "food of plant origin", or "food of animal origin". European Economic Council permits use in processing foodstuffs of both plant and animal origin, or for the regulation of pH in yeast production. Japan Agriculture Standards permits use in processed vegetables or rice products, sausage, for dairy products, and for cheese.

Environmental Issues:

The fermentation process produces calcium sulfate waste (sometimes sold as fertilizer) but it is not known to create any negative environmental impacts.

Discussion:
Lactic acid is a "Direct Food Substance Affirmed as Generally Recognized as Safe," or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061.

Lactic acid is one of the most widely distributed acids and preservatives in nature. It is produced naturally by humans, animals, and microorganisms. Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with sour milk. It occurs naturally in two isomers (D) and (L). (D) is harmful to humans so (L) is the preferred isomer for food and pharmaceuticals. It functions as a flavor agent, preservative and acidity adjuster in foods.

There is no known organic alternative to lactic acid. Currently, it is not being produced organically. Since raw material sourcing for dextrose or sucrose could include corn and beet sugar, the TR (lines 569-572) stated the purification process would remove any traces of GMO DNA from the final product.

Past public comments for relisting were mostly in favor. Some comments expressed a concern that because of the chemical reactions in the purification process lactic acid should be considered synthetic.

Additional information requested by Subcommittee: None

Calcium chloride

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Calcium chloride.**
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:
Use: Used in a wide variety of food processing applications including as a firming agent (in tofu, cut fruit and canning applications), as a sodium replacement, to adjust water mineral content in brewing applications and as a nutritional electrolyte application.

Manufacturing: Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified as nonsynthetic. The starting material is a natural brine solution that is pumped out from underground salt beds. Synthetic materials are used in the purification process, but without changing the chemical structure of the material. Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (TR 2015)

International: Calcium chloride is allowed for use with various annotations under the Canadian, EU, Japanese, IFOAM and Codex standards.

Discussion: None

Additional information requested by Subcommittee:

Is this material currently in use by the organic food processing industry and in what applications?

Dairy cultures

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Dairy cultures.**
Technical Report: 1995 TAP; 2014 TR for Ancillary Substances
Petition(s): N/A
Past NOSB Actions: 05/2003 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review

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

Background from subcommittee:
Use: Dairy cultures are used by organic dairy processors to make yogurt, cheese, cultured sour cream and other fermented milk products. The use of these cultures can increase the digestibility of milk products, create different flavors and textures, and provide potential health benefits to the consumer.

Manufacture: There are a variety of ways a dairy culture can be produced but generally a dairy or other medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different traditional dairy products.

International: According to the 2014 TR on microorganisms, there is widespread international acceptance of microorganisms and dairy cultures:

European Union: Article 19 states, "The following conditions shall apply to the composition of organic processed food: ...(b) only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes...may be used, and only in so far as they have been authorized for use in organic production in accordance with Article 21." "In addition, the products and substances referred to in Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market."

Canada - Canadian General Standards Board Permitted Substances List: Microorganisms are permitted in organic processed foods as nonorganic ingredients that are not classified as food additives. This appears in 32.311 Table 6.4 as follows: "Microorganisms (processing derivatives) derived from genetic engineering or with the addition of chemosynthetic substance are prohibited."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) Joint FAO/WHO Food Standards Programme: Microorganisms, probiotics, and enzymes are allowed for use as additives and processing aids. "Substances found in nature from biological/enzymatic processes and microbial processes (e.g., fermentation)" are allowed for use "as additives or processing aids in the preparation or preservation of food" (Section 5.1(c)). Any preparation of microorganisms can be used in food processing except those derived from genetic engineering (Table 3.4).

European Economic Community (EEC) Council Regulation: EC No. 834/2007 and 889/2008: Microorganisms and enzymes "normally found in food processing" are permitted for use (Article 2y(1)(b)).

Japan Agricultural Standard (JAS) for Organic Production: Microorganisms do not specifically appear in the JAS standard for Organic Processed Food (Article 3) nor they considered food additives (Table 1). However, the JAS Standard includes language that indicates that microorganisms are allowed (see the TR for more details).

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM standard, Section 7.2.5, states, "preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products.

Ancillary Substances: Ancillary substances may be present in dairy cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in dairy cultures in 2015. These include:

Functional class	**Substance name**
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Discussion:
Dairy cultures have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of certain dairy products. They pose minimal health risks, and in many cases can enhance health. In the October 2015, NOSB review of dairy cultures comments were received from trade associations, industry, certifiers and a technical organization. All comments were generally in favor of continued allowance of dairy cultures. The question was asked whether these should be listed separately or combined with microorganisms. Most industry stakeholders, while agreeing the dairy cultures were covered under microorganisms, still wanted a separate listing for dairy cultures. Several certifiers and a technical organization agreed that the listing of dairy cultures was redundant to microorganisms and could be removed. The ancillary substances used in dairy cultures has raised potential concerns about their compatibility with organic handling standards, but that has not prevented the support for continued listing of these cultures.

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances not listed in the chart?
2. Is the dairy culture listing redundant and should it be combined with the microorganism listing?

Enzymes

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.**
Technical Report: 1995 TAP; 1996 TAP; 2011 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:
Use: Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients. Commonly used in the production of sweeteners, chocolate syrups, bakery products, alcoholic beverages, precooked cereals, infant foods, fish meal, cheese and dairy products, egg products, fruit juice, soft drinks, vegetable oil and puree, candy, spice and flavor extracts, and liquid coffee, and are used for dough conditioning, chill proofing of beer, flavor development, and meat tenderizing. Enzymes can also be used to help reduce production costs, reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-148)

Manufacture: Microbial rennet describes a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic agriculture.

Bromelain is extracted from the pineapple's fruit, stem, peel and juice. First the fruit is crushed. Bromelain is then further isolated, separated, and purified using chromatography, ultrafiltration, precipitation, freeze drying, and other procedures. (TR 2011 494-496)

Pectinase is produced by the controlled fermentation of nonpathogenic and nontoxigenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

International:

Canadian General Standards Board: Permits the use of egg white lysozyme and animal-derived rennet in organic food processing. Animal-derived rennet is described as a nonorganic ingredient that is not classified as a food additive… Animal-derived enzymes, including rennet, should be from an organic source unless no such source is commercially available. The Canadian General Standards Board also permits the use of any preparations of enzymes normally used in food processing derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria. Therefore, the Canadian organic standards allow the use of pectinase and bromelain in organic food processing.

The European Economic Community (EEC) Council: Regulation (EC) No 889/2008, Article 27, 1(b) indicates that the use of "enzymes normally used in food processing" is permitted in organic food processing practices (EC No 889/2008). This would include animal-derived rennet, egg white lysozyme, pectinase preparations from Aspergillus niger, and plant-based enzymes such as bromelain.

The Codex Alimentarius Commission: Organic food guidelines allow preparations of microorganisms and enzymes, specifically, "any preparations of micro-organisms and enzymes normally used in food processing, with the exception of micro-organisms genetically engineered/modified or enzymes derived from genetic engineering" (Codex Alimentarius Commission, 1999; USDA, 2000).

International Federation of Organic Agriculture Movements (IFOAM): Basic Standards considers enzymes acceptable for use in organic food processing provided they are based on the established Procedure to Evaluate Additives and Processing Aids for Organic Food Products (IFOAM, 2005; USDA, 2003). These standards are generally parallel to the OFPA criteria.

Ancillary substances: Explained in the Enzymes Technical Evaluation Report – Limited Scope, (NOP 2015):

"Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.

To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

The following additional ancillary substances were identified through public comment during the last sunset review:

Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.

Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.

Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.

Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.

pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Discussion: During the last sunset review in 2015, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.
The 2011 TR did not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.
The 2011 TR did not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances to list for enzymes?

L-Malic acid

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **L-malic acid (CAS # 97-67-6).**
Technical Report: Malic Acid April 2003; *2019 TR pending (to be posted at https://www.ams.usda.gov/rules-regulations/organic/national-list/l)*
Petition(s): L-Malic Acid 11/01/02
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Background from Subcommittee:

Use:

There are two forms of Malic acid, D-Malic and L-Malic. D-Malic acid is not approved on the National List because a non-synthetic viable alternative is available. (TAP 2003). L-Malic acid is used as a flavor enhancer, flavoring agent and adjuvant, and as a pH control agent in a variety of foods to inhibit bacterial growth. Malic acid is more versatile for commercial black tea production and storage than citric acid. There are no alternatives to malic acid for this application.

Approximately 55% of all industrially produced L-Malic acid is used in beverages, and 20% is used in food.

GRAS: Title 21, Chapter 1, Part 184 of the Code of Federal Regulation Direct food substances affirmed as generally recognized as safe (GRAS), except for use in infant foods. Is approved for use as a Flavor enhancer, flavoring agent, adjuvant, and pH control agent (included in Appendix A, Exhibit 2).

OMRI: Organic Materials Review Institute includes malic acid on the January 2001 Processing and Handling Materials OMRI Generic Materials list as an allowed non-organic ingredient. (included in Appendix A, Exhibit 3)

Pennsylvania Certified Organic - approved use of Malic Acid by Honest Tea through 12/31/02, and during petitioning process until September 31, 2003 (letter of initial approval included in Appendix A, Exhibit 4)

Manufacture:

L-Malic acid is the natural form of malic acid occurring in fruits such as apples and cherries. It is produced by the fermentation of fumaric acid. Fumaric acid can be produced by fermentation from glucose.

International Acceptance:

CODEX: Malic Acid meets the specifications of the Food Chemicals Codex, 3rd Edition (1981)

pp. 183-184. Available from the National Academy Press, 2101 Constitution Ave., NW. Washington, D.C. 20418 (included in Appendix A, Exhibit 1).

Canada: CAN/CGSB-32-310 - National Standard of Canada Organic Agriculture - Malic acid is allowed without restriction in Appendix D, Permitted Substances List for Processing (Appendix 4) (included in Appendix B, Exhibit 1)

Australia: the Organic Federation of Australia Inc.'s guide to the Use of the National Standard for Organic Produce includes malic acid as a substance approved for post-harvest/ storage requirements.

Europe: EU 2092/91 - UKROFS Standards for Organic Food Production - Malic acid is approved as an allowed material for organic food processing in Annex VI, section A with no restrictions (included in Appendix B, Exhibit 2).

Japan: Japanese Agricultural Standard of Organic Agricultural Product Processed Foods - Malic acid is allowed to be used as a food additive without restriction in Article 5, Food Additives Table 1, Appendix B (included in Appendix B, Exhibit 3).

Environmental Issues:
Malic acid is sometimes combined with citric acid to make a mild pesticide. Because it is easily metabolized in the body and occurs naturally in many fruits, there are no known reports of animal or human toxicity (Cornell Cooperative Extension 2016).

Malic acid is listed on the EPA active chemical code report with no restrictions. Prolonged exposure can result in dermatitis.

Discussion:
The NOSB received public comment in 2014 from one certifier with 7 current clients using L-Malic acid in the wine, juice and bottled tea sectors. Another large producer gave comment confirming their current use and need for this substance. Two other commenters expressed concern that the original TAP review evaluated DL-malic acid, the synthetic form, rather than L-malic acid, the non-synthetic form currently listed. However, a review of the 2003 TAP shows that the reviewers very clearly accounted for the fact that there are two forms of this substance, and recommended that the synthetic form not be listed, and that L-malic acid be listed on 205.605(a).

L-Malic acid (CAS #97-67-6) was added to the National List (Federal Register Vol. 71, No. 175) §205.605(a) on September 11, 2006. This addition was based on a review of L-malic acid by the NOSB at its May 13-14, 2003 meeting. This material underwent its first sunset review at the Fall 2009 NOSB meeting and was relisted. The 2009 Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written).

In 2014 the Handling Subcommittee requested a TR, but one was not contracted. A TR was contracted in 2018 and is currently pending.

Additional information requested by Subcommittee: None

Magnesium sulfate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).")
Reference: 205.605(a) Nonsynthetics allowed. **Magnesium sulfate, nonsynthetic sources only.**
Technical Report:1995 TAP ; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Magnesium Sulfate has a wide variety of uses in food processing and personal care products. It is used as a firming agent in the production of tofu. According to the 2011 technical report (TR), magnesium sulfate is sometimes combined with other coagulators in the production of tofu. Natural nigari (derived from seawater) is a popular coagulant in Japan that contains magnesium sulfate and a number of other minerals. Nigari is predominantly magnesium chloride, with much smaller amount of magnesium sulfate, sodium chloride, potassium chloride, and other minerals. However, natural nigari is not approved by the FDA for use in the US and is not generally recognized as safe (GRAS). Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages.

Magnesium sulfate is generally regarded as safe (GRAS), listed at 21 CFR 184.1443. The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population. A common name for magnesium sulfate is Epsom salt.

Manufacture:

Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite ($MgSO_4 \bullet H_2O$) and epsomite (($MgSO_4 \bullet 7H_2O$), respectively.

International:

The Canada Food Inspection Agency, Food and Drug Regulations permit the use of non-synthetic sources of magnesium sulfate, which are classified as a food additive. Sulfates produced using sulfuric acid are prohibited.

Ancillary Substances:

None identified.

Discussion:

The 2011 TR notes that dietary doses of magnesium generally do not pose health risks. The TR does not fully address the environmental impact of mined forms of magnesium sulfate, noting it is not mined in the U.S. and therefore mining-related impacts are not an issue in the U.S. The TR does not address international mining impacts.

A number of alternative coagulants can be used in tofu production; however, these alternatives will affect texture, chewiness, color and other properties of the final product.

Calcium sulfate can be used in beer processing as an alternative to magnesium sulfate to increase water hardness and its mined form is on the National List.

While many other flavor enhancers are on the National List, it is unclear if any of these substances are suitable alternatives to magnesium sulfate.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

Microorganisms

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Microorganisms—any food grade bacteria, fungi, and other microorganism.**
Technical Report: 2003 TAP; 2014 TR; 2015 Ancillary Substances
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 minutes and vote; 11/2009 sunset recommendation
Recent Regulatory Background: Added to National List with annotation 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date 9/12/2021

Background from Subcommittee:
Use:
Microorganisms used in organic handling include those that are used as probiotics, for fermentation, and bacteriophages used for food safety. Microorganisms are used by organic processors to make many well-known products including miso, shoyu, sake, and yogurts. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

Manufacture:
There are a variety of ways microorganisms can be produced. As noted in the 2014 technical report (TR), generally a medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different products. Depending on the organism desired, different mediums ranging from milk products to rice may be used to create the starter culture. After a culture is generated, the starter culture may be inoculated directly into a product that will be altered by the microorganisms or the culture may be preserved by drying, encapsulating, freezing or other method and used at a later time in the handling process.

International:
According to the 2014 TR on microorganisms, there is widespread international acceptance of microorganisms:

European Union: Article 19 states, "The following conditions shall apply to the composition of organic processed food: ...(b) only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes...may be used, and only in so far as they have been authorized for use in organic production in accordance with Article 21." "In addition, the products and substances referred to in

Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market."

Canada - Canadian General Standards Board Permitted Substances List: Microorganisms are permitted in organic processed foods as nonorganic ingredients that are not classified as food additives. This appears in 32.311 Table 6.4 as follows: "Microorganisms (processing derivatives) derived from genetic engineering or with the addition of chemosynthetic substance are prohibited."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) Joint FAO/WHO Food Standards Programme: Microorganisms, probiotics, and enzymes are allowed for use as additives and processing aids. "Substances found in nature from biological/enzymatic processes and microbial processes (e.g., fermentation)" are allowed for use "as additives or processing aids in the preparation or preservation of food" (Section 5.1(c)). Any preparation of microorganisms can be used in food processing except those derived from genetic engineering (Table 3.4).

European Economic Community (EEC) Council Regulation: EC No. 834/2007 and 889/2008: Microorganisms and enzymes "normally found in food processing" are permitted for use (Article 2y(1)(b)).

Japan Agricultural Standard (JAS) for Organic Production: Microorganisms do not specifically appear in the JAS standard for Organic Processed Food (Article 3) nor they considered food additives (Table 1). However, the JAS Standard includes language that indicates that microorganisms are allowed (see the TR for more details).

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM standard, Section 7.2.5, states, "preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products.

Ancillary Substances: Ancillary substances may be present in microorganism cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in dairy cultures in 2015. These include:

Functional class	**Substance name**
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.

Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Discussion:
Microorganisms have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of many products. They pose minimal health risks, and in many cases can enhance health. As noted in the 2014 TR, the health effects can be expressed directly through the interactions of the ingestion of the live microorganisms (probiotic effect) or indirectly as the result of ingesting the metabolites synthesized by the microbes during fermentation (biogenic effect). Food-grade bacteria may also be used for improved vitamin production, raw food materials are often fortified with food grade bacteria that produce an excess of B vitamins in situ and bacteriophages are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post- harvest, and during food processing (2014 TR).

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated in negative health effects, but are something that should be continually monitored.

In general, microorganisms are essential to the production of many organic foods and they are widely used in the industry.

Additional information requested by Subcommittee:

1. Are there any additional ancillary substances not listed in the chart?

Perlite

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Perlite—for use only as a filter aid in food processing.**
Technical Report: 1996 TAP
Petition(s): N/A
Past NOSB Actions: 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Perlite is used as a filter aid in food processing, such as filtration of juices, beer, wine, and vegetable oils.

Manufacture:
Perlite is an amorphous volcanic glass that occurs naturally and is sourced primarily from mines in the U.S., Greece, Turkey and China. The high-water content of the mineral causes it to expand many times its original volume when exposed to temperatures of 850-900 °C.

International:
Canada General Standards Board Permitted Substances List allows the use of perlite as a filtering aid.

Codex Alimentarius lists perlite as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

IFOAM Norms Appendix 4 – Table 1 lists perlite as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of perlite for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

Ancillary Substances:
None identified.

Discussion:
The listing of perlite has been consistently supported by the NOSB and organic stakeholders. There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

Additional information requested by NOSB:
Is this material still essential to organic production?

Potassium iodide

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(a) Nonsynthetics allowed: **Potassium iodide.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 Formal recommendation by the NOSB; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)

Sunset Date: 3/15/2022

Background from subcommittee:
Use: Potassium iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points. Iodization of salt completely eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as a food additive in the following functions:

- A nutrient in table salt as a source of iodine
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment. (2015 TR pg 15)

Manufacture: Potassium iodide can be refined nonsynthetically from sea water and salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] (2015 TR pg 27).

International: Nonsynthetic potassium iodide is listed on the Canadian standards for use where required by law and the synthetic form is allowed in products in the 70-95% category. It could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: In the past public comment has been limited. It is unclear if potassium iodide is being used for sanitizing purposes or only as a dietary supplement.

Additional information requested by Subcommittee:

1. Is potassium iodide utilized as a sanitizing agent for food processing equipment? If so, in what applications?
2. If potassium iodide is used for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If so, should this separate listing be removed?
3. Are certifiers limiting the use of potassium iodide to non-synthetic forms even with the 205.605(b) synthetic allowance for Nutrient Vitamin and Mineral listing?

Yeast

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Reference: 205.605(a) Nonsynthetics allowed: **Yeast—When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.**

Technical Report: 1995 TAP (Smoked Yeast); 1995 TAP (Baker's Yeast); 2014 TR

Petition(s): 2006 Petition; 2010 Petition Supplement; 2010 Petition memo

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 3/2007 NOSB committee recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290): Renewed 03/15/2017 (82 FR 14420)

Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value, and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

In general, yeast species (brewer's yeast) used in anaerobic conditions are for fermentation whereby they convert sugars to ethanol. This process includes ciders, beers, wines, and distilled spirits. Other uses for yeast are generally in aerobic conditions where they may be used as leavening agents (baker's yeast), for the addition of vitamins or minerals (nutritional yeast, chromium yeast, selenium yeast, torula yeast), as probiotics that may prevent or treat pathological conditions (probiotic yeast), and for flavoring (smoked yeast, torula yeast) (2014 TR). As the TR notes, they may be used synergistically or in conjunction with bacteria or other materials to create specific foods such as when kombucha is fermented with yeast and acetic acid bacteria to create fermented, sweetened tea.

The way the yeast is used in processing as well as the action of the yeast depends on the type of end products produced as well as the specific type of yeast being utilized.

Manufacture: Many yeasts are ubiquitous in the environment and in some cases handlers use these wild yeasts to make breads or for fermentation. However, since most handlers prefer more control over the specific type and strain of yeast that is utilized, most yeasts are grown under controlled conditions and then sold to end users. Typically, yeast is grown in a lab environment so as to prevent contamination from undesirable or pathogenic organisms. The lab grown yeast is then used to inoculate growth media for industrial production (2014 TR). In a number of cases there are several iterations of inoculation and addition of growth media in order to achieve the desired quantities. The yeast may then be used directly for food production or be concentrated and packaged for future use. Traditionally, smoked yeast is made by passing smoke through dried yeast but it may also be manufactured using chemical processes. This necessitated the annotation that when smoked yeast is used, documentation that the yeast is smoked by natural processes must be submitted by the user.

International: According to the 2014 TR, yeast is listed separately as an allowed substance in Canada and the European Union whereas it is indirectly referred to by CODEX Alimentarius, Japan and IFOAM. Listed below are excerpts from the TR listings – refer to the TR for additional details.

> **Canadian General Standards Board:** Table 6.4, titled “Non-organic Ingredients Not Classified as Food Additives” of the Canadian Permitted Substance List states that only non-synthetic yeast is allowed in organic handling. The types of yeast include “autolysate, bakers’ (may contain lecithin, obtained without the use of bleaches and organic solvents), brewers’, nutritional, and smoked. Non-synthetic smoke flavouring process shall be documented. Growth petrochemical substrate and sulfite waste liquor are prohibited.”
>
> **CODEX Alimentarius:** Yeast in the CODEX Alimentarius does not appear separately as it does in the USDA organic regulations. Under Additives and Processing Aids, "probiotics, microorganisms and enzymes are allowed." GL 32-1999 section 3.4 states that “any preparations of microorganisms and enzymes normally used as processing aids in food processing” are permitted for use “with the exception of genetically engineered/modified organisms and enzymes derived from genetically engineered/modified organisms.”
>
> **European Economic Community Council:** Article 20 allows for the labeling of organically produced yeast as organic, and states that "only organically produced substrates are to be used for the production of organic yeast and organic yeast should not be present in organic food or feed together with non-organic yeast"
>
> **Japan Agricultural Standard (JAS):** The JAS Standard for Organic Processed Food does not specifically identify the allowance for yeast, in Table 1: Food Additives of the Japanese Agricultural Standard for Organic Processed Foods (Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606) 2005). However, the standard includes the following language that indicates that microorganisms, including yeasts, are allowed: “Only physical method or method using biological function (except for those produced by the recombinant DNA technology; hereafter the same) shall be used for the manufacturing or processing.”
>
> **International Federation of Organic Agriculture Movements (IFOAM):** Yeast is permitted in IFOAM per Section 7.2.5 which states that “preparations of micro-organisms and enzymes

commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products. Cultures that are prepared or multiplied in-house shall comply with the requirements for the organic production of microorganisms."

Ancillary Substances: According to the 2014 TR, there are a few yeast species that are formulated with no ancillary substances, however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products. During the prior sunset review in 2015, the following functional classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as being problematic with regard to exposure.

Discussion: Yeast is widely used and has been for centuries. Many organic products rely on the use of yeast for their distinctive features and characteristics. While there has been broad support for the relisting of yeast on the National List in past reviews, significant discussion has been centered on ancillary substances and whether organic forms of yeast are available. Yeast underwent a significant review that led to a change in the listing in 2010. The 2014 technical review added information about the current status of various yeasts and looked at the ancillary substances. As part of the prior sunset review many commenters noted that organic yeast forms are readily available, but that for certain uses there are some forms that are not yet organically produced in sufficient quantity or quality. These included torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. This led to the extensive annotation on the National List for the yeast.

During the prior sunset review in 2015, the following functional classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as being problematic with regard to exposure.

Finally, it should be noted that while yeast itself is often considered as a minimal risk material to both the environment and in use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR).

Additional information requested by Subcommittee:

1. Are there still types or forms of organic yeast that are not available in sufficient quality or quantity for production of organic products? Specifically, have organic forms of torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast become available since the last sunset review in 2015?
2. Have there been changes in ancillary materials added to yeast compounds since the 2014 TR?

§205.605(b) Synthetics allowed:

Acid, Alginic

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Alginic acid (CAS #9005-32-7).**
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2015 formal recommendation (reclassification)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Proposed rule 1/17/2018 (83 FR 2498); Reclassified effective 01/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Background from subcommittee:
Use:
Alginic acid is used in the food industry as an emulsifier, emulsifier salt, formulation aid, and thickening agent for soups and soup mixes. FDA limits the use of alginic acid as a stabilizer, emulsifier and thickener in soups and soup mixes.

Manufacture:
Alginic acid is derived from wild harvested brown cold-water seaweeds. Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment, and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in a pure alginic acid and its classification as a synthetic. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, the free acid form does not appear in nature (2015 TR – Alginic Acid, Lines 283-286).

International Acceptance:
The 2015 TR noted the following:
Canadian General Standards Board - permits the use of alginic acid under the Organic Production Systems Permitted List as a non-organic food additive. It is also found in the same table under the heading Alginates.
CODEX – alginic acid is permitted under the Guidelines for the Production of Organically Produced Foods as a food additive of non-agricultural origin for foods of plant origin. The General Standard for Food Additives within CODEX list a number of provisional uses that FDA does not identify such as a bulking agent, foaming gent, glazing agent, in various food types.
European Economic Community (EEC) lists alginic acid as an approved food additive for use in the production of processed organic foods.
Japan Agricultural Standards (JAS) allows alginic acid as a food additive limited to only processed foods

of plant origin.
The International Federation of Organic Agriculture movements (IFOAM) lists alginic acid as an approved additive for use in organic processed products without any annotations.

Environmental Issues:
Alginic acid is derived from harvesting brown wild seaweed. There has been little research into production of alginic acid and alginates from a biological fermentation process. However, commercially available quantities are sourced from brown seaweed, (2015 Technical Review – Alginic Acid, Lines 299-300). Most are derived from wild harvested seaweed, but some seaweed is cultivated. Brown seaweed is harvested in cold water. Recent public comments expressed concern of over-harvesting and the impact on local ecosystems. Some negative comments cited that wild harvested seaweed is a bio-accumulator of heavy metals and because alginic acid is used primarily to enhance texture in foods it is therefore not "essential" according to OFPA criteria. The 2015 TR did not cite any evidence supporting those concerns.

Discussion:
In the 1995 TAP review for alginic acid, reviewers determined the material was non-synthetic. However, given the Classification of Materials document (in draft form in 2015) and the information presented in the 2015 TR, it was recommended by the NOSB that alginic acid be reclassified as synthetic. In January 2019, it was relisted from 205.605(a) nonsynthetic, to 205.605(b) synthetic. The majority of public comment from the 2015 sunset review was in favor of relisting of alginic acid. Those in favor of its relisting note the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting and assert that the properties imparted by alginic acid are essential for some processed food formulations. Those opposed cited that wild seaweed is a bio-accumulator of heavy metals, and over harvesting was detrimental to local ecosystems. The Board did recognize in October 2018 that further research may be needed on the sustainability of harvest practices. There was one public comment in October 2018 in favor of relisting alginic acid under 205.605(b) citing that harvesting practices of wild seaweed were safe and sustainable.
The Federal Register Notice published December 27, 2018, effective January 28, 2019 (Vol. 83, No.247, pp 66559-66574), amends the National List and moves Alginic Acid from 606.605(a), nonsynthetic substances allowed etc. to 606.605(b), synthetic substances allowed etc. The complete listing under 205.605(b) is Alginic acid (CAS# 9005-32-7)

Additional information requested by Subcommittee:

1. Is there a way to assess whether or not current brown seaweed harvesting practices are sustainable or damaging to local ecosystems?

Activated charcoal

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.**
Technical Report: 2002 TAP
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 sunset recommendation ; 11/2009 sunset recommendation.
Regulatory Background:
Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Background from Subcommittee:
Use:
Activated charcoal is used in processing as mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity.

Manufacture:
Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

International:
Canada General Standards Board Permitted Substances List allows the use of activated charcoal as an ingredient classified as a food additive. Shall be of plant origin. Prohibited for use in the production of maple syrup.

Codex Alimentarius lists activated carbon as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists activated carbon for the preparation of foodstuffs of plant origin.

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of active carbon for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists charcoal for oenological use, with a restriction that limits use to musts and new wines still in fermentation, rectified concentrated grape must and white wines. No more than 100g dry production per hl.

Ancillary Substances:
None identified.

Discussion:
Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

Ascorbic acid

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Ascorbic acid.**
Technical Report: 1995 TAP; *2019 TR pending (to be posted at https://www.ams.usda.gov/rules-regulations/organic/national-list/a)*
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. Ascorbic acid is one of the most common sources of Vitamin C. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties.

Manufacture:
The majority of industrial production of ascorbic acid is synthesized using the Reichstein and Grussner process which is a six-step process developed in the 1930's that begins with D-glucose and involves hydrogenation, oxidizing, and treatment with acetone and then hydrogen chloride to yield L-ascorbic acid. Modern industrial production processes use fermentation with additional bio-oxidation steps adding a bio-catalyst which eliminates the need for the chemical steps. Synthetic ascorbic acid is

identical in molecular structure and in function to natural ascorbic acid. The majority of industrial production comes from China.

International Acceptance:
Ascorbic acid is GRAS as a chemical preservative (21CFR182.3013), a dietary supplement (21CFR182.5013), and nutrient (21CFR182.8013) when used in accordance with Good Manufacturing Practices. It is allowed by CODEX and the European Union.

Environmental Issues:
Ascorbic acid is considered non-toxic. The quantities needed to cause harm to humans are in the magnitude of one quart per 150 lbs. body weight. The potential for environmental pollution is slight (TR pp. 20).

Discussion:
Ascorbic acid is a vital nutrient necessary for humans and other primates. Humans cannot synthesize Vitamin C and must rely on dietary intake. It is added to many foods to restore Vitamin C lost during processing (Fall 2015 pp. 1146). Some FDA regulations require Vitamin C fortification, which is often achieved with ascorbic acid. It is manufactured using a culture process from dextrose.
Public comment for ascorbic acid was divided, with some comments remarking that ascorbic acid is being used as a preservative and therefore not consistent with organic agriculture. However, the majority of commenters strongly supported relisting of ascorbic acid, stating the ingredient to be critically essential to maintaining nutrients and freshness in their products (Ref: Transcript Fall 2015, pp.67-69). There is no known substitute in food processing.

Additional information requested by Subcommittee:
(*May be addressed in the pending TR*). Is the modern industrial manufacturing process which utilizes additional bio-oxidation an excluded method?

Calcium citrate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Calcium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 4/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:

Calcium citrate is used as an ingredient in dietary supplements, although there are other calcium sources for supplementation purposes permitted at §205.605(b) under the listing Nutrient Vitamins and Minerals. Calcium citrate can be used as a sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), as a raising agent and an emulsifying salt. It is also used to improve the baking properties of flours and as a stabilizer. It can also be used as a water softener due to its chelation properties. It is used to wash processing equipment in order to eliminate off flavors, and as a pH adjuster and chelator in cleaning and sanitizing products. It is also used for its chelating properties to remove scale from boilers, evaporators and other processing equipment. Calcium citrate is widely used in cosmetic and personal care products for many of these same functions.

Manufacture:

Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization.

Citric acid is listed under 21 CFR 184.1195 as Generally Recognized as Safe (GRAS). It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate. It is permitted in food with no limitations other than current good manufacturing practice. It is also permitted by FDA in infant formula.

Calcium citrate is GRAS as listed at 184.1195

The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inerts).

International:

Allowed by Canada, European Economic Community (EEC) (as an ingredient in the preparation of foods of animal origin), and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary Substances:

According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:

According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including calcium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of calcium citrate was not addressed in terms of potential harm to the environment.

The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts

Additional information requested by Subcommittee: None

Ferrous sulfate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).**
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 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.). Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues. Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function. (2015 TR, pg 15)

Manufacture: Ferrous sulfate is made by reacting sulfuric acid with iron. [21 CFR 184.1315] (TR 2015, pg 28)

International: Ferrous sulfate is listed on the Canadian standards for use where required or allowed, it could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: It appears this material is solely used is as a nutritional additive to address population-based iron deficiency.

Additional information requested by Subcommittee:

1. If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this item be removed?

Hydrogen peroxide

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Hydrogen peroxide.**
Technical Report: N/A (2015 TR Crops)
Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Hydrogen Peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H_2O_2. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR §205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as "organic" or "made with organic(specified ingredients or food group(s))." (7 CFR 205.605(b)).

Manufacture:
According to the TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H_2) and oxygen (O_2): $H_2 + O_2 \rightarrow H_2O_2$

International:
Canada: Allowed for many uses, including as food-grade cleaners, disinfectants and sanitizers" that are allowed without mandatory removal of residues, and "cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production"

European Union: Allowed for similar uses to Canada and U.S.

IFOAM: Allowed as cleanser and disinfectant among other uses.

Japan: Not listed.

Codex: Allowed as a cleanser and disinfectant among other uses

Ancillary substances:
None. Inerts may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials including caprylic acid and mono-and di-potassium salts of phosphorous acid.

Human Health and the Environment:
Concentrated solutions may be corrosive to eyes, exposed skin, and mucous membranes. Warnings for high concentrations include:

Corrosive. Causes irreversible eye damage. May be fatal if swallowed or absorbed through the skin. Causes skin burns or temporary discoloration on exposed skin. Do not breathe vapor. Do not get in eyes, on skin or on clothing. Wear protective eyewear such as goggles or face shield. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Extensive toxicological testing of hydrogen peroxide has been completed, and it is unlikely to cause chronic systemic toxicity or reproductive, development, or carcinogenic effects. However, chronic exposure to vapors may damage lungs. Hydrogen peroxide is described to have low to moderate toxicity to aquatic invertebrates and no danger to fish. Because hydrogen peroxide is unstable and breaks down into water and oxygen gas, long-term impacts on the environment are unlikely. According to the TR, some toxic chemicals used to manufacture hydrogen peroxide including alkyl anthraquinones, aromatic solvents and metal catalysts (e.g., nickel and palladium) are removed from the product and can be returned to the reactors to make more product. Overall, this material is relatively safe but should be used according to FDA, USDA, and EPA labels and regulations.

Discussion:
Like peracetic acid, this material has received strong support and has been consistently relisted on the National List. Its overall profile is relatively safe, especially compared to many other sanitizers, such as chlorine compounds, and when used appropriately should not have adverse impacts on human health and the environment. In summary, hydrogen peroxide is an important tool for handling.

Additional information requested by Subcommittee:
Is this material still essential for the production and handling of organic products?

Nutrient vitamins and minerals

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.**
Technical Report: 1995 TAP - Minerals; 1995 TAP - Vitamins; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2011 Handling Subcommittee Proposal; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Nutrient vitamins and minerals are used to recreate or add nutritional content to foods. Sometimes this nutritional content is added due to public health guidance (e.g. Iron in cereal to combat iron anemia), to mimic analog products (calcium fortification of non-dairy milks, fortification of infant formulas), to make up nutrients lost in processing (Vitamin A in skim milk) or for product marketing purposes (enriched flours). There are very few legally required fortified foods. Those that are required to be fortified are listed in the chart below, as noted in the 2015 technical review:

Standards of Identity in Title 21 CFR that require Nutrient Fortification

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.100 21 CFR 107.10	All nutrients known to be essential and listed therein
Margarine	21 CFR 166.110	Vitamin A
Milk	21 CFR Part 131	Vitamins A & D (required by some states)

There are more food classes with standards of identity that allow for the use the fortification, however these fortifications are optional. It should be noted that foods eligible for the "Women, Infants and Children" federal programs may be required to be the fortified standard of identity form.

Use of vitamins and minerals will depend on the application and the specific substances being used. These substances will often be processed with accessory additives to make the vitamins or minerals stable and useable in food applications.

Manufacturing: The 2015 technical review states:

> According to Vandamme (Vandamme 1992), "vitamins are now either prepared chemically or biotechnologically via fermentation or bioconversion processes. Several vitamins and related biofactors are now (1992) only or mainly produced chemically (vitamin A, cholecalciferol (D3), tocopherol (E), vitamin 432 K2, thiamine (B1), niacin (PP or B3), pantothenic acid (B5), pyridoxine (B6), biotin (H or B8), folic acid (B9)]or via extraction processes (β-carotene or provitamin A, provitamin D3, tocopherol, vitamin F-group). However, for several of these compounds microbiological or algal methods also exist or are rapidly emerging. Other vitamins are produced practically exclusively via fermentation (ergosterol or provitamin D2, riboflavin (B2), cyanocobalamin (B12), orotic acid (B13), vitamin F-group ATP, nucleosides, coenzymes, etc.] or via microalgal culture (β-carotene, E, F). Both chemical and microbial processes are run industrially for vitamin B2, while vitamin C (ascorbic acid) is produced via a combination of chemical reactions and fermentation processes. In the past twenty-five years, numerous patents have been issued disclosing fermentations by genetically modified microorganisms to produce various water-soluble vitamins… As the above descriptions detail, most vitamin and mineral nutrients are synthetic substances, even including some with natural or agricultural origins… Most vitamins and minerals are not available from nonsynthetic sources…. The current National List listings creates confusion for those nutrient vitamins and minerals specifically listed at §205.605(a), which requires a nonsynthetic source, whereas "Nutrient vitamins and mineral" are a class of "allowed synthetics." For example, the producer of a nutritional product may not be sure if supplemental magnesium as magnesium sulfate is restricted to a nonsynthetic source. "

The technical report details many individual manufacturing methods.

International: The Codex and EU standards only allow the use of synthetic vitamins and minerals where required by law. The Canadian standards allow synthetic vitamins and minerals where required by law as well as in "non-dairy substitute products" on a "voluntary basis, if legally permitted." Canadian standards also allow for the use of "Ferrous sulphate—Shall be used if legally required and may be used, on a voluntary basis, if legally permitted." IFOAM allows by law or when "strongly recommended in

food products in which they are incorporated." Japanese standards do not allow for vitamins and minerals (2015 TR, pg 20-21). All standards list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate) – the review above does not include these individual substances, just categorical listings.

Discussion:
Brief history:

- In 1995 the NOSB added nutrient vitamins and minerals to the National List with the following annotation, ''Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.'' A second recommendation was also passed entitled ''Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.'' This stated, ''Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.''

- The final rule published in 2000 (65 FR 13512) included the current annotation. It was recognized soon after that the cross reference to the FDA's fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing was necessary.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamins and minerals.

- In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a memo to the NOSB in April 2010 explaining this clarification.

- The existing annotation is not what the original NOSB recommended in 1995. In 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting and the NOSB supported relisting with the existing annotation for the 2012 sunset review.

- On January 12, 2012 a proposed rule was published in the Federal Register (77 FR 1980) to change the annotation to: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food groups(s)).''

    (b) Synthetics allowed,

    Vitamins and minerals. For food— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10.

- This proposed rule clarified that "nutrients" that were not in these CFR sections had to be petitioned individually for the National List because this listing did not include them.

- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule (77 FR 59287), which renewed without change the original listing, as per the NOSB April 2011 recommendation.

- In 2011 through 2013 many other nutrients were petitioned. Some were recommended for listing by the NOSB while others were not. No rulemaking in this area has occurred.

- In 2014 the Handling Subcommittee commissioned a new technical report in preparation for Sunset 2017 reviews. This was completed in February 2015 and clarifies which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.

- In 2015 the NOSB voted to renew the listing noting the following about the technical review and public comment:

  "Since this is a huge group of different substances, the TR went into length about their manufacturing processes, effects on human health, effects on the environment and uses. There was no information among these pages that gave concern that these substances did not meet the review criteria. Likewise, public comment was received with concerns about the unnecessary use of synthetic ingredients, but no new information was provided in comments from the first posting regarding the review criteria beyond the alternatives and compatibility issues.

  Regarding alternatives, the primary alternative is for people to get their vitamins and minerals from the food itself rather than supplementation. …There is no literature to suggest that the manufacture or use of vitamins and minerals with ancillary substances is harmful to the environment or to biodiversity."

- In 2016 the Handling Subcommittee brought forward a discussion document with two options:

  Option 1

  Proposed Annotation #1: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed only when their use is required by law or to meet an FDA standard of identity in which they are incorporated.

  Proposed Annotation #2: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic" (except as noted in annotation #1).

  Proposed Annotation #3: §205.605 (a) Vitamins and minerals, non-synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled Organic.

  Option 2

  Proposed Annotation #4: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9.

For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and “made with organic (specified ingredients or food group(s))”.

•To Date the NOSB has taken no further action on this subject

Additional information requested by Subcommittee:

1. Is the current listing meeting the needs of the organic community, certifiers and industry – if not, how should it be revised?
2. How are certifiers currently dealing with non-synthetic nutrient vitamins and minerals?
3. It is speculated that the 2012 rulemaking was stopped due to the impact this change would have on the currently established organic infant formula market which has both established manufacturers and consumers. How should the NOSB move this topic forward in light of this issue?
4. Given that added vitamins and minerals need to be listed on ingredient panels, are consumers enabled enough to make educated purchasing decisions on fortified foods? If not, please explain.

Peracetic acid

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
Reference: 205.605(b) Synthetics allowed: **Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.**
Technical Report: 2000 TAP; 2016 TR

Petition(s): 2008 Petition

Past NOSB Actions: 11/2000 sunset recommendation; 04/2004 NODB meeting summary; 11/2009 NOSB formal recommendation

Recent Regulatory Background: Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)

Sunset Date: 9/12/2021

Background from Subcommittee:
Use:
Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products according to FDA limitations, and to sanitize food contact surfaces, including dairy-processing equipment and food-processing equipment and utensils. It is an important sanitizer used in organic handling. It is widely used as a sanitizer on food contact surfaces and as a disinfectant for fruits and vegetables. Peracetic acid/Peroxyacetic acid was added to the National List on September 12, 2006, with the annotation, “for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.” (It is also on the National List at §205.601 and §205.603 for use in Crops and Livestock respectively). Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture:
According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Commercial grades are available in concentrations ranging from about 0.3 to 40 % by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide.

International:
Japan: Not listed
Codex: Not listed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary substances:
HEDP and dipicolinic acid (DPA) are added to peracetic acid solutions to chelate metals, especially iron, copper and manganese, because decomposition of peracetic acid and, thus, loss of sanitizing power is accelerated by these impurities. However, in past reviews, stakeholders did not declare the inclusion of ancillary substances (See below).

Human Health Environment:
peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

Discussion:
Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has generally been strong support for continued availability. Overall, this material is considered effective and offers a less toxic profile then several other sanitizing materials, including many chlorine compounds. The TR does not offer new evidence of unacceptable adverse impacts on human health or the environment. During the last review, use of a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition were judged to be "inerts" for EPA registration as an antimicrobial and not subject to review as an ancillary substance. Furthermore, the annotation currently states "for use in wash and/or rinse water according to FDA limitation", which defines the permitted stabilizers.

Additional information requested by Subcommittee:

1) Is peracetic acid still essential for handling and processing of organic products?

Potassium citrate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Potassium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Uses: Antioxidant, acidulant, pH control, flavoring agent, sequestrant, emulsifying salt, stabilizer, and as a dispersant in flavor or color additives. Commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat products. It is also used to wash processing equipment to remove off flavors. Potassium citrate is used to replaced sodium citrate whenever a low sodium content is desired.

Manufacture:
Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization.
Potassium citrate is Generally Recognized as Safe (GRAS) as listed under 21 CFR 184.1625.

International:
Allowed by Canada and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including potassium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of potassium citrate was not addressed in terms of potential harm to the environment. The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

Additional information requested by Subcommittee: none

Potassium phosphate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).")
Reference: 205.605(b) Synthetics allowed: **Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s)),"** prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP, 2016 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Potassium phosphate can be used as a pH control in milk and dairy products, to make acidified milk products and in milk protein stabilization. It can also be used as a nutritional additive for a source of potassium and as a nutrient in yeast. Potassium phosphate can also be used in prepared meat applications and liquid eggs. The initial technical advisory panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled "organic," but was only approved for use in "made with" products.

Manufacture: The initial technical report (TR) noted that potassium phosphates are isolated from brines or salt deposits. However, the 2015 TR explained the manufacturing process to be as follows: All of the orthophosphate derivatives of potassium can be generated by neutralization of phosphoric acid with potassium hydroxide (Budavari 1996). Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate (Budavari 1996). Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm. [21 CFR 184.1631]. (2015 TR, pg 30-31)

International: Potassium phosphate is not listed in CODEX, does not appear on the EU, JAS or IFOAM organic standards, but is listed in the Canadian organic standard for products in the 70%-95% category only.

Discussion: During the 2017 sunset review cycle, the NOSB received public comment in support of potassium phosphate, noting it is an efficient pH buffering substance with no organic alternatives. The industry indicated that potassium phosphate is used in non-dairy beverages; it prevents precipitation and impaired mouthfeel; that the alternatives are not as good; and loss of this product would mean impaired quality and marketability. Other commenters noted a concern with the use of phosphates in production of processed foods and that phosphorus may not appear on the nutritional panel making it difficult to be informed about total phosphorous intake– although they would appear on the ingredient list. In particular there were concerns raised about the cumulative health impacts of phosphorous additives in food and in 2015 the NOSB requested a technical review and work agenda item to study this issue further. Concerns were based on peer reviewed research indicating that the cumulative effects of

phosphates as a group are contributing to renal damage and failure, osteoporosis, and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal renal function, from cumulative phosphorus. A daily limit of 70 mg/kg/day was recommended in one study. Populations are at risk for bone health and kidney failure were especially impacted. In 2016 the NOSB Handling Subcommittee published a discussion document on the cumulative health impacts of phosphates and the NOSB decided to address phosphates individually during sunset reviews. Sodium phosphate was reviewed in 2017 and the NOSB came to the following conclusion:

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

Additional information requested by Subcommittee:

1. Does industry still find the listing for potassium phosphate necessary? In what applications is this substance currently being used in products marketed as "made with organic."
2. If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this listing be removed?

Sodium acid pyrophosphate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.**
Technical Report: 2001 TAP (Sodium Phosphates); 2010 TR; 2016 TR
Petition(s): 10/2002 petition; 03/2007 petition for expand use
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation; 04/2011 sunset recommendation
Regulatory Background: Added to National List 09/12/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Background from Subcommittee:
Use:
Sodium acid pyrophosphate is a common food additive for the purpose of a sequestrant/chelating agent in processed potatoes, an emulsifying agent in cheese, an inhibitor agent in canned tuna, and a curing accelerator in processed meats. This listing limits its use as a leavening agent. Sodium acid pyrophosphate is used as a leavening agent in baked goods, where it reacts with baking soda (sodium

bicarbonate) to liberate carbon dioxide, 'leavening' the dough and creating the desired 'airy' texture that consumers expect of baked goods such as cakes and cookies. It is GRAS, listed at 21 CFR 182.1087.

Manufacture:
Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220ºC to form sodium acid pyrophosphate. It is expressed by the formula Na2H2P2O7 and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

International:

The Canadian General Standards Board Permitted Substances List (CAN/CGSB 32.311-2006) permits these phosphate salts with usage annotations identical to the NOP regulations.

CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (GL 32-1999)

These guidelines only permit monocalcium phosphate (341(i)) and "only for raising flour" (as a leavening agent).

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

ANNEX VIII, Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a), Section A – Food Additives, including Carriers, lists only monocalcium phosphate (341(i)) as a "Raising agent for self-raising flour" (as a leavening agent).

Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the Ministry of

Agriculture, Forestry and Fisheries of October 27, 2005)

Table 1, "Food Additives," lists INS 341(i), Calcium dihydrogen phosphate (a.k.a. monocalcium phosphate), with the annotation "Limited to be used for powders as expanding agent" (as a leavening agent).

IFOAM – Organics International (IFOAM)

The IFOAM norms for Organic Production and Processing, Version 2014, list monocalcium phosphate, INS 341, as a food additive "Only for 'raising flour'" (as a leavening agent).

Ancillary Substances:
None identified.

Discussion:
During the last sunset review, this material received positive support from stakeholders. While excess phosphates in wastewater contributed to environmental degradation in the past, this was largely due to

its use in detergents. Its use in detergents has waned and in this use as a food additive, phosphates would have little environmental impact.

The 2016 technical report (TR) on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and completely bioavailable upon consumption whereas "food" phosphorous is much less available.

High blood phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

Yeast, a natural leavener used for time immemorial, is a common and alternative to chemical leavening. However, yeast leavened baked goods have a different physical texture and require more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes such as found with muffins, pancakes and cookies.

Additional information requested by Subcommittee:
Is this material still essential to organic production?

Sodium citrate

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Sodium citrate.**
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 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Uses: Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy. Also used as dispersants in flavor or color additives, and to wash processing equipment in order to eliminate off flavors.
During the last review of sodium citrate in 2015, public comment included these specific reasons for use:

- Potassium citrate is an option, but it has an unpleasant metallic taste. Sodium phosphates are another option but they need to be used in higher quantities and are not as effective.
- We use sodium citrate as part of the process of preparing fresh fruit for use in our yogurts. We use sodium citrate primarily for its ability to buffer pH, neither citric acid nor potassium citrate would have the same buffering effect in our products.
- Sodium citrate is used in a personal care product (lubricant).

Manufacture:
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.
Sodium citrate is listed under 21 CFR 184.1751 as Generally Recognized as Safe (GRAS). The listing allows its production from citric acid and sodium hydroxide or sodium carbonate. It is allowed as an ingredient used in food with no limitation other than current good manufacturing practice.
The EPA lists citric acid and its salts in the 2004 List 4A (minimal risk inerts).

International:
Canada: Sodium citrate is allowed but restricted to use with sausages or milk products.
CODEX Alimentarius Commission: Sodium citrate is listed for sausages/pasteurization of egg whites/milk products.
European Economic Community (EEC): Sodium citrate is allowed as an ingredient in the preparation of foods of animal origin.
Japan Agricultural Standard (JAS): Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.
International Federation of Organic Agriculture Movements (IFOAM): allowed as an additive.

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including sodium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of sodium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

Additional information requested by Subcommittee: None

Tocopherols

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Reference: 205.605(b) Synthetics allowed: **Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.**
Technical Report: 1995 TAP; 2015 limited scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review; 09/2016 Handling Subcommittee proposal additional listing of Tocopherol
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Synthetic tocopherols are currently permitted for use in organic agriculture handling/processing as an antioxidant ingredient in foods (2015 TR). Tocopherols are added to foods to help prevent oxidation of the fatty acids present in the lipid components of the food. Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" when rosemary extracts are not a suitable alternative (7 CFR 205.605[b]).

Manufacture:
Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables. As described in the 2015 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation. The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

International:
Japan: Listed for processed meats.
Codex: Allowed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary Substances:
Table 1 from the most recent Technical Review (TR) shows some of the more common formulations along with their ancillary substances.

Table 1. Commercially Available Tocopherols Products Used as Antioxidants in Foods

Manufacturer	Product Name	Formulation	Ancillary Substance(s)	Source(s)
Advanced Organic Technologies (Buenos Aires, Argentina)	Tocomix™	Liquid	Sunflower oil	AOM, 2014
Archer Daniels Midland Company (Decatur, IL)	Decanox™	Liquid	Unknown	ADM, 2014
		Powder	Unknown	
BASF (Germany)	Covi-ox®	Liquid	Soybean oil	Brenntag Specialties, Inc., date unknown; BASF, 2013
		Powder	Gum acacia	
BTSA (Madrid, Spain)	Tocobiol®	Liquid	Sterols, squalene, monodiglycerides*, soybean or sunflower oil	BTSA, 2014a; BTSA, 2013
		Powder	Calcium carbonate	
	Nutrabiol® T	Liquid	Soybean or sunflower oil	BTSA, 2014b; BTSA, 2012
		Powder	Silica	
DuPont Danisco (global)	Guardian® tocopherol extract	Unknown	Unknown	DuPont Nutrition and Health, 2014a
Kemin Industries, Inc. (Des Moines, IA)	Fortium® mixed tocopherols	Liquid	Sunflower oil	Kemin, 2014a; 2014b
		Powder	Rice maltodextrin	
Nutralliance (supplier) (Yorba Linda, CA)	Sunvitol™ MT	Powder	Unknown	Nutralliance, 2014
Organic Technologies (Coshocton, OH)	Natural mixed tocopherols	Liquid	Organic sunflower oil	Organic Technologies, 2013
		Powder	Tapioca starch	
Sigma-Aldrich (St. Louis, MO)	Mixed tocopherols	Liquid	Unknown	Sigma-Aldrich Co. LLC, 2014
The Scoular Company (Minneapolis, MN)	Natural source mixed tocopherols	Liquid	Unknown	The Scoular Company, 2014
		Powder	Unknown	
Vitablend (Wolvega, The Netherlands)	Tocoblend®	Liquid	Unknown	Vitablend, 2014
		Powder	Unknown	
VitaeNaturals (Toledo, Spain)	Vitapherole® T	Liquid	Unknown	Vitae Caps S.A., 2012
		Powder	Unknown	
Wilmar Spring Fruit Nutrition Products Co. (Jiangsu, China)	Natural mixed tocopherols	Liquid	Soybean or sunflower oil	Wilmar International Ltd., 2014
		Powder	Unknown	
ZMC-USA (The Woodlands, TX)	CarolE™ ET and PT	Liquid	Unknown	ZMC-USA, date unknown
		Powder	Unknown	

* Piñol del Olmo (date unknown) reports that sterols, squalene, and monodiglycerides are naturally present in Tocobiol® from the sou vegetable oil.

Background from subcommittee:

The NOSB has consistently relisted this material due to its essentiality for many processed food products. However, there has been extensive discussion about the need for synthetically derived tocopherols. Public comment has historically been divided on the relisting due to concerns that the

material's primary use is as a preservative and therefore inconsistent with organic production. Additionally, commenters have asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic. However, many past commenters have expressed strong support of relisting, stating that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers. Given past feedback on the commercial availability of non-synthetic tocopherols, the Handling Subcommittee considered the possibility of reclassifying tocopherols to 205.605(a), or listing on both 205.605(a) and 205.605(b) with different uses annotated for each listing and/or an annotation about availability; however, as discussed at the Fall 2017 meeting, the Handling Subcommittee concluded to not move forward with the tocopherol annotation change. The meeting transcripts note that "if there is sufficient commercial availability of this material in another form, we encourage members of the public or industry to petition the NOSB to make this change, and we would take it up at that time".

Human Health and the Environment:
Tocopherols are one of the main sources of Vitamin E. No major impacts on human health or the environment are likely.

Additional information requested by Subcommittee:

1) Are there any additional ancillary substances not listed in the chart that should be considered?
2) Since the last sunset review, are new sources of non-synthetic tocopherols available that fulfill the needs of organic food processing?

Reference: 7 CFR §205.606

Celery powder

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(c) **Celery powder.**
Technical Report: N/A
Petition(s): 2007 Petition; *2018 TR pending*
Past NOSB Actions: 03/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:

Use:
Celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide "cured" meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled "uncured."

Manufacture:
Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, heated and vacuum dried. According to the original petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf), "the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load." Celery powder is typically standardized to a specific nitrite content. According to past information reviewed by the NOSB, meat preservation via natural nitrites/lactic acid is an ancient technology. Concerns have been raised during past reviews that production of high nitrate conventional nonorganic celery used for celery powder production requires enhanced use of synthetic nitrate fertilizers. According to the Kerry Inc. patent, other plants high in nitrate that could be used "include, but are not limited to, celery, beet, spinach, lettuce, cabbage, cucumber, eggplant, mushroom, green pepper, butternut squash, zucchini, mixed salad greens, carrot, artichoke, green bean, lima bean, broccoli, cauliflower, collard green, com, mustard, okra, onion, Chinese pea pod, black eyed pea, green pea, potato, turnip, sauerkraut, radish and the like. Other edible plant material containing nitrate, preferably at least about 50 ppm nitrate, also can be used. Any mixture or combination of plant materials can be

used to make the curing agent."

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

Ancillary substances:
Possibly materials listed in the patent: "including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates."

Human Health and the Environment
Nonorganic celery is used to produce celery powder, with concomitant use of allowed conventional pesticides and fertilizers. These materials may pose risks to workers, consumers and the environment. Additionally, health concerns have been raised about the use of synthetic nitrates and nitrites in processed meats (allowed in the European Union). For example, the International Association for Research in Cancer (IARC) listed processed meats as carcinogenic to humans, albeit with low potency, and the review committee was not unanimous. Nitrates and nitrites from celery powder may pose similar risks.

Discussion (including OFPA criteria):
Celery powder was listed as a nonorganic handling material in response to a 2007 petition asserting the need for a uniform, agriculturally produced material necessary to produce organic processed meats such as bacon, hot dogs, and sausages. Several commenters argue that this material allowed substantial growth of the organic meat industry while complying with the "organic" or "made with organic" claims of processed foods. However, concerns were, and continue to be, raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to "supercharge" the product used for celery powder manufacture.

Celery powder was last reviewed by the NOSB in 2015, and there were extensive comments by celery powder manufacturers, trade groups, producers, and the larger organic community about the need for this material, as well as commitments by producers to address the lack of organically sourced material going forward to the next sunset review, which is occurring now. To address these concerns and in lieu of a technical report, the NOSB will be convening a panel discussion at the Spring 2019 NOSB meeting that will include agronomic specialists, celery powder manufactures, meat processors, and experts in meat science and nitrates and nitrites. This discussion will help flesh out the information needed for the Fall 2019 review and vote on whether to relist celery powder.

Additional information requested by Subcommittee:

1. Is nonorganic celery powder still essential for the production of processed meats?
2. Compared with growing celery for vegetable production, is increased use of synthetic nitrogen fertilizers required to produce source plants with enough nitrate for celery power production?
3. Since 2015, what progress has been made on the production of organic celery for powder production?
4. Are there strategies to produce organic celery powder that is standardized to consistently meet

safety and other requirements of the meat processing industry?

5. If not, enough organic celery is being produced to support the meat industry, why not?
6. Are there commercially available agriculturally produced alternatives to celery powder? What is your experience with them? Are they organic? Does their use vary by application? Are they more effective in one application compared to another?
7. What is the latest information on the human health risks of nitrate and nitrites present in processed meats from either synthetic or plant-based sources?

Fish oil

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

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

Technical Report: 2015 TR

Petition(s): 2007 Petition

Past NOSB Actions: 03/2007 sunset recommendation; 04/2010 sunset recommendation ; 10/2015 NOSB Final Review

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

Sunset Date: 3/15/2022

Background from subcommittee:

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

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

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

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

History: Fish Oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report or TAP. The 2007 NOSB recommendation indicated that the OFPA criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the NOSB final recommendation from May 9, 2007 stated …"pursuant to the judgment in Harvey v. Johanns, the NOSB was instructed to develop criteria for determining

commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed on §205.606. These criteria were finalized in the NOSB "Recommendation for the Establishment of Commercial Availability Criteria National List §205.606" of October 19, 2006. "That recommendation allows for pro-active listing on §205.606 of materials which may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather or trade-related issues. Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a §205.606-listed material may be used, on a case by case basis. …" "…. After discussion, the Board decided to add an annotation to the recommendation to list fish oil to the National List. The annotation states: "stabilized using only allowed ingredients on the National List." The Board considered this annotation to be not overly prescriptive since a nonorganic material that falls within the annotation exists on the market." The NOSB (2007) further noted that "There were no public comments specifically opposing the listing of fish oil on §205.606…."

In its five-year review in April 2010 the NOSB received no public comment and fish oil remained on the List. In February 2015 the NOSB posed the following questions in the first posting of this material under the new sunset procedure:

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

In addition, in preparing for the 2017 sunset review the NOSB requested a full technical report (TR) which was received in March 2015. The 2015 TR provides a valuable in-depth analysis and provides up to date research and citations allowing the Subcommittee to re-evaluate fish oil comprehensively against the OFPA criteria. Sources: Fish oil is derived from a wide range of wild caught fish species including, tuna, mackerel, sardines, anchovy, halibut, (TR lines 69-79). NOTE: The TR also lists fish oil from whales and seal under fish, although these are mammals. (TR lines 75-76).

Fish oil is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil (TR lines 283-284). Farmed fish are not a source of fish oil; they are often fed fish oil supplements to boost their own levels of omega 3 fatty acids (TR 332-333). Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States (Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). (TR 90-110)

Manufacturing: Fish oil remains intact through the purification process and is not chemically modified (TR 338). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using

a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002) (TR 307320). There are also other purification methods, which are discussed in the TR.

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

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

However, the health benefits from consumption of fish oil is currently a debated topic in the scientific community (TR 471) and some sources suggest that there are health risks from fish consumption that may outweigh the benefit of omega 3 fatty acids from fish oil (TR 489-494). Fish bioaccumulate many contaminants (TR 503-507). A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). It should be noted however, that these tests were on fish oil supplements, not on fish oil used in food products which is controlled under different regulations than dietary supplements. The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012).

PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 415 8) ppb (Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012). Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009).

The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively (GOED, 2012). There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. (TR 404-426). Note: The TR addresses the February 2015 NOSB Questions 1, 2, 3 and 6 listed above under History, and partially answers Question 4, but it is not clear if the Voluntary Standard for contaminant limits is still in effect (Question 5).

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

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

The NOSB and public were divided with regard to this substance during the 2015 review. . There was high consumer demand and industry strongly supports continued listing, especially as there are no organic sources. Industry comments (April 2015) include the following: "Used in Gummy Confections, Gummy Nutritional Supplements, Panned Jelly Beans…. Fish Oil is used in our products as a natural source of DHA. An organic form is not available…. No alternative management practices that would eliminate the need for the specific substance. This ingredient is essential to our organic products." Other Industry comments: "Fish oil provides nutritional benefits which our consumers are seeking"; "Peru fisheries are well regulated"; "specification sheets indicate levels of PCB's, arsenic, cadmium and lead are tested 3 times a year to meet very strict guidelines; plant sources of omega 3 are not as complete as found in fish oil". On the other hand, conservation groups are concerned about impact on word fisheries, and NGO's, concerned about the cumulative risk impact of fish oil on human health, recommend removing fish oil as it fails to meet OFPA criteria relating to human health, environmental conservation, and compatibility with a sustainable system of agriculture. The NOSB received public comment about the essentiality of this substance, however, essentiality is not a criterion in OFPA or the Organic regulations used to review agricultural substances. . Essentiality is only a criterion applied to synthetic substances, adjuvants and processing aids. In the end the NOSB did not vote to remove fish oil and the substance was renewed.

Additional information requested by Subcommittee:

1. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB's for example? How is purity assessed?
2. How is industry controlling for the risk of contaminants such as heavy metals and PCBs?
3. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
4. How can the annotation be modified to control for the noted conservation concerns?

Gelatin

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Reference: 205.606(g) **Gelatin (CAS # 9000-70-8).**

Technical Report: 2002 TAP; 2019 TR

Petition(s): 2001 Petition ; 2007 Petition

Past NOSB Actions: 05/2002 NOSB Recommendation; 05/2007 Recommendation to add to the national list; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review

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

Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Gelatin is used in a wide range of products as a clarification or fining agent in teas, juice, and wine, as a stabilizer, texturizer, thickener, and in capsules. It may either be an ingredient or a processing aid in candies (gummy bears), desserts (puddings, jello, marshmallows), dairy products (yogurt, sour cream, ice cream), cereals and cosmetics. Fish gelatin is widely preferred for uses in kosher foods. Collagen gel has recently been petitioned for inclusion on the National List under §205.606.

Manufacture:

Gelatin can be made from many different sources of collagen. Cattle bones, hides, pigskin, and fish are the principle commercial sources. Gelatin may be prepared in a way that is more like cooking and could be considered nonsynthetic. However, gelatin may also be processed in ways that would render it synthetic. All manufacturing operations extract and hydrolyze collagen found in fish skins, bovine bone, and porcine skin with subsequent purification, concentration, and drying operations. These can be either simple or complicated operations.

International:

EU 2092/91 — Annex VI — Gelatin is listed under "Processing aids and other products which may be used for processing of ingredients of agricultural origin" in Section B and under "Ingredients of Agricultural Origin Which Have Not Been Produced Organically" in Section C.

Codex Alimentarius — Guideline for the Production, Processing, Labelling, and Marketing of Organically Produced Foods CAC/GL 32-1999, Table 2 Substance for Plant Pest and Disease Control, 1. Plant and Animal: listed. Table 4: Listed under "processing aids which may be used for the preparation of products of agricultural origin."

IFOAM — Basic Standards for Organic Production and Processing, September 2000, Appendix 4 List of Approved Ingredients of Non-Agricultural Origin and Processing Aids Used in Food Processing, Processing Aids and Other Products: listed for use in fruit & vegetable products and wine.
Ministry of Agricultural, Forestry and Fisheries of Japan (MAFF) — Japan Agricultural Standard, Notification #60, Table 2 of food additives: allowed, with no annotation.
Canada — Canadian General Standards Board National Standard for Organic Agriculture (CAN/CGSB-32.310-99), June 1999: permitted as a clarifying agent.
Certified Organic Associations of British Columbia (COABC) — British Columbia Certified Organic Production Operation Policies and Farm Management Standards, Section 9.14 Processing and Handling Materials List, March 2001: non hydrolyzed or hydrolyzed, regulated as a processing production aid; Either form of gelatin maybe used as a product processing aid, for now, but the producer must submit to the certifying agency written details of their search to replace the hydrolyzed gelatin format with a non-hydrolyzed gelatin or a completely different product. Allowed for fruits and vegetables and in winemaking.
Naturland, Germany — Listed in the August 1999 General Processing Standards in the "List of Permitted Ingredients, Additives, and Auxiliary Products" as "food gelatin without additives (exclusively for cream-like masses)."

Ancillary Substances:
It does not appear that there are any ancillary ingredients used regularly for gelatin, such as anti-caking agents, preservatives, colorings etc.

Discussion:
There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. For animal-based gelatin, public comment stated concern over gelatin sourced from conventional animal sources.

Additional information requested by Subcommittee:

1) Are there organic sources of collagen that preclude the listing of gelatin as a non-organically produced agricultural product allowed as ingredients in or on processed products labeled as 'organic'?
2) Are there any ancillary ingredients typically found in commercially available gelatin?

Orange pulp, dried

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(n) **Orange pulp, dried.**
Technical Report: N/A
Petition(s): 2008 Petition
Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National List; 10/2015 NOSB Final Review
Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

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

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

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

Ancillary substances:
No ancillary substances were noted in the petition.

Discussion:
The 2015 NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received supporting relisting or addressing commercial unavailability of dried orange pulp. No organic handlers commented in favor of the material. While the NOSB could not find organic dried orange pulp during a search of publicly available sourcing resources in February 2015, there were several listed organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp.

Additional information requested by Subcommittee:

1) Is there an organic supply of international orange pulp, dried?
2) Is there a domestic supply of organic orange pulp, dried?
3) Have manufacturers using this nonorganic orange pulp in organic products tried to develop an organic orange pulp?
4) Please describe any barriers to the production of organic orange pulp?
5) Are there other organic agricultural products or materials on the national list that have the same function and could replace the nonorganic orange pulp where it is currently used?
6) Are there any ancillary ingredients contained in dried organic pulp when sold commercially?

Seaweed, Pacific kombu

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(q) **Seaweed, Pacific kombu.**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Added to NL effective 03/15/12 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 03/15/2022

Background from subcommittee:
Use:
Marine plants (seaweed) and algae are included in the National List in several sections and allowed for use in organic production and handling:

1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the 46-extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar, carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.
3) In §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (q) Pacific kombu; and (u) Wakame seaweed (*Undaria pinnatifida*).

4) In addition, calcium used for fortification may be derived from marine plants In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production, also known as wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).

Currently, Kombu is used as an ingredient to make stock for Instant Miso Soup and Yuzu Ponzu. Kombu is integral to the preparation of most Japanese traditional foods as stock.

Manufacture:
Kombu is harvested from the ocean. After the crop is harvested, it is sun-dried. In general, the preparation of stock for Japanese traditional food, dried Kombu is boiled in water.

International:
Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted a medium for mushroom spawn production.
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.
European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.
Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.
International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan

and alginates are allowed as food additives (IFOAM, 2014).

Ancillary substances:
It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of Pacific Kombu products.

Discussion:
This material is discussed in the larger discussion document about marine algae and related materials.

Additional information requested by Subcommittee:

1. Are there any ancillary ingredients contained in Pacific Kombu seaweed when sold commercially?
2. Are there any organic seaweeds commercially available?

Wakame seaweed

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(u) **Wakame seaweed (*Undaria pinnatifida*).**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from subcommittee:
Use:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy. Marine plants (seaweed) and algae are included in the National List in several sections and allowed for use in organic production and handling:
1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the 46-extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar and carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.

3) In §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ‘‘organic’’ when the specific product is not commercially available in “organic” form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (q) Pacific kombu; and (u) Wakame seaweed (*Undaria pinnatifida*).
4) In addition, calcium used for fortification may be derived from marine plants
In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production or wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).
Wakame seaweed is a traditional accompaniment to Miso Soup in Japanese cuisine.

Manufacture:
Wakame is naturally occurring in the ocean. It is harvested and sun dried. It is often cut into smaller pieces and salted for shelf life.

International:
Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted a medium for mushroom spawn production.
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.
European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.
Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan and alginates are allowed as additives (IFOAM, 2014).

Ancillary substances:
It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of wakame products, other than salt.

Discussion:
This material is discussed in the larger discussion document about marine algae and related materials.

Additional information requested by Subcommittee:

1) Are there any ancillary ingredients contained in wakame seaweed when sold commercially?
2) Are there any organic seaweeds commercially available?

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 petitioner resubmitted a petition, in July 2016, 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, brussels 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 re-petition dated July 2016, the Crops Subcommittee requested a limited scope technical report (TR) to address outstanding issues. These issues were as follows and were addressed in the TR dated February 12, 2018:

- 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.

On lines 100-107, the TR states that AITC or AITC-containing plant materials possess good potential to serve as alternative nematicides that are safer and more environmentally benign than traditional synthetic fumigants. However, the effectiveness of AITC can be selective. In a 2005 study, the nematicidal activity of AITC was evaluated using seven different species of nematodes, including six of the most important parasitic nematode species in agriculture world-wide (Yu 2005). The study found that the susceptibility or tolerance of nematode species was highly variable. While AITC was found to be toxic and possess anti-hatching activity against all the species in the study, the required concentrations of AITC for effective nematicidal activity was different across the species studied.

Additionally, the TR notes that one of the degradation products of AITC is carbon disulfide, CS2 (CDS). There are concerns regarding exposure to CDS because it is listed by the State of California on the Proposition 65 list as a developmental toxicant (OEHHA, 2014) and is known to induce neuropathological changes and other toxic effects in rodents exposed through inhalation over an intermediate during of less than one year (OEHHA, 2001). Because CDS is a major degradant of AITC, the human and environmental toxicity of CDS should be considered as part of the evaluation of AITC for use in organic crop production.

According to TR lines 210-211, several international organizations and regulatory bodies do not permit the use of AITC in organic crop production. Additionally, lines 993-994 indicate that in addition to traditional crop rotation, the available information suggests that the variety of available management techniques preclude the application of synthetic biofumigants such as AITC in organic crop production. For example, the TR indicates that some organic growers, including organic strawberry producers, are adopting mustard seed meal as a natural option for soil pest control. Synthetic AITC acts as a broad-spectrum fumigant. This broad-spectrum effect on both beneficial and pest species is not compatible with organic production.

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).

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 TR (lines 603-608) notes that AITC is a broad-spectrum antimicrobial compound that effectively kills both plant pathogens and beneficial soil microorganisms. Additionally, it is known that certain species of soil fungi enhance the bioavailability of organic soil nutrients and mediate the uptake of these nutrients by their mycorrhiza host plants. AITC drift would therefore be problematic for both the beneficial soil fungi and associated plants. 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.

   Also noted in the TR, very few peer-reviewed papers on the ecological toxicity of AITC are available. The aquatic toxicity of AITC was evaluated for Japanese rice fish (Oryzais latipes) using a continuous-flow-mini-diluter system and five concentrations of AITC. Significant mortality was observed in O. latipes exposed to AITC on an acute basis (96-hour LC50 = 0.077 mg/L), and the maximum allowable toxicant concentration (MATC) for chronic (28-day) exposure to AITC was 0.013 mg/L (Holcombe, 1995). Another study found that pure AITC and essential oil extracts containing AITC are completely larvicidal in mosquitoes (A. aegypti) even at the lowest concentration tested (0.1 mg/mL); however, this measurement indicates that AITC is significantly less toxic compared to some synthetic pesticides. In addition, AITC was toxic to the freshwater water flea (Daphnia magna) with a 50% effective concentration value of 0.735 mg/L based on combined mortality and immobility measurements (Park, 2011). As expected, AITC is also highly toxic to soil microorganisms and nematodes, such as the non-parasitic free-living soil nematode Caenorhabditis elegans (Donkin, 1995).

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 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. Because AITC is a volatile organic compound and has the potential to cause irritation and systemic toxicity, exposure of and potential adverse effects on non-target receptors (humans and wildlife) is likely considering its proposed use pattern as a pre-plant soil biofumigant at the application rates proposed (85-340 lbs/ac) (TR, lines 378-381).

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, data on long-term soil effects is relatively non-existent, as other fumigation agents 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).

   The 2018 TR (lines 603-608) cites reports that provide direct evidence that AITC does not specifically target soil pests; rather, AITC is a broad-spectrum antimicrobial compound that

effectively kills both plant pathogens and beneficial soil microorganisms. Additionally, it is known that certain species of soil fungi enhance the bioavailability of organic soil nutrients and mediate the uptake of these nutrients by their mycorrhiza host plants AITC drift would therefore be problematic for both the beneficial soil fungi and associated plants. As such, AITC is expected to negatively impact biodiversity.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials.

   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, thus AITC is not essential to organic agriculture.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture?

   AITC can have a short-term deleterious effect on beneficial soil microorganisms and mutualistic fungal interactions, which is observed for other broad-spectrum fumigants, such as methyl bromide and Telone II (2018 TR, lines 634-636). This broad-spectrum effect is not compatible with a system of sustainable agriculture. In addition, the availability of cultural methods or use of natural mustard plant cover crops precludes AITC from being essential to organic agriculture.

Classification Motion:

Motion to classify allyl isothiocyanate (AITC) as synthetic
Motion by: Jesse Buie
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add allyl isothiocyanate (AITC) at §205.601
Motion by: Jesse Buie
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, February 9, 2019

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Ammonium Citrate
February 5, 2019

Summary of Petition for Ammonium Citrate:

Alpha Chelates has petitioned for the inclusion of ammonium citrate on the National List at §205.601 (synthetic substances allowed for use in organic crop production). This re-petition follows a petition in 2016 of Ammonium Citrate during which time the NOSB determined in its fall 2016 recommendation that alternatives exist, including lignin sulfonate, humic acids, fulvic acids, and non-synthetic citrate. 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 current petition and second addendum were submitted in 2018. At its Fall 2018 board meeting, the NOSB presented a petitioned materials discussion document to solicit stakeholder feedback. Questions were posed regarding the need expressed by farmers for the petitioned material and the efficacy of the petitioned chelating agent over currently approved chelating agents.

Ammonium citrate is used as a chelating agent with inorganic metal micronutrients copper, iron, manganese, or zinc for high pH soils. Chelates are used to provide micronutrients that are readily available to plants in deficient soils. Ammonium citrate is not being petitioned to be applied to crops alone but in its chelated forms.

During its 2016 review, the Board determined that there was insufficient information in the justification statement regarding the necessity of this material 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 this substance to the National List as there are natural alternatives and one allowed synthetic already available, and as far as the NOSB knows, the permitted products are adequate to meet farmers' needs.

The most recent re-petition was 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 put forth a case that the use of the term "chelating agent" in the regulations needs to be revisited. 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, a **2018 TR** was solicited in response to the second application, both to review the petitioned material and to investigate the broader issue of nomenclature and technical errors elaborated by the petitioner.

Summary of Review:
The Crops Subcommittee determined that in its fall 2016 recommendation that alternatives to the proposed substance exist as stated earlier. The most recent repetition by Alpha Chelates asserted "the technology concerning chelating agents and micronutrient chelates has been significantly misunderstood by [the] NOSB". To address this concern a revised technical review was requested by the Crops Subcommittee. The revised technical review, dated October 5, 2018, was provided to the Crops Subcommittee shortly thereafter. The Subcommittee asked that the technical review address twelve questions ranging from the Subcommittee's interpretation of language related to the physical chemical definition of terms to the environmental fate of the proposed materials to whether or not tractable alternatives exist. On the latter two points, if used as proposed, ammonium citrate has no known adverse environmental impacts; however, the report reiterated that many alternatives exist and are currently available for use in organic production.

On the Subcommittee's use and interpretation of language regarding "chelates" and "chelating agents," a point the petitioner asserted the subcommittee had misapplied, the technical review concluded we were in fact interpreting their meaning correctly and had consistently done so in past reviews. The October 5, 2018 technical review provides a detailed review (top of page 4 through the middle of page 6) of terms and definitions of those terms pertaining to "chelates", "chelating agents" and "ligands." Specifically, the technical review went on to state: "the NOP requested technical clarification of the terms "ligand," "chelating agent," and "chelate." The petitioner claims that NOP has used "chelating agent" incorrectly and suggests replacing the term "chelating agent" with "ligand." Therefore, it seems that, prior to the analysis of NOP's usage of the term "chelating agent," a discussion of the two terms may be helpful. A ligand has been defined as an ion or molecule that is covalently bonded to a metal atom that can also have an independent existence. A chelating agent is a specific type of ligand and is characterized by its ability to form multiple bonds to the metal center from multiple attachment points (i.e., a polydentate ligand). Based on these definitions, it is technically correct to classify all chelating agents as ligands. However, in the United States (the petitioning company is Australian), it is far more common to refer to these polydentate ligands as "chelating agents," rather than the more general "ligand." Moreover, the term chelating agent is typically reserved for ligands that not only have the capacity to form multiple attachment points, but also ligands that tend towards forming these attachment points as a rule—a tendency that results in a specific set of properties and applications. In conclusion, the term ligand is *not* synonymous with chelating agent, with chelating agents comprising a specific mode of coordination while ligand refers to anything molecule or ion that coordinates to a metal atom."

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.

   No

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and

minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No. Ammonium citrate does not contain any of the materials listed in (A). However, as copper is an essential micronutrient for plant development, it may be used in concert with ammonium citrate in the form of a chelate. In this form, the copper is unlikely to be reactive due to the multiple coordination points of the citrate, although the water solubility of the copper (if used) is likely to be increased.

When used as petitioned, ammonium citrate serves as an inert ingredient for the delivery of micronutrients. The citrate chelated micronutrients are inert due to their multiple points of attachment to the micronutrient. The petitioned substance is not listed by the EPA as an inert of toxicological concern and is not listed in 40CFR 180, per (B).

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)]

   Chelates occur in nature and are used at low rates in organic farming, so there should be no 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)]

   Ammonium hydroxide and citric acid are introduced in a reaction vessel to produce ammonium citrate, a salt. The amino acid citric acid is neutralized by the alkali ammonium hydroxide. Ammonium citrate is reacted in a solution with copper, iron, manganese, or zinc salt to form a liquid chelate of the given metal. Chelates are applied in low dosages; application rates for the chelates manufactured by the petitioner are 1.2-2.5 kg/ha.

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

   The petition states that there is minimal chance of environmental or human contamination during the manufacturing process as the reaction takes place inside a sealed vessel. As stated above, the petitioned substance is an ingredient in a finished product and is converted into a metal salt chelate and is therefore not subject to questions of disposal. However, ammonium hydroxide is used in the manufacture of the substance, and ammonium hydroxide is produced by the reaction of ammonia with water. Ammonia can be harmful to human health and aquatic life if spilled or improperly handled.

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

The petition states that “in the unlikely event of contact of reaction vessel contents with human skin, there is a very low level of hazard as the substance is at a low concentration, is not toxic, and can be easily washed off with water”.

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 Subcommittee is not aware of negative effects of the petitioned material on biological and chemical interactions in the agroecosystem.

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

   None known.

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)]

   Yes, alternatives exist. There are a range of natural chelating agents that are excreted by plants and microorganisms, or are produced from the decomposition of organic matter, and aid in the delivery of micronutrients in the soil. These compounds are broadly classified as phytosiderophores or phytometallophores. These compounds are wide ranging and include organic (carboxylic) acids and non-synthetic amino acids. However, organic or amino acids must first undergo a neutralization reaction with bases in the soil before they are able to acts as chelating agents. In basic (alkaline) soils, the application of these natural organic and amino acids will result in their neutralization, and the subsequent anions may act as chelating agents for micronutrient sources already existing in the soil.

   There are a variety of synthetic substances approved in 7 CFR 205.601 that may be used in place of the petitioned substance as a means of increasing the water solubility of micronutrients. Most of these substances are acids, which would result in a pH change in the soil, converting insoluble hydroxide salts into more soluble micronutrient salts. The approved acids are the following: peracetic acid, boric acid, humic acids, and sulfurous acid. However, like the application of natural organic and amino acids to access natural chelating agents, the application of approved synthetic acids could result in the negative outcomes associated with soil acidification.

   Lignin sulfonate, or lignosulfonate, is a synthetic chelating agent that is approved by the NOP for use in organic agricultural production at 7 CFR 205.601. Like ammonium citrate, lignosulfonates can form chelates with cationic micronutrients, increasing their water solubility and bioavailability. Lignosulfonates are derived from the biopolymer lignin via the pulping process. Studies have shown that these chelating agents increase the uptake of both zinc and iron micronutrients in crops.

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

In so far as this substance is a synthetic material designed for enhancing uptake of micronutrients, a process which naturally occurs in soils, and for which a range of alternatives already exist, it is difficult to see how the substance is compatible with a system of sustainable agriculture.

Classification Motion:

Motion to classify ammonium citrate as synthetic
Motion by: Dave Mortenson
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add ammonium citrate as petitioned at §205.601
Motion by: Dave Mortenson
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, February 9, 2019

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Ammonium Glycinate
February 5, 2019

Summary of Petition for Ammonium Glycinate:

Alpha Chelates has petitioned for the inclusion of ammonium glycinate on the National List at 205.601 (synthetic substances allowed for use in organic crop production). This repetition follows a petition in 2016 of Ammonium glycinate during which time the NOSB determined in its fall 2016 recommendation that alternatives exist, including lignin sulfonate, humic acids, fulvic acids, and non-synthetic citrate. Also on file for this material 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 current petition and second addendum were submitted in 2018. At its fall 2018 board meeting, the NOSB presented a Petitioned Materials Discussion Document to solicit stakeholder feedback. Questions were posed regarding the need expressed by farmers for the petitioned material and the efficacy of the petitioned chelating agent over currently approved chelating agents.

Ammonium glycinate is used as a chelating agent with inorganic metal micronutrients copper, iron, manganese, or zinc for high pH soils. Chelates are used to provide micronutrients that are readily available to plants in deficient soils. Ammonium glycinate is not being petitioned to be applied to crops alone but in its chelated forms.

During its 2016 review, the Board determined that there was insufficient information in the justification statement regarding the necessity of this material 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 this substance to the National List as there are natural alternatives and one allowed synthetic already available, and as far as the NOSB knows, the permitted products are adequate to meet farmers' needs.

The most recent re-petition was 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 put forth a case that the use of the term "chelating agent" in the regulations needs to be revisited. 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, a **2018 TR** was solicited in response to the second application, both to review the petitioned material and to investigate the broader issue of nomenclature and technical errors elaborated by the petitioner.

Summary of Review:
The Crops Subcommittee determined that in its fall 2016 recommendation that alternatives to the proposed substance exist as stated earlier. The most recent repetition by Alpha Chelates asserted "the technology concerning chelating agents and micronutrient chelates has been significantly misunderstood by [the] NOSB". To address this concern a revised technical review was requested by the Crops Subcommittee, the revised technical review dated October 5, 2018 was provided to the Crops Subcommittee shortly thereafter. The Subcommittee asked that the technical review address twelve questions ranging from the Subcommittee's interpretation of language related to the physical chemical definition of terms to the environmental fate of the proposed materials to whether or not tractable alternatives exist. On the latter two points, if used as proposed, the ammonium citrate has no known adverse environmental impacts however, the report reiterated many alternatives exist and are currently available for use in organic production.

On the Subcommittee's use and interpretation of language regarding "chelates" and "chelating agents", a point the petitioner asserted the subcommittee had misapplied, the technical review concluded we were in fact interpreting their meaning correctly and had consistently done so in past reviews. The October 5, 2018 technical review provides a detailed review (top of page 4 through the middle of page 6) of terms and definitions of those terms pertaining to "chelates", "chelating agents" and "ligands". Specifically, the technical review went on to state: "the NOP requested technical clarification of the terms "ligand," "chelating agent," and "chelate." The petitioner claims that NOP has used "chelating agent" incorrectly and suggests replacing the term "chelating agent" with "ligand." Therefore, it seems that, prior to the analysis of NOP's usage of the term "chelating agent," a discussion of the two terms may be helpful. A ligand has been defined as an ion or molecule that is covalently bonded to a metal atom that can also have an independent existence. A chelating agent is a specific type of ligand and is characterized by its ability to form multiple bonds to the metal center from multiple attachment points (i.e., a polydentate ligand). Based on these definitions, it is technically correct to classify all chelating agents as ligands. However, in the United States (the petitioning company is Australian), it is far more common to refer to these polydentate ligands as "chelating agents," rather than the more general "ligand." Moreover, the term chelating agent is typically reserved for ligands that not only have the capacity to form multiple attachment points, but also ligands that tend towards forming these attachment points as a rule—a tendency that results in a specific set of properties and applications. In conclusion, the term ligand is *not* synonymous with chelating agent, with chelating agents comprising a specific mode of coordination while ligand refers to anything molecule or ion that coordinates to a metal atom."

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.

   No

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and

minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No. Ammonium glycinate does not contain any of the materials listed in (A). However, as copper is an essential micronutrient for plant development, it may be used in concert with ammonium glycinate in the form of a chelate. In this form, the copper is unlikely to be reactive due to the multiple coordination points of the glycinate, although the water solubility of the copper (if used) is likely to be increased.

When used as petitioned, ammonium glycinate would serve as an inert ingredient for the delivery of micronutrients. The glycinate chelated micronutrients are inert due to their multiple points of attachment to the micronutrient. The petitioned substance is not listed by the Environmental Protection Agency (EPA) as an inert of toxicological concern and is not listed in 40 CFR 180, per (B).

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)]

   Chelates occur in nature and are used at low rates in organic farming, so there should be no 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 chelated micronutrient acts to increase the bioavailability of the metal cation to ensure its uptake by crops. Due to the use of the petitioned as a precursor to micronutrient chelates, they will exist in many possible combinations that are dependent on the micronutrient in question, as well as the inorganic salt that is chosen as the micronutrient source. Therefore, an analysis of the individual ions in the environment is important. Once the water-soluble micronutrient has been absorbed by plant life, the glycinate anion and ammonium salt remain in the soil. However, both ammonium and glycinate ions are prevalent in nature, are readily metabolized by a variety of organisms, and therefore are not anticipated to have any toxicological impact on the environment. Furthermore, the need for micronutrients in trace amounts would lead to the introduction of minimal amounts (ppm applications) of ammonium glycinate as a micro nutrient chelate when used as petitioned.

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

   The petition states that there is minimal chance of environmental or human contamination during the manufacturing process as the reaction takes place inside a sealed vessel. As stated above, the petitioned substance is an ingredient in a finished product and is converted into a metal salt chelate and is therefore not subject to questions of disposal. However, ammonium hydroxide is used in the manufacture of the substance, and ammonium hydroxide is produced

by the reaction of ammonia with water. Ammonia can be harmful to human health and aquatic life if spilled or improperly handled.

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

   The petition states that "in the unlikely event of contact of reaction vessel contents with human skin, there is a very low level of hazard as the substance is at a low concentration, is not toxic, and can be easily washed off with water".

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 Subcommittee is not aware of negative effects of the petitioned material on biological and chemical interactions in the agroecosystem.

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

   None known.

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)]

   Yes, alternatives exist. There are a range of natural chelating agents that are excreted by plants and microorganisms, or are produced from the decomposition of organic matter, and aid in the delivery of micronutrients in the soil. These compounds are broadly classified as phytosiderophores or phytometallophores. These compounds are wide ranging and include organic (carboxylic) acids and non-synthetic amino acids. However, organic or amino acids must first undergo a neutralization reaction with bases in the soil before they are able to acts as chelating agents. In basic (alkaline) soils, the application of these natural organic and amino acids will result in their neutralization, and the subsequent anions may act as chelating agents for micronutrient sources already existing in the soil.

   There are a variety of synthetic substances approved in 7 CFR 205.601 that may be used in place of the petitioned substance as a means of increasing the water solubility of micronutrients. Most of these substances are acids, which would result in a pH change in the soil, converting insoluble hydroxide salts into more soluble micronutrient salts. The approved acids are the following: peracetic acid, boric acid, humic acids, and sulfurous acid. However, like the application of natural organic and amino acids to access natural chelating agents, the application of approved synthetic acids could result in the negative outcomes associated with soil acidification.

   Lignin sulfonate, or lignosulfonate, is a synthetic chelating agent that is approved by the NOP for use in organic agricultural production at 7 CFR 205.601. Like ammonium glycinate, lignosulfonates can form chelates with cationic micronutrients, increasing their water solubility and bioavailability. Lignosulfonates are derived from the biopolymer lignin via the pulping

process. Studies have shown that these chelating agents increase the uptake of both zinc and iron micronutrients in crops.

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

   In so far as this substance is a synthetic material designed for enhancing uptake of micronutrients, a process which naturally occurs in soils, and for which a range of alternatives already exist, it is difficult to see how the substance is compatible with a system of sustainable agriculture.

Classification Motion:

Motion to classify ammonium glycinate as synthetic
Motion by: Dave Mortenson
Seconded by: Harriet Behar
Yes: 7 No:0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add ammonium glycinate as petitioned at §205.601
Motion by: Dave Mortenson
Seconded by: Dan Seitz
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, February 9, 2019

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Calcium Acetate
January 29, 2019

Summary of Petition [Calcium Acetate]:

Calcium acetate can occur naturally but is more often formulated by chelating finely ground limestone (calcium carbonate) with acetic acid. During this process calcium acetate is formed and comprises about 5% of the calcium in the final product. The remainder of the final product is primarily calcium carbonate. Other materials such as xantham gum and/or humic acids may be added to make a proprietary product.

Calcium acetate has a variety of potential uses. This petition asks for approval for organic use as a soil amendment, plant micronutrient, soil pH adjuster and as a sunscald protectant. Calcium acetate is also currently registered for yellowjacket control in conventional crops. In each of these uses, the calcium acetate product is mixed with water and applied by spray to the crop, soil, or structure/covering.

In the crops/soils use, the calcium acetate has an advantage in that it is much more water soluble than calcium carbonate and is more readily available to the plant. Other traditional sources of calcium, such as calcium carbonate, do not become water soluble until they have been acted on by soil microbes or acidic conditions. Products that include calcium acetate as well as other slower acting calcium sources can have both an immediate impact on the plant as well as an extended release effect as those less soluble materials are made plant available.

For sunscald protection, the material acts to block direct transmission of sunlight due to its opacity. Sunscald occurs when exposure to sunlight overheats crops and causes scarring. This scarring can affect keeping quality, cosmetic appearance, taste, and texture. An aqueous mixture containing calcium acetate may be sprayed on black plastic to lower soil temperatures or as a coating on greenhouses to lower inside temperatures. The opacity of the material is primarily due to the calcium carbonate remaining in the product after the calcium acetate is formed (2018 TR).

Summary of Review:

Several public comments were received during the Fall 2018 NOSB meeting in which a discussion document on this petition was part of the agenda. One commenter indicated that they would support the addition of calcium acetate to the National List if the petitioner was able to document better calcium uptake than other available products. The commenter recommended an annotation be added, “For use as a foliar spray to treat a physiological disorder associated with calcium uptake.” However, another commenter noted that this product should not be approved since good organic practices should resolve calcium deficiencies and that this product is not essential.

With regard to sunscald, one commenter noted that they might support listing with the annotation, “For use on plants, greenhouses, and plastic films for protection against excess sun exposure.” Another commenter stated that the need to approve one synthetic product to remediate issues with another synthetic product, such as black plastic, is non-sensical for organic production.

The 2018 TR reviewed international certification agencies and found no listing for calcium acetate by other certifiers. Calcium acetate is not listed for organic production by the Canadian General Standards Board Permitted Substances, CODEX Alimentarius Commission, European Economic Community, Japanese Agricultural Standard or the International Federation of Organic Agriculture Movements.

The petition and the 2018 TR concur that the environmental and human health impacts of calcium acetate are minimal. Since calcium is already common in the environment and calcium acetate can and does occur naturally, the use of this material for plant nutrition or pH adjustment is unlikely to cause unwanted environmental impacts. It is rapidly utilized and integrated into plant and soil systems.

While there are numerous calcium disorders documented in crops and supplemental calcium may need to be applied to ameliorate these disorders, the 2018 TR notes that other, already approved, chelating agents can improve bioavailability of existing calcium sources in the soil and cites references for various alternatives. These alternatives include calcium chloride and several other chelated calcium products. While this product might be slightly different than other products already approved for organic production, it is difficult to make the argument that this product is essential for organic production. Without compelling evidence that the currently available alternatives are not effective, this material is not essential to organic production.

For sunscald protection, this material is easy to apply and environmentally benign as well as being readily adapted to changing conditions. However, alternatives already exist, and this material is not essential for organic production.

Category 1: Classification

1. For CROP use: Is the substance **Non-synthetic** 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.

   Calcium acetate is made from finely ground limestone which is chelated with acetic acid. It is a naturally occurring substance, which is produced and broken down in the metabolic cycles of humans and animals (2018 TR), however, it is most commonly synthesized by the neutralization of acetic acid and calcium carbonate. The petitioner and the 2018 TR both state that the material is synthetic.

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

   The petitioner is asking for calcium acetate to be classified as a synthetic compound under vitamins and minerals. In its use as a plant micronutrient or, possibly, as a pH adjuster, the use would fall under minerals. For its use as a sunscald protectant or shading material it could be interpreted as a production aid.

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)]

   Calcium is widely used and available in agricultural ecosystems and calcium acetate is simply a more soluble form of calcium that is rapidly bioavailable. In general, calcium products are positive additions since calcium forms the building blocks of cell structures and functions. However, the 2018 TR notes two potential negative impacts. First, calcium acetate could bind phosphates, thus making them unavailable to plants as a nutrient source. This would primarily happen with the improper use of phosphoric acid. Phosphoric acid is only approved as an equipment cleaner and should have no direct contact with organically managed land or livestock. Secondly, if overapplied it could cause an over adjustment of pH and could result in increased soil alkalinity.

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

   The 2018 TR states that there are no published studies on the environmental persistence of calcium acetate. Various EPA documents are cited noting that calcium acetate may be present in the metabolic cycles of animals; therefore, no risk is posed to the environment. The EPA has placed calcium acetate on the Safer Chemical Ingredients List (SCIL) for processing aids and additives as a safer replacement for traditional ingredients. Moreover, the EPA has designated calcium acetate as "verified to be of low concern based on experimental and modeled data," and has "not identified any toxic endpoints for birds, plants, aquatic, or soil organisms" (2018 TR).

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

   In general, the environmental impacts of this material should be minimal, but the 2018 TR notes that the greatest potential for environmental degradation is the mining necessary to source the calcium carbonate. This mining could degrade or disrupt ground water, surface water, and ecosystems in the vicinity of the mine and could cause contamination from spills. There could also be additional carbon dioxide released to the atmosphere due to fossil fuel burned by mining equipment.

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

   Calcium acetate is widely used for human health as treatment for calcium deficiency and to treat patients with hyperphosphatemia in end stage renal disease. It can be used as a stabilizer and preservative in many food substances. The 2018 TR quotes various sources in that it has been authorized for human consumption without limitation by the Joint FAO/WHO Expert Committee on Food Additives, FDA has granted it GRAS status as a sequestrant and direct food substance, and EPA has placed it on the Safer Chemical Ingredients List for processing aids and additives.

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)]

   When used as petitioned, calcium acetate is applied as an aqueous mixture with calcium carbonate. While the calcium carbonate could provide calcium, it is not readily absorbed by plants. Calcium acetate has been reported to increase plant absorption of calcium ions (Ca^{2+}) compared to salts with other organic and inorganic anions (e.g., lactate, citrate, oxalate, chloride, nitrate) (2018 TR). Calcium is necessary for cell wall formation and stabilizes lipids within cell membranes. It helps to regulate cell processes such as transport across cellular membranes and enzymatic functions (2018 TR). It may also aid in the uptake of other micronutrients and may increase the storage life of fruits and vegetables. Common symptoms of insufficient calcium in fruits and vegetables include blossom end rot in tomatoes and bitter pit in apples.

   Calcium is common in the environment and the application of calcium acetate simply makes calcium more readily available for absorption. EPA has "not identified any toxic endpoints for birds, plants, aquatic, or soil organisms" (2018 TR) so the application of calcium acetate should not have negative ecosystem effects except in the case of where it might be overapplied and create excess soil alkalinity.

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

   There are no published studies on the environmental impacts of calcium acetate; however, the EPA has "not identified any toxic endpoints for birds, plants, aquatic, or soil organisms" (2018 TR) The 2018 TR goes on to note that calcium acetate acts as a water-soluble and bioavailable source of calcium, especially important in soils with high pH. The petitioned substance also increases the pH of the soil. Additionally, when used as petitioned, the substance can provide protection from sunscald as well as act as a mechanism for regulating plant temperature due to the opaque nature of the applied liquid. Once introduced into agricultural soils, the salt may result in several different outcomes, including absorption by plants, reacting with acidic chemicals in the soil, or dissolving and entering water systems, depending on the environmental conditions of the soil.

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)]

   Calcium carbonate can also act as a soil amendment, pH adjuster, and micronutrient source, but is less rapidly available. The 2018 TR notes that other, already approved, chelating agents can improve bioavailability of existing calcium sources in the soil and cites references for various alternatives. Lignin sulfonate, or lignosulfonate, is a synthetic chelating agent that is approved by the NOP for use in organic agricultural production, at 7 CFR 205.601. Lignosulfonates can form chelates with cationic micronutrients, increasing their water solubility and bioavailability. Humic acids have also been shown to increase plant absorption of micronutrients, while also promoting the growth of soil microorganisms. Additionally, sodium carbonate (Na_2CO_3) and potassium bicarbonate ($KHCO_3$) are capable of pH adjustments and, due to their water solubility, provide a more suitable alternative to calcium acetate than calcium carbonate mineral sources,

calcium hydroxide, and lime sulfur. Calcium chloride is readily available to plants but may not be compatible with other organic materials such as oils and can cause phytotoxicity under some environmental conditions.

A compost program can also be an alternative to calcium acetate. The 2018 TR cites literature that organic compost includes micronutrients, natural chelates, and microbes that produce natural chelating agents and when used as part of a program could alleviate the need for additional calcium applications.

For sunscald, alternative practices include pruning, and the installation of shade cloth or overhead sprinklers. Applications of clay-based sprays to plastic, structures, or the crop itself may reduce temperatures of soils and crops. Conversely, pruning and the installation of shade cloth can be labor intensive and expensive, and the use of clays may cause problems with packing equipment and cleaning the produce for market.

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

   Since calcium is already common in the environment and calcium acetate can and does occur naturally, the use of this material for plant nutrition or pH adjustment is unlikely to cause unwanted environmental impacts. It is rapidly utilized and integrated into plant and soil systems. Based on the evidence reviewed in the TR and public comments, it was determined that this material is not essential for organic production. It does potentially provide a faster means to deliver calcium to plants, but there are other materials already available to growers that make the same claim, for example, calcium chloride or several chelated calcium products. Without compelling evidence that the currently available alternatives are not effective, this material is not essential to organic production.

   For sunscald protection, this material is easy to apply and environmentally benign as well as being readily adapted to changing conditions. However, alternatives already exist. Without compelling evidence that other natural alternatives are ineffective, adding a new synthetic material to the National List is not essential for organic production.

Classification Motion:

Motion to classify calcium acetate as synthetic
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add calcium acetate at §205.601
Motion by: Steve Ela
Seconded by: Emily Oakley
Yes: 0 No: 6 Abstain: 1 Absent: 1 Recuse: 0

Approved by Steve Ela, Subcommittee Chair to transmit to NOSB, January 29, 2019

National Organic Standards Board
Crops Subcommittee Proposal
Strengthening the Organic Seed Guidance April 2019
February 19, 2019

Introduction and Background

The planting of organic seed/planting stock is required under the USDA organic regulations, unless these items are not commercially available. While there has been some growth in the availability and use of organic seed, progress towards reaching a goal of 100% organic seed and planting stock has been slow. The NOSB provided recommendations to the NOP in 2005 and 2008 focused upon increasing the use of organic seed. The NOP has addressed this issue with draft and final guidance in 2011 and 2013, respectively.

Organic seed/planting stock breeders work closely with organic producers to build in varietal characteristics that address regional organic production system challenges. Organic seed breeders focus on specific traits that provide consistent yields of high-quality crops that meet the unique needs of the organic marketplace. The use of organic seed can aid in the protection and expansion of genetic resources as well as offer additional economic opportunities for farmers and seed breeders/sellers. Continued growth of organic seed and planting stock availability will build a resilient future through continued development of varieties and cultivars focused on the needs of organic producers and the organic market.

The goal of the NOSB is 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/planting stock 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/planting stock due to lower price, unfamiliarity with organic 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.

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

In October 2018, the NOSB passed the following recommendation, in bold below, as an addition to the change to the organic regulation. Public comment was almost unanimous in favor of this regulatory improvement.

(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 must be demonstrated every year with the goal of using only organic seed and planting stock.

These improvements to NOP 5029 guidance are covered in this proposal:

2. Changes to NOP 5029 Guidance
The Guidance for Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production should be amended as follows, the bold/italic are the recommendations and will be repeated again as a clean document at the end of this proposal. The areas struck out are language that has been changed from either the current NOP 5029 guidance, or from a previous proposal.

4.1 Sourcing of Seeds

No changes to 4.1.1.

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.**

Public Comment and Subcommittee Response:
In the fall 2018 proposal, the phrase in bold above was removed since public comment stated this is currently required by certifiers. Further public comment stated it should remain, and the crops subcommittee agrees. There are over 80 accredited certifiers and in order to encourage consistency, including this phrase is no hardship for certifiers and operators already providing this documentation This statement provides clear guidance to all NOP certifiers, both foreign and domestic, that providing this proof is needed when nonorganic seed is planted of a type that has a GMO equivalent. The bold addition above will remain as part of this proposal.

No changes to 4.1.2a
No changes to 4.1.2b

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.**~~ **If trials are not performed, the producer can use catalog or website seed descriptions, to document there are no organic seeds that have equivalent characteristics to the nonorganic seed in use.**

Public Comment and Subcommittee Response:

This is an addition to the current NOSB 5029 guidance and is included based upon public comment. Performing trials on organic seed helps an operator determine if the organic seeds 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 seed varieties 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. Use of seed characteristic descriptions in catalogs or on websites can also be used to illustrate the producer is searching for equivalent organic varieties and they were not found.

4.1.2(d) **Documentation of on-farm trials or seed characteristic searches can be provided at the annual inspection. This documentation can 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.**

Public Comment and Subcommittee Response:

This is an addition to NOP guidance 5029. It provides more clarification on producer methods of trialing or searching for an "equivalent" organic variety. Since this is guidance only, the word "must" was removed from this section and replaced with the word "can". It is important to encourage growers to document that the organic seed varieties are not "equivalent" to the nonorganic seeds they are using. As stated above, many organic seed varieties may have different names or numbers, but could be considered equivalent to a nonorganic seed in most, if not all, characteristics sought by a grower.

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.**~~

Public Comment and Subcommittee Response:

There was not universal support for this suggested addition, and it has been removed. There were comments stating this section was problematic for a variety of reasons, and the crops subcommittee believes that dealing with GMO contamination of seed can be better addressed in a separate recommendation, rather than this proposal which supports the use of organic seed.

No changes to 4.1.3, 4.1.4, 4.1.5

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 **or an organic vegetative crop only** after 12 months of organic management *§*205.204 (a)(4).

Public Comment and Subcommittee Response:
As 4.1.6 is currently written, certifiers can allow sale of an organic crop for consumption from nonorganic planting stock immediately after planting it, but would not allow any cuttings from that planting stock, to be sold as organic planting stock for at least a year. As an example, an organic grower can purchase a nonorganic rosemary plant, plant it in their organic field, cut it immediately and sell it as an organic crop. However, as written, if they make a cutting, put it in water and root it, they cannot sell that plant for a year as organic planting stock. *§*205.204 (a)(4) states:

Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year.

This allowance for a crop to be sold from nonorganic planting stock that has not been under organic management for at least one year, was to provide for the sale of fruit from nonorganic strawberry plants within the first year of planting on organic land. Typically, other perennial plants do not produce fruit/nuts or other nonvegetative crops within the first year, so this one year wait time for a crop from nonorganic planting stock planted into organic ground is not a hardship for other perennial crops. However, vegetative growth that would be sold from the nonorganic planting stock would have been managed nonorganically. It does not make sense to sell this vegetative crop as organic. but Strawberry fruit would not be present at the time of planting, and therefore the sale of this fruit as organic had been considered to be more in line with current regulations.

4.2 Recordkeeping for Organic Producers

4.2.1 The following records should be maintained by organic producers:

4.2.1 (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, **or other descriptions illustrating seed characteristics**, can be used to demonstrate lack of equivalent seed or planting stock varieties/cultivars for site specific conditions.

Public Comment and Subcommittee Response:

Numerous certification agencies and producers provided negative comments about the statement removed above, 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. On-farm trials or descriptions that specifically illustrate characteristics can provide justification there was no organic equivalent to the nonorganic seed or planting stock used.

4.2.1 (b)

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 and planting stock varieties should include but is not limited to:

(i) Documentation of contact with at least three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock, including date, variety requested, quantity of seed, as well as if the seed is available organically, or was out-of-stock.

(ii) Improved timeliness of seed/planting stock ordering by documenting the date(s) of orders. Earlier ordering can result in a greater chance of organic seed/planting stock availability. For larger orders, suppliers need to be given sufficient lead time to provide the quality, quantity and variety/cultivar within the timeframe needed by the organic producer.

(iii) Work with seed/planting stock suppliers that provide a quick response of organic availability, to enable the producer to request seed, in a timely manner, of other suppliers if organic seed was not available from the first supplier.

(iv) Demonstrate an increase in *the percentage* of organic seed/planting stock used over time by the operation.

(v) Search suppliers that are known to carry organic varieties or cultivars of the type they seek.

(vi) Discuss and document their desire to purchase equivalent organic varieties or cultivars with their current nonorganic suppliers.

(vii) 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.

~~***Five sources must be contacted for seed of crops at risk for excluded method contamination.***~~

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 and others did not. A variety of commenters suggested a more practical approach to this seed search describing a variety of typical search activities that could result in higher use of organic seed. The list of (i)-(vii) summarizes these activities suggested by commenters and NOSB crop subcommittee members. The number of seed searches required by the certifier remains at three in this proposal, and gives the certifiers and operators more options to judge if the seed search was done in an effective manner, as well as the option to require more activities, if the certifier feels the quality of the search could be improved.

No changes to 4.2.1 (b) 2.

4.2.1 b. 3.

If seed/planting stock is sourced or mandated by the buyer of a contracted organic 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 could include:

(a) The handler's organic search documents there are no organic equivalents in quality, quantity or function, to the nonorganic seed/planting stock they require.
(b) The handler has discussed the development of an equivalent organic seed/planting stock source with their nonorganic seed supplier, as well as with organic seed breeders.
(c)The handler seeks out organic growers, either those that are contracted to grow organic crops from that nonorganic seed/planting stock source, or known organic growers who are experienced in seed/planting stock production, to trial production of an organic equivalent variety/cultivar.
(d) The handler clearly documents that mandating use of nonorganic seed/planting stock is not solely based upon the possibly higher monetary cost of an organic equivalent variety.
(e) The handler can be required to illustrate they have performed the items required of producers in 4.2.1 (b), where the certifier feels this is appropriate, in order to achieve the goal of full compliance in the use of only organic seed/planting stock.

Public Comment and Subcommittee Discussion

This section addresses the common occurrence of a buyer either supplying the seed, or requiring a specific seed and source, when working with a contracted producer for the final crop. When the buyer requires a nonorganic seed, the grower is constrained by their contract and will not perform an organic seed search. In discussions with the National Organic Program, it became clear that it is difficult through regulatory channels, to require a handler to have a seed search as part of their business' Organic System Plan. Therefore, this section requires the farmer to obtain documentation from the organic handler who is requiring their contracted organic farmer to use a nonorganic seed to grow an organic crop. The handler needs to provide documentation that they searched for organic seeds and provide this to the grower to become part of the grower's OSP. Handlers have unique opportunities when requiring nonorganic seed, and this section suggests a variety of methods they could increase the use of organic seed/planting stock when working with contracted growers.

No changes to 4.3, 4.3.1, 4.3.2, 4.3.3

4.4 Role of Certifying Agents

No changes to 4.4.1, 4.4.2, 4.4.3

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.

4.4.4

(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:

(i) The certifier's communication detailing commercially availability organic seed/planting stock and continued non-use by the farmer

(ii) Organic seed searches that do not include suppliers who carry organic seed/planting stock of that specific crop.

(iii) The producer's lack of on-farm seed trials, or reference to descriptions, for judging equivalency between nonorganic seed and organic seed.

(iv) Return to nonorganic seed/planting stock use for a crop, if the organic equivalent seed/planting stock was *not* documented as having a significant yield, market or other loss.

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 noncompliances, and these items listed above are based upon public comment and NOSB member input.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops grown by the organic operator, at-risk of GMO contamination.

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 organic seed, as well as those that sell organic seed to others, should include practices that specifically address GMO contamination prevention. Certifiers should be reviewing these contamination prevention measures to lessen the presence of this contamination in the organic seed supply chain.

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: <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, **and the conventional replacement variety can be documented as being produced without the use of excluded methods.**

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. If trials are not performed, the producer can use catalog or website seed descriptions, to document there are no organic seeds that have equivalent characteristics to the nonorganic seed in use.

4.1.2

d. Documentation of on-farm trials or seed characteristic searches can be provided at the annual inspection. This documentation can 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.

4.1.6 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 **or an organic vegetative crop only** after 12 months of organic management *§*205.204 (a)(4).

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, **or other descriptions illustrating seed characteristics**, can be used to demonstrate lack of equivalent seed or planting stock varieties/cultivars 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 and planting stock varieties **should include but is not limited to:**

i. Documentation of contact with at least three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock, including date, variety requested, quantity of seed, as well as if the seed is available organically, or was out-of-stock.

ii. Improved timeliness of seed/planting stock ordering by documenting the date(s) of orders. Earlier ordering can result in a greater chance of organic seed/planting stock availability. For larger orders, suppliers need to be given sufficient lead time to provide the quality, quantity and variety/cultivar within the timeframe needed by the organic producer.

iii. Work with seed/planting stock suppliers that provide a quick response of organic availability, to enable the producer to request seed, in a timely manner, of other suppliers if organic seed was not available from the first supplier.

iv. Demonstrate an increase in *the percentage* of organic seed/planting stock used over time by the operation.

v. Search suppliers that are known to carry organic varieties or cultivars of the type they seek.

vi. Discuss and document their desire to purchase equivalent organic varieties or cultivars with their current nonorganic suppliers.

vii. 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.

4.2.1 b. 2. (no changes)

4.2.1 (b) 3. If seed/planting stock is sourced or mandated by the buyer of a contracted organic 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 could include:

i. The handler's organic search documents there are no organic equivalents in quality, quantity or function, to the nonorganic seed/planting stock they require.

ii. The handler has discussed the development of an equivalent organic seed/planting stock source with their nonorganic seed supplier, as well as with organic seed breeders.

iii. The handler seeks out organic growers, either those that are contracted to grow organic crops from that nonorganic seed/planting stock source, or known organic growers who are experienced in seed/planting stock production, to trial production of an organic equivalent variety/cultivar.

iv. The handler clearly documents that mandating use of nonorganic seed/planting stock is not solely based upon the possibly higher monetary cost of an organic equivalent variety.

v. The handler can be required to illustrate they have performed the items required of producers in 4.2.1 (b), where the certifier feels this is appropriate, in order to achieve the goal of full compliance in the use of only organic 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:

1. The certifier's communication detailing commercially availability organic seed/planting stock and continued non-use by the farmer

2. Organic seed searches that do not include suppliers who carry organic seed/planting stock of that specific crop.

3. The producer's lack of on-farm seed trials, or reference to descriptions, for judging equivalency between nonorganic seed and organic seed.

4. When producer returns to nonorganic seed/planting stock use, if the organic equivalent seed/planting stock was *not* documented as having a significant yield, market or other loss.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops grown by the organic operator, at-risk of GMO contamination.

Motion to accept all changes to the National Organic Program Guidance 5029 as described in the proposal section above.
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Approved by Jesse Buie, Subcommittee Vice Chair to transmit to NOSB, February 19, 2019

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Paper (Plant Pots and Other Crop Production Aids)
February 19, 2019

I 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 historically been 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)."*

Paper pots are used by small scale farming operations to efficiently transplant using a non-motorized machine transplanting system, or are planted individually to avoid removing plants from plastic pots at transplanting. Research on paper-based planting pots has brought to our attention the significant use of synthetic fibers in addition to the cellulose-based fibers used in newspaper. A variety of synthetic fibers, from vinylon, rayon, and polyester, as well as others we may not know of, are used in current "paper pots" on the market in amounts ranging from 15%-100% in We have been told that a research is being conducted on the use of natural hemp fibers to replace the synthetic ones. Hemp fiber is becoming more available in the marketplace and could offer the strength found in synthetic fibers, but the current supply is somewhat erratic. In Fall 2018, there were numerous public comments that requested that the allowance for paper be expanded to include a variety of production aids.

Many of the adhesives and fibers typically used in paper have been described and reviewed in the technical review on newspaper. However, the use of synthetic fibers was not covered in sufficient detail, and therefore the Crops Subcommittee has requested a technical review (TR) of the synthetic fibers used in paper-based pots, seed tape, collars, and hot caps. The TR scope for paper-based crop production aids is to include: the types of synthetic fibers used, the percentage of the synthetic fiber that biodegrades and in what time frame, as well as the standard OFPA criteria for a material used in organic production.

II Questions:

1. Are there other paper-based production aids that are not mentioned in this discussion document beyond mulch, compost feedstock, pots, seed tape, hot caps, or collars?

2. What synthetic fibers are used in paper-based crop production aids, what is the percentage of synthetic fiber in the paper-based product, and how long, if at all, does it take for the synthetic fiber to completely biodegrade?

3. Are the synthetic fibers used in paper as a crop production aid, also used in newspaper or recycled paper that is currently allowed on the National List?

III Vote in Crops Subcommittee

Motion to accept the paper (plant pots and other crop production aids) discussion document
Motion by: Harriet Behar
Seconded by: Rick Greenwood
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Jesse Buie, Subcommittee Vice Chair, to transmit to NOSB, February 19, 2019

Sunset 2021
Meeting 1 - Request for Public Comment
Crops Substances
April 2019

Introduction

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

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2019 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2019 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 4, 2019 as explained in the meeting notice published in the Federal Register.

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances under Review:

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

(1) not harmful to human health or the environment;

(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

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

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

For Comments Addressing the Availability of Alternatives:

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

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

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

Written public comments will be accepted through April 4, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2021
Meeting 1 - Request for Public Comment
Crops Substances
April 2019

Note: With the exception of Ferric Phosphate and Hydrogen Chloride 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: 205.601 Synthetic substances allowed for use in organic crop production.

Hydrogen peroxide (a)
Hydrogen peroxide (i)
Soaps, ammonium
Oils, horticultural (e)
Oils, horticultural (i)
Pheromones
Ferric phosphate
Potassium bicarbonate
Magnesium sulfate
Hydrogen chloride

Reference: 205.602 Nonsynthetic substances prohibited for use in organic crop production.

Ash from manure burning
Sodium fluoaluminate

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Hydrogen peroxide—§205.601(a)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. **(4) Hydrogen peroxide.**
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation -deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation
10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022
Background from Subcommittee:
Use
Hydrogen peroxide is widely used as a disinfectant and bleaching agent. It is an effective and an environmentally benign substance used to reduce and control microorganisms for food safety purposes. It is critical for sanitizing aseptic packaging. It is a weak acid but a strong oxidizer, and this makes it very useful as a fungicide, cleaning agent, and for disease control.

Manufacture
Hydrogen peroxide is a very simple molecule with a formula of H_2O_2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

International Acceptance
The 2015 TR notes that a subset of the international organizations surveyed have provided guidance on the application of hydrogen peroxide for disinfection and plant disease control in organic crop production.

Canadian General Standards Board: allows numerous uses of hydrogen peroxide in organic production. Under Section 4.3: “Crop production aids and materials,” hydrogen peroxide is not allowed in maple syrup production but is allowed for use as a fungicide. Section 5.3: “Health care and production aids for livestock production” lists pharmaceutical grade hydrogen peroxide for external use as a disinfectant, and food-grade hydrogen peroxide for internal use (e.g., livestock drinking water). Hydrogen peroxide is also listed in Section 7.3: “Food-grade cleaners, disinfectants and sanitizers” that are allowed without mandatory removal of residues, and 7.4: “Cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production” (CAN, 2011).

European Union: According to Annex VII of EU regulation 889/2008, hydrogen peroxide is allowed for cleaning and disinfection of buildings and installations for animal production. Specifically, hydrogen peroxide can be used to satisfy Article 23 (4), which states that "housing, pens, equipment and utensils shall be properly disinfected to prevent cross-contamination and the buildup of disease carrying organisms." Hydrogen peroxide is also permitted for use in the production of gelatin under Section B of Annex VIII: and substances for use in production of processed organic food (EC, 2008).

International Federation of Organic Agriculture Movements: Hydrogen peroxide is permitted under Appendix 4 – Table 2 of the IFOAM Norms as an equipment cleanser and disinfectant. In addition, Appendix 5 lists hydrogen peroxide as an approved substance for pest and disease control and disinfection in livestock housing and equipment (IFOAM, 2014). The Norms make no mention of hydrogen peroxide for plant disease control and prevention.

UK Soil Association: Standards permit the use of hydrogen peroxide only as a cleaning product for livestock housing areas. No conditions are provided allowing the use of hydrogen peroxide for plant disease control and prevention (Soil Association, 2014).

Environmental Issues (could include human health issues)
Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

Discussion:
A technical report (TR) was commissioned in 2015 for hydrogen peroxide since the information from the previous 1995 TAP was old and incomplete. It showed that hydrogen peroxide is inherently unstable and breaks down readily into oxygen and water. (TR Evaluation question 3-5). While it is toxic to disease spores and cells on contact, it has absolutely no residual effect. It has low or no impacts on birds, humans, or fish if it is used according to the label and protective application measures are taken. There can be some effects on soil microbiota in the very top layer of soil where it may come in contact, but because it breaks down so quickly, soil life is quickly restored. (TR 2015 Evaluation Question #8).

While there are some alternatives on the National List for sanitizers and disinfectants, as well as some essential oils with antiseptic properties, the National List items are not necessarily any better or safer than hydrogen peroxide, and the essential oils have not been studied to compare with hydrogen peroxide side-by side to see if they are equally as effective and equally benign. (TR Evaluation question 11). Certain bacterial and fungal products that are beneficial in controlling plant diseases may be valid alternatives for some uses as a fungicide, but often these are best used as preventatives and are not effective once a disease has taken hold, and they are not good substitutes in all situations. Likewise, some biological, cultural and physical methods keep the need for use of hydrogen peroxide to a minimum, but don't apply to every situation. (TR Evaluation question 12).

In the 2015 sunset review most public commenters supported keeping hydrogen peroxide on the National List. It was frequently mentioned that it is one of the few tools left against fire blight now that

antibiotics cannot be used. It is widely used to clean equipment, in mushroom production, and to alternate with other materials for resistance management. No comments were put forward with new information that would contribute to the OFPA criteria review. The NOSB found the material to meet OFPA criteria and had no objection to continued listing. No significant new issues were raised by the public.

Additional information requested by Subcommittee: None

Hydrogen peroxide—§205.601(i)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(i) As plant disease control. **(5) Hydrogen peroxide.**
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation -deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation
10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use
Hydrogen peroxide is widely used as a disinfectant and bleaching agent. It is an effective and an environmentally benign substance used to reduce and control microorganisms for food safety purposes. It is critical for sanitizing aseptic packaging. It is a weak acid but a strong oxidizer, and this makes it very useful as a fungicide, cleaning agent, and for disease control.

Manufacture
Hydrogen peroxide is a very simple molecule with a formula of H_2O_2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

International Acceptance
The 2015 TR notes that a subset of the international organizations surveyed have provided guidance on the application of hydrogen peroxide for disinfection and plant disease control in organic crop production.

Canadian General Standards Board: allows numerous uses of hydrogen peroxide in organic production. Under Section 4.3: "Crop production aids and materials," hydrogen peroxide is not allowed in maple syrup production but is allowed for use as a fungicide. Section 5.3: "Health care and production aids for livestock production" lists pharmaceutical grade hydrogen peroxide for external use as a disinfectant, and food-grade hydrogen peroxide for internal use (e.g., livestock drinking water). Hydrogen peroxide is also listed in Section 7.3: "Food-grade cleaners, disinfectants and sanitizers" that are allowed without mandatory removal of residues, and 7.4: "Cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production" (CAN, 2011).

European Union: According to Annex VII of EU regulation 889/2008, hydrogen peroxide is allowed for cleaning and disinfection of buildings and installations for animal production. Specifically, hydrogen peroxide can be used to satisfy Article 23 (4), which states that "housing, pens, equipment and utensils shall be properly disinfected to prevent cross-contamination and the buildup of disease carrying organisms." Hydrogen peroxide is also permitted for use in the production of gelatin under Section B of Annex VIII: and substances for use in production of processed organic food (EC, 2008).

International Federation of Organic Agriculture Movements: Hydrogen peroxide is permitted under Appendix 4 – Table 2 of the IFOAM Norms as an equipment cleanser and disinfectant. In addition, Appendix 5 lists hydrogen peroxide as an approved substance for pest and disease control and disinfection in livestock housing and equipment (IFOAM, 2014). The Norms make no mention of hydrogen peroxide for plant disease control and prevention.

UK Soil Association: Standards permit the use of hydrogen peroxide only as a cleaning product for livestock housing areas. No conditions are provided allowing the use of hydrogen peroxide for plant disease control and prevention (Soil Association, 2014).

Environmental Issues (could include human health issues)
Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

Discussion:
A technical report (TR) was commissioned in 2015 for hydrogen peroxide since the information from the previous 1995 TAP was old and incomplete. It showed that hydrogen peroxide is inherently unstable and breaks down readily into oxygen and water. (TR Evaluation question 3-5). While it is toxic to disease spores and cells on contact, it has absolutely no residual effect. It has low or no impacts on birds, humans, or fish if it is used according to the label and protective application measures are taken. There can be some effects on soil microbiota in the very top layer of soil where it may come in contact, but because it breaks down so quickly, soil life is quickly restored. (TR 2015 Evaluation Question #8).

While there are some alternatives on the National List for sanitizers and disinfectants, as well as some essential oils with antiseptic properties, the National List items are not necessarily any better or safer

than hydrogen peroxide, and the essential oils have not been studied to compare with hydrogen peroxide side-by side to see if they are equally as effective and equally benign. (TR Evaluation question 11). Certain bacterial and fungal products that are beneficial in controlling plant diseases may be valid alternatives for some uses as a fungicide, but often these are best used as preventatives and are not effective once a disease has taken hold, and they are not good substitutes in all situations. Likewise, some biological, cultural and physical methods keep the need for use of hydrogen peroxide to a minimum, but don't apply to every situation. (TR Evaluation question 12).

In the 2015 sunset review most public commenters supported keeping hydrogen peroxide on the National List. It was frequently mentioned that it is one of the few tools left against fire blight now that antibiotics cannot be used. It is widely used to clean equipment, in mushroom production, and to alternate with other materials for resistance management. No comments were put forward with new information that would contribute to the OFPA criteria review. The NOSB found the material to meet OFPA criteria and had no objection to continued listing. No significant new issues were raised by the public.

Additional information requested by Subcommittee: None

Soaps, ammonium

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(d) **As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.**
Technical Report: 1996 TAP; *2019 TR pending (to be posted at* https://www.ams.usda.gov/rules-regulations/organic/national-list/a)
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); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use
Ammonium soaps are used as animal repellents to protect organically produced crops from unwanted browsing, primarily from deer and rabbits. USDA organic regulations allow ammonium soaps as a "synthetic substance allowed for use in organic crop production" at 7 CFR 205.601.

Manufacture
Ammonium soaps are manufactured by hydrolysis of fats (triglycerides) with an alkaline source in a saponification process. In this process, the base reacts with the fatty ester to break the ester linkages, resulting in the formation of a salt with the cation of the base and the carboxylate anion that remains at the end of the hydrolysis. A wide range of fats may be used in the saponification process, including both plant and animal fats. Because of the relative abundance of fats and their low cost, most soaps are produced by the saponification of natural fats. Ammonium cations also exist in nature and play an

important role in the metabolic pathways of a range of organisms , as well as being a key component of the nitrogen cycle. Soaps, however, do not naturally exist in nature but are manufactured.

International acceptance
Canadian General Standards Board Permitted Substances List - Ammonium soaps are listed in the CAN/CGSB-32.311-2015 - Organic production systems - permitted substances lists.

Environmental issues and human health
Studies conducted by the EPA estimate that ammonium soaps will undergo rapid degradation in the environment, primarily through microbial metabolism, yielding an environmental half-life of less than one day. Interesting to note that the toxicological profile of the substance differs based on the environment in which it is located. They are regarded as having low toxicity to terrestrial organisms, with little impact to mammals and avian animals. The EPA has placed them in Toxicity Category IV, the lowest available classification. They are, however, moderately toxic in aquatic environments. Ammonium soaps have been classified as "highly toxic" to crustaceans by the EPA. Due to the potential toxicity to aquatic environments, ammonium soap repellent product labels stipulate "This product may be hazardous to aquatic invertebrates. Do not apply to water bodies such as ponds or creeks.

The EPA has given ammonium soaps the lowest possible toxicity classification (Toxicity Category IV). They have also concluded that the oral intake of dangerous levels of the substance is highly unlikely due to the recognizable and undesirable soap taste. Despite the low toxicity of ammonium soaps there are some health risks. They are primarily irritation-based. Occasional skin irritation upon prolonged exposure has been reported as potential problems with direct exposure in the eye.

Discussion
There are some alternative methods that make the use of ammonium soaps unnecessary. They include population control of animals, alteration of habitat or physical barriers. As such, fencing is widely acknowledged as the most effective means of preventing crop damage from unintended browsing. There are also natural (non-synthetic) substances which may be used in place of ammonium soaps. These all have similar limitations to the soaps and include fear-based area repellents such as coyote urine, smell-based area repellents such as human hair, and contact repellents that include capsaicin and black pepper oil.

Additional information requested by Subcommittee: None

Oils, horticultural—§205.601(e)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(e) As insecticides (including acaricides or mite control). **(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.**
Technical Report: 1995 TAP; *2019 TR pending (to be posted at* https://www.ams.usda.gov/rules-regulations/organic/national-list/n)
Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as acaricides, miticides, and insecticides. According to the 2018 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2018 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2018 TR).

Manufacture: Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2018 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2018 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International: According to the 2018 TR, oils are accepted for organic production by a number of international bodies.

Canada
Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.3. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (CAN/CGSB 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Table 2 of the Codex Alimentarius Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods lists "Paraffin oil" as a substance permitted for plant pest and disease control, with the limitation "Need recognized by certification body or authority" (FAO/WHO Joint Standards Programme 1999).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Paraffin oil is permitted as an insecticide and acaricide in Annex II of the European Council Regulation governing organic standards (EU Commission 2008).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard for Organic Plants, Table 2 allows mixed oil emulsion, petroleum oil aerosol, and petroleum oil emulsion for plant pest and disease control without annotation (Japan MAFF 2000).

IFOAM – Organics International
The IFOAM—Organics International standards Appendix 3 permits the use of "light mineral oils (paraffin)" without annotation for plant pest and disease control (IFOAM 2014).

Environmental Issues: The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2018 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2018 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2018 TR).

Discussion: Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the

use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself.

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils, however, they are not widely used and may not be widely available. The 2018 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga,* and *Bacillus thuringiensis* (*Bt).* Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2018 TR).

Previous sunset reviews included discussions around whether vegetable oils could serve as a natural replacement for the horticultural oils. During those discussions it was discovered that vegetable oils contained synthetic emulsifiers (mainly derived from a petroleum base), that if excluded, would prevent the oils from working properly. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop. It was also determined that the vegetable oils would not control certain pests adequately compared to the horticultural spray oils.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Organic stakeholders provided a clear message to the full NOSB that this material remains a necessary tool in organic crop production and in fact has increased in use due to the recent growth of organic production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Additional information requested by Subcommittee:

1) Are non-petroleum-based oils available and could they be substituted for petroleum-based oils?

Oils, horticultural—§205.601(i)

§205.601 Synthetic substances allowed for use in organic crop production.

Reference: 205.601(i) As plant disease control. **(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.**

Technical Report: 1995 TAP; *2019 TR pending (to be posted at* https://www.ams.usda.gov/rules-regulations/organic/national-list/n)

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 3/15/2022

Background from Subcommittee:

Use: Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as acaricides, miticides, and insecticides. According to the 2018 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2018 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2018 TR).

Manufacture: Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2018 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2018 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International: According to the 2018 TR, oils are accepted for organic production by a number of international bodies.

Canada
Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.3. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (CAN/CGSB 2015).

CODEX Alimentarius Commission, **Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**
Table 2 of the Codex Alimentarius Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods lists "Paraffin oil" as a substance permitted for plant pest and disease control, with the limitation "Need recognized by certification body or authority" (FAO/WHO Joint Standards Programme 1999).

European Economic Community (EEC) **Council Regulation, EC No. 834/2007 and 889/2008**
Paraffin oil is permitted as an insecticide and acaricide in Annex II of the European Council Regulation governing organic standards (EU Commission 2008).

Japan Agricultural Standard (JAS) **for Organic Production**
The Japanese Agricultural Standard for Organic Plants, Table 2 allows mixed oil emulsion, petroleum oil aerosol, and petroleum oil emulsion for plant pest and disease control without annotation (Japan MAFF 2000).

IFOAM – Organics International
The IFOAM—Organics International standards Appendix 3 permits the use of "light mineral oils (paraffin)" without annotation for plant pest and disease control (IFOAM 2014).

Environmental Issues: The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2018 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2018 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity.

These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2018 TR).

Discussion: Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself.

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils, however, they are not widely used and may not be widely available. The 2018 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga,* and *Bacillus thuringiensis* (*Bt).* Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2018 TR).

Previous sunset reviews included discussions around whether vegetable oils could serve as a natural replacement for the horticultural oils. During those discussions it was discovered that vegetable oils contained synthetic emulsifiers (mainly derived from a petroleum base), that if excluded, would prevent the oils from working properly. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop. It was also determined that the vegetable oils would not control certain pests adequately compared to the horticultural spray oils.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Organic stakeholders provided a clear message to the full NOSB that this material remains a necessary tool in organic crop production and in fact has increased in use due to the recent growth of organic production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Additional information requested by Subcommittee:
Are non-petroleum-based oils available and could they be substituted for petroleum-based oils?

Pheromones

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(f) As insect management. **Pheromones.**
Technical Report: 1995 TAP; 2012 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); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use: Pheromones are volatile chemicals produced in nature by a given species to communicate with other individuals of the same species to affect their behavior. Pheromones are produced naturally by many organisms and are synthetically produced for use in agriculture. Insect pheromones are generally comprised of very specific esters, that alone, or in combination, create a species-specific communication system. Pheromones may be released from various types of dispensers into the surrounding air. Inert ingredients may be used as part of the formulation process but generally do not contact crops since they are contained within the dispensers. Pheromones are considered generally non-toxic and have a low persistence in the environment.

Pheromones are used by organic (and many conventional) crop producers and are especially important for organic tree fruit production. Pheromones are used by growers in a variety of ways such as monitoring insect presence and population density, mass trapping, 'attract and kill' systems, and for use in mating disruption or confusion.

The use of pheromones to attract insects to traps has long been used as a means of monitoring populations, determining whether controls need to be applied, and infer the timing of controls applications. Varying types of dispensers are impregnated with the pheromone and then placed in some sort of monitoring trap. Trapping can field check insect development models as well as be used to determine when a threshold has been reached that might require further action by a farmer. Mass trapping using pheromones as an attractant can also be used to help in reducing the overall numbers of an insect pest. A variant of mass trapping is the attract and kill system. Rather than trapping the insect, these systems use the synthetic pheromone as an attractant to get the insect to come into contact with an insecticide.

Mating disruption/confusion uses a synthetic pheromone to saturate a targeted area. The male of the targeted species is unable to differentiate between the pheromone released by the female and that applied by dispensers. This can cause the male to become confused and disoriented and thus unable to locate the species female for mating. Normally in organic crop production these pheromones are dispersed for use via a passive or active pheromone dispenser (including traps and lures). Some forms of

passive dispensers are pheromone-impregnated polymer spirals, ropes, coils, twist ties, or tubes. The use of wires, clips, or circular tubes allows these pheromone dispensers to be placed directly in the intended area of usage. Active dispensers, commonly called puffers, distribute a larger amount of pheromone on a programmed schedule. They are usually used at lower densities than passive dispensers and can be programmed to only release pheromone when the target insect might be active.

Manufacture: As the 2012 technical report notes, while pheromones are produced naturally by insects and other organisms, they are difficult to isolate in sufficient quantities for commercial production. Thus, most commercially used pheromones are synthetically produced and attempt to replicate the natural pheromone. The synthesis of the pheromones is complex and normally involves a number of conversion steps.

The TR further cites various studies showing that insect pheromones are generally comprised of very specific esters. These esters vary in carbon chain length. The primary components of sex pheromones (esters) are the most critical part of the chemical complex, but are reliant on the presence or absence of secondary components, which greatly affect an insect's response sequence.

International:

Canadian General Standards Board allows pheromones. (List 4A & List 4B3)

European Economic Community, Council Regulations # 889/2008 allows for their use

Codex Alimentarius Commission allows for their use.

Environmental Issues: During past reviews there has been concern raised over the inerts used in pheromones because they do include known irritants, sensitizers, and allergens. The 2012 TR mentions that some compounds could potentially be linked to asthma, cancer, or endocrine disruption. However, under the current use of pheromones it is not believed that they would release enough volume to leave any kind of residue on the agricultural crops being treated. It also states that dissipation takes place via volatilization and degradation, rapidly into the environment.

In past reviews, some concerns were raised around the use of "encapsulated pheromones" (those concerns mentioned harm to honey bees and concerns over aerial applications). These involve small pheromone containing capsules that might be applied in water or by air and could have direct crop contact. However, use of these forms of pheromones has not generally reached commercial application.

The 2012 TR notes that based on low observed toxicity in animal testing, and expected low exposure to humans, there is no risk to human health expected from the use of pheromones. EPA data shows that no human health concerns had been reported in the ten years prior to the TR.

Discussion: Pheromones continue to be an integral and highly used component of organic agriculture. Their use in trapping and monitoring provides a basis for integrated pest management and helps to

ensure that other pest control materials are only applied where and when needed. For certain pests in organic systems their use in mating disruption may be the only viable control option and in other systems their use precludes the need for more disruptive control options.

Public comments from previous sunset reviews have been strongly supportive of the relisting of pheromones. Other commenters have noted that their delisting would lead to the loss of many acres of organic tree fruits. Comments noted that the use of pheromones in organic crop production has continued to increase, as various formulations have been developed for specific target species

Additional information requested by Subcommittee:

1. Have any health or environmental effects from pheromones been noted since the writing of the 2012 technical report?
2. Are there any formulations of pheromones that might cause concern in organic agricultural applications?
3. Are there any pheromones synthesized with excluded methods?

Ferric phosphate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: §205.601(h) As slug or snail bait. **Ferric phosphate (CAS #s 10045-86-0).**
Technical Report: 2004 TAP, 2010 TR, Supplemental TR 2012
Petition(s): 05/2003 , Supplemental Information 02/2005, Petition to remove: 07/2009
Past NOSB Actions: 03/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2012 recommendation on petition to remove from national list; XX/2016 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 71 FR 53299; Renewed 08/03/2011 76 FR 46595; Renewed 09/12/16 81 FR 8821
Sunset Date: 9/12/2021

Background from Subcommittee:

Use
Ferric phosphate is used as a molluscicide slug and snail suppressant. Ferric phosphate accumulates in the calcium spherules of slug and snail digestive glands, thereby interfering with calcium metabolism, and in turn, disrupting feeding and mucus production. After ingesting ferric phosphate slugs and snails stop feeding, and death due to starvation will occur three to six days later. Ferric phosphate occurs naturally in soil but at considerably lower concentrations than that present in the formulated, baited product.

Manufacture
Ferric phosphate occurs naturally in the soil; however, to achieve concentrations toxic to mollusks, ferric phosphate must be supplemented through applications, most often with ferric phosphate formulated with a chelating agent. To produce ferric phosphate synthetically, an aqueous iron sulfate solution is mixed with an aqueous disodium phosphate solution in a stainless-steel boiler. The mixture is heated to 50-70 °C in order to precipitate ferric phosphate. The precipitate is filtered from the solution, washed with distilled water, and dried with hot air. The baited pellets contain approximately 1% by mass of ferric phosphate with the remainder of the pellet comprised of a chelating agent and carbohydrate inerts. The EPA describes

ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied.

International acceptance by other international certifying bodies
The European Union, the Canadian General Standards Board, The International Federation of Organic Agriculture Movement and the Japanese Organic Standard for Organic Plants all list ferric phosphate for use as a molluscicide in the protection of plants.

Environmental/Health Issues
The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied. Small concentrations of ferric phosphate are made available in soil solution when it is solubilized by commonly occurring soil microorganisms such as *Penicillium radicum*.

Ferric phosphate by itself appears to be less toxic to a range of soil borne organisms (including slugs and snails) than when formulated with a chelating agent (EDTA or EDDS for example). The chelating agent enhances iron uptake by organisms in general. A number of published studies document that when formulated with a chelating agent, the efficacy for control of slugs and snails increases significantly. However, the increased efficacy also means its activity on non-target organisms like earthworms, domestic animals and humans also increases. The LD50 for ferric phosphate alone is greater than 10,000 mg kg, while it drops to 80 mg kg when it is formulated with the chelating agents EDTA or EDDS (Ethylene diamine tetracetic acid – EDTA and Ethylene diamine disuccinic acid (EDDS).

Discussion
The July 26, 2012 technical review addressed four questions regarding the efficacy of ferric phosphate alone and the synergizing effects of chelating agents (EDTA and EDDS). This review concluded that without the chelating agent, ferric phosphate did not provide sufficient or consistent suppression of slugs and snails. In fact, the efficacy of ferric phosphate was so low that it is hard to see why it would be used for slug and snail suppression without the chelating agent. The TR then asked, what risk does the use of ferric phosphate and its associated chelating agents pose to soil organisms and water quality. Here the existing data are scant. What has been researched (three studies published between 2006 and 2009) indicates a range of responses from non-significant to highly significant adverse effects of chelated ferric phosphate on a range of non-target organisms.

Additional information requested by Subcommittee:

1. What new findings have been reported since 2009 that would inform our understanding of the influence of ferric phosphate alone and ferric phosphate in combination with commonly used chelating agents on the soil micro and macro fauna with particular attention to earthworm populations.
2. To what extent is ferric phosphate used for slug and snail management in organic production?
3. How are the products formulated that are detailed in (2) above?
4. Since the July 26, 2012 technical review, have additional studies been conducted documenting the effects of fieldworker exposure to ferric phosphate bait handling including inhalation of dust resulting from field applications.

Potassium bicarbonate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(i) As plant disease control. **(9) Potassium bicarbonate.**
Technical Report: 1999 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting 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); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022
Background from Subcommittee:
Use:
Potassium bicarbonate is a plant disease control material. It is used by organic crop producers to control *alternaria* in cucurbits and cole crops; anthracnose in cucurbits, blueberries, grapes, spinach, and strawberries; black dot root rot and early blight in potatoes; sooty blotch and powdery mildew in apples; downy mildew in cucurbits, cole crops, grapes, and lettuce; gray mold (*Botrytis cinerea*) in beans, lettuce, and strawberries. These are just a few of the crops and specific diseases it helps to control. It is best suited for many of the powdery mildew diseases (TR lines 80-1) and early blight (1999 TAP). It has proven to be an important disease control aid in organic crop production.

Manufacture:
Potassium bicarbonate is produced by carbonating potassium hydroxide to K_2CO_3, which is then carbonated to $KHCO_3$. Carbonation is accomplished by injecting carbon dioxide gas into an aqueous solution of potassium hydroxide. (1999 TAP)

International Acceptance by Other Certification Agencies:
Canada - Canadian General Standards Board Permitted Substances List permits use of potassium bicarbonate as a "pest and disease control in greenhouses and other crops".
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999 lists potassium hydrogen carbonate for plant pest and disease control.
European Economic Community (EEC) Council Regulation, EC No. 2092/91 has no mention of potassium bicarbonate for crop production.
Japan Agricultural Standard (JAS) for Organic Production lists potassium hydrogen carbonate (water soluble powder) for plant pest and disease control.
International Federation of Organic Agriculture Movements (IFOAMl lists potassium bicarbonate under "Crop Protectants and Growth Regulators".

Environmental/Health Issues:
The 1999 TAP review states that the decomposition products are potassium carbonate, water, and carbon dioxide, all of which readily dissipate in the environment. It found this material to be compatible with organic crop production, safe, and more environmentally friendly than many of the synthetic alternatives. Potassium bicarbonate is a mild respiratory and eye irritant.

Discussion:
During the 2015 sunset review, a limited scope technical report (TR) was requested. The TR provided possible alternative materials or practices that might replace this material. *Bacillus amyliquifaciens* strain

D747, *Bacillus subtilis, Bacillus pumilis,* gibberellic acid, and *Streptomyces griseovirdis and lydicus, Gliocladium catenulatum,* and extracts of giant knotweed are all listed as natural alternatives for numerous plant diseases across many crops. Bordeaux mixture, kaolin, lime sulfur and sulfur, hydrogen dioxide, and neem extracts are offered as alternatives for both treatment and disease prevention across myriad crops and diseases, in addition to a variety of cultural and mechanical practices. Further clarification was sought in 2015 from stakeholders using this material to help explain under what conditions or scenarios the alternatives might be applied. Organic producers responded that while alternative materials and/or practices exist, potassium bicarbonate remains necessary for their particular crop production practices. Potassium bicarbonate is an important tool in powdery mildew resistance management. In addition to its efficacy on powdery mildew, stakeholders said its unique mode of action helps control other diseases under certain conditions or scenarios better than the alternative materials or practices.

There was continued support for the continued listing of this material in 2015. One commenter was concerned that this material does not fit into any of the categories under §6517(c)(1)(B)(i) of OFPA. Others noted its extensive listing in Organic Systems Plans. Based on extensive public comment, the NOSB continued to find potassium bicarbonate compliant with OFPA criteria and did not recommend removal from the National List.

Additional Information Requested by the Subcommittee:

The following questions were posed during the 2015 sunset review, and the CS is re-issuing them for this current sunset review:

1. Have you used any of the many alternative materials or methods on your farm, and did they provide the desired result for disease control?
2. Is potassium bicarbonate still needed in your organic farming operation? If so, why?

Magnesium Sulfate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(j) As a plant or soil amendment. **(6) Magnesium sulfate—allowed with a documented soil deficiency.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use:
Magnesium sulfate is used to correct for magnesium soil deficiencies and helps to improve the uptake of nitrogen and phosphorus by crops, helps seeds germinate, increases chlorophyll production, aids in the production of flowering, and is vital in maintaining crop growth and yield.

Manufacture:
Magnesium sulfate can be obtained from naturally occurring sources (kieserite or epsomite open-pit mines) or can be manufactured by a chemical process. Mineral forms of magnesium sulfate are dehydrated, purified, and reacted with sulfuric acid to create the synthetic version of magnesium sulfate. Historically, there have been no commercially available products containing mined, raw mineral magnesium sulfate in bulk quantities suitable for agriculture. For this reason, the production of synthetic magnesium sulfate has been necessary.

International Acceptance by Other Certification Agencies:
Canada - Canadian General Standards Board Permitted Substances List allows magnesium sulfate from "Mined sources. A source of magnesium and sulphur".
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) permits use of magnesium sulfate as Epsom salt.
European Economic Community (EEC) Council Regulation, EC No. 2092/91 lists "magnesium sulfate (for instance: kieserite)" under Fertilizers and Soil Conditioners.
Japan Agricultural Standard (JAS) for Organic Production limits to the use of magnesium sulfate to "those derived from natural sources, or natural sources without the use of chemical treatment".
International Federation of Organic Agriculture Movements (IFOAM) lists "magnesium rock, kieserite and Epsom salt (magnesium sulfate)" under "fertilizers and Soil Conditioners.

Environmental/Health Issues:
As stated in the 2011 technical report (TR) (lines 320-23): "If applied as a foliar feed in recommended doses (assuming also that a magnesium deficiency has been documented), magnesium sulfate would not be expected to produce toxic effects. However, if too much magnesium sulfate is added to the soil, or if the substance is added when a magnesium deficiency has not been determined, the uptake of other important nutrients will be affected." The TR goes on to state that when used properly, it is unlikely to cause environmental or human health harm.

Discussion:
During the 2015 review, the Crops Subcommittee asked stakeholders if non-synthetic magnesium sulfate is available in the marketplace. Public comment indicated that the only form of non-synthetic magnesium sulfate that has been reviewed is potassium magnesium sulfate, or langbeinite; however, this material is not a reliable alternative because it is only available in limited quantities, and it is impossible to determine upon purchase whether langbeinite is synthetic or non-synthetic. There was substantial public comment in support of relisting magnesium sulfate. It is actively used by stakeholders and continues to be considered necessary to the production of fruit and vegetables. One commenter opposed the relisting, stating that nonsynthetic magnesium sulfate is available as langbeinite and dolomite. As noted above, other commenters indicated that langbeinite is constrained by supply and classification issues. While dolomite can be used to treat a magnesium deficiency, the TR states that it is not as effective as magnesium sulfate and was not referenced by other commenters as a viable alternative. No significant new issues were raised, and the NOSB continued to find magnesium sulfate compliant with OFPA criteria and did not recommend removal from the National List.

Additional information requested by Subcommittee:
1. Is non-synthetic magnesium sulfate available in sufficient form and quantity?
2. The 2011 TR references non-synthetic dolomite as an alternative material and lists several OMRI-approved products containing it. It also states that it is not as effective as magnesium sulfate. Please describe any experience with non-synthetic dolomite products and their efficacy.

Hydrogen chloride

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: §205.601(n) Seed preparations. **Hydrogen chloride (CAS # 7647-01-0)—for delinting cotton seed for planting.**
Technical Report: 2003 TAP, 2014 Limited Scope TR
Petition(s): Hydrogen Chloride 10/30/02
Past NOSB Actions: 05/2004 NOSB recommendation for National List; 11/2009 sunset recommendation
Recent Regulatory Background:
Added to National List 09/11/06 (71 FR 53299); Renewed 08/03/2011 (76 FR 46595)
Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Background from Subcommittee:
Use
Hydrogen chloride (2HCl) (CAS# 7647-01-0) forms a strong acid used for delinting cotton seed for planting. Hydrogen chloride is a liquid anhydrous hydrogen gas that is vaporized and then sprayed on cotton seeds after the ginning process. The gas mixes with the moisture in the seeds, resulting in acidic properties under which the lint on the seeds becomes weakened and is buffed off before planting. Because many fibers are attached to the seeds even after ginning, delinting improves handling (i.e., flowability) for subsequent planting by mechanized equipment.

Manufacture
There are several methods used to produce hydrogen chloride. It can be synthesized directly or as a byproduct from manufacturing other chlorinated or fluorinated compounds.

International acceptance
Canadian General Standards Board Permitted Substances: Not listed.
CODEX Alimentarius: Not Listed
European Economic Community (EEC) and India (NPOP): Hydrogen chloride not listed. Hydrochloric acid is listed for gelatin production and cheese processing (EEC)
Japan Agricultural Standard (JAS) for Organic Production: Not listed
International Federation of Organic Agriculture Movements (IFOAM): Not listed.

Ancillary substances
None

Impacts on health and the environment
Hydrogen chloride gas and subsequently produced hydrochloric acid are strongly corrosive materials and can cause skin burns, severe respiratory damage, circulatory system failure and death. Spills during manufacture or handling can injure workers or locally damage the environment.

Discussion
Hydrogen chloride for delinting cottonseed was recommended by the NOSB to be added to the National List in April 2004, and has been recommended each time it has subsequently been reviewed. However,

hydrogen chloride, and the subsequently formed hydrochloric acid, are very corrosive materials and pose potential environmental and health threats if not handled properly. The 2014 limited scope TR identified several alternative, nonsynthetic delinting processes under development that were not commercially available at that time. The decision to relist was based on the lack of viable alternatives and the hope "that mechanical or other delinting processes are available to organic cotton growers by the next sunset review, so this very corrosive acid can be removed from the National List." During the last sunset review it was stated: "The Crops Subcommittee is interested in hearing from the organic community as to the relative efficacy of mechanical delinting techniques and whether these techniques are feasible and/or available in commercial scale organic cotton production. The Crops Subcommittee is also interested in hearing whether the NOSB can encourage safer methods of delinting seeds." The 2014 limited TR included information (see Table 1 below) describing several alternatives to hydrogen chloride, and also referenced a new mechanical cottonseed delinter built by the USDA Agricultural Research Service, Southern Plains Area, Cropping Systems Research Lab, 1604 East FM 1294, Lubbock, TX 79403. The new delinter is intended to replace chemical delinting commonly used in the industry and has produced nearly naked seed during initial testing.

Table 1 Methods for preparing cottonseed for planting

Method	Applications	Approved for USDA Organic?
No treatment	Seed is planted manually. Not suitable for large farms	Yes
Concentrated Sulfuric Acid Delinting	Used commercially to permit metered planting	No
Dilute Sulfuric Acid Delinting	Used commercially to permit metered planting	No
Acid-Gas Delinting using Hydrogen Chloride	Used commercially to permit metered planting	Yes, allowed synthetic substance.
Power Roller Gin Relinting	Used in conjunction with coating	Yes
New Sawless Mechanical Delinter	No chemical treatment or coating is necessary. Not currently commercialized.	Yes
Baobab Tree Extract Delinting	Small scale, localized use.	Yes, nonsynthetic
Mud and Dung Coating	Small scale, localized use.	Yes, nonsynthetic
Starch Based Coating	In development for large scale use.	Only if starch is nonsynthetic. Dextrin was previously petitioned as a synthetic seed coating and was not recommended by NOSB.
Clay Based Coating	In development for large scale use.	Yes, if nonsynthetic
Chitosan	In use for rice, other seeds to follow	No.

Additional information requested by Subcommittee:

1. Is hydrogen chloride still used to delint seed in preparation for planting on organic farms?
2. Are hydrogen chloride cotton seed delinting methods still necessary for seed preparation and planting on organic cotton farms?
3. Are alternative methods that don't require synthetic acids being used and are they commercially available?

Ash from manure burning

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
Reference: 205.602(a) **Ash from manure burning.**
Technical Report: none
Petition(s): 2014
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation, 10/2015 sunset recommendation; 4/2016 NOSB formal recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: In some areas of nonorganic agriculture, the burning of manure to create an ash is used to lessen the volume of material (manure) transported to a field for fertilizer and to recover some of the nutrients in a more concentrated form (phosphorus, calcium, potassium and magnesium). The ash can then be used as a fertility input that is high in these nutrients. This ash from manure has also been touted as a feed ingredient for livestock. The NOP organic standards do not allow re-feeding of manure to organic livestock.

Manufacture: Manure can be thermally decomposed through combustion to produce this ash.

International: Canadian standards do not allow ash from manure burning to be used to crop organic crops. The EU does not allow manure from confined animal operations to be used on organic crops.

Discussion:
In April 2016, the NOSB responded to a petition to allow ash from manure burning with an annotation of "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients". The petitioner stated they source manure from Concentrated Animal Feeding Operations (CAFOs) and use a staged thermochemical reactor to extract minerals from their poultry manure source. The NOSB stated the following to support their recommendation to keep this material, as listed, as a prohibited nonsynthetic:

"*Ash from manure burning was placed on §205.602 based on its incompatibility with organic production: "Burning these materials is not an appropriate method to recycle organic wastes and would not be considered a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content. Burning as a disposal method of these materials would therefore not be consistent with section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1))." (Preamble to proposed rule, December 16, 1997. 62 FR 241: 65874)"*

The USDA organic regulations require "soil-building" as a basic foundational principle, to improve soil tilth, water retention, nutrients and carbon sequestration. *"§205.203 (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content…."*

Soil microbiological life increases when provided with carbon-based sources containing a variety of nutrients, and extraction of nutrients while destroying others (such as nitrogen) does not meet either the letter, nor spirit of the USDA organic law or regulations.

Additional information requested by Subcommittee:
Does ash from manure burning supply nutrients or other benefits that cannot be obtained from any other material?

Sodium fluoaluminate (mined)

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
Reference: 205.602(g) **Sodium fluoaluminate (mined).**
Technical Report: none
Petition(s): N/A
Past NOSB Actions: 05/1996 NOSB meeting 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); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Use: Sodium fluoaluminate (Na_3AlF_6)—also known as "sodium fluoroaluminate," "aluminum sodium fluoride," "trisodium hexafluoroaluminate," and "cryolite"—is a colorless to white halide mineral. It is used as a solvent for bauxite in the electrolytic production of aluminum and has various other metallurgical applications, and it is used in the glass and enamel industries, in bonded abrasives as a filler, and in the manufacture of insecticides (see www.britannica.com/science/cryolite for information on cryolite). Sodium fluoaluminate is also produced synthetically.

Manufacture: Sodium fluoaluminate is a colorless to white halide mineral. It occurs in a large deposit at Ivigtut, Greenland, and in small amounts in Spain, Colorado, U.S., and elsewhere.

International: There were no references to either sodium fluoaluminate or cryolite in the Canadian and European organic regulation websites.

Environmental Issues: According to an EPA memorandum dated March 16, 2011, on the subject of "Cryolite. Human Health Assessment Scoping Document in Support of Registration Review" (link to document available via https://fluoridealert.org/researchers/pesticide/cryolite/):

> Cryolite [sodium aluminofluoride or sodium aluminum fluoride or sodium hexafluoroaluminate] is an insecticide used to control a variety of pests including various weevils, leaf rollers, various moth and worm species, and grape skeletonizers. Cryolite can be used on a wide array of agricultural crops including grapes (wine, table, raisin), cole crops, citrus, berries, tomatoes, cucumber, lettuce, and many types of ornamentals. Formulations include dusts, wettable powders, water dispersible granules, and baits/solids. Some formulations can contain as much as 96 percent active ingredient by weight. A recent evaluation of cryolite use indicates almost 2 million pounds per year are applied on about 300,000 acres, most of which are on grapes (92% of total pounds applied and 96% of treated acres) (Prieto, 2010). Use in California accounts for the vast majority of cryolite use (97%). In agriculture, groundboom, airblast, and aerial applications are typical but applications as a pure dust can also occur which may dictate other specialized forms of equipment being used. Applications to ornamentals may also be made using handheld

equipment such as low- and high-pressure handgun sprayers and backpack sprayers. There are no cryolite containing products that appear to be marketed for sale to homeowners nor are there products which appear to be labeled for use by professionals in the residential marketplace (i.e., outdoors or indoors). Maximum application rates for most agricultural crops are in the 5 to 16 pounds product per acre range while some uses, especially on ornamentals can be higher (i.e., up to 30 lb/A using a 96% formulation).

The potential toxicity of sodium fluoaluminate/cryolite is due to the release of fluoride into the environment due to the dissociation of cryolite into fluoride. The EPA memorandum cited above references a number of animal toxicological studies on this substance; other studies related generally to fluoride toxicity are also referenced, since fluoride enters the environment in multiple ways—including fluoridated water—and therefore can have a cumulative adverse impact on health.

Discussion: Given the toxicity associated with fluoride pollution in the environment and the multiple sources of such pollution, continued prohibition of the use of this substance in organic production seems prudent.

Additional information requested by Subcommittee:
Are there any reasons why the long-standing prohibition on using sodium fluoaluminate in organic production should be reconsidered by the NOSB?