National Organic Standards Board Meeting
St. Anthony Hotel, Anacacho Ballroom, San Antonio, TX April 29 – May 2, 2014

****IMPORTANT NOTE REGARDING PUBLIC COMMENTS****

Many of the proposals that would have been discussed at the cancelled October 2013 NOSB meeting will be discussed at the April 2014 meeting instead. If you submitted comments at that time, and the NOSB has not revised the proposal, you **DO NOT** need to resubmit your comments. See key below for proposal status.

*** Fall 2013 document revised**

+ New for spring 2014

Lack of notation indicates no revisions to fall 2013 document

National Organic Standards Board Meeting

St. Anthony Hotel, 300 East Travis Street, San Antonio, TX 78205 Anacacho Ballroom

April 29 – May 2, 2014

Tentative Agenda

Schedule at a Glance

	Tuesday April 29	Wednesday April 30	Thursday May 1	Friday May 2
MORNING	- Call to Order - NOP Update - Policy Development Subcommittee - Presentation: Organic Agriculture at USDA - Overview of USDA NRCS - Discussion: Overarching Ideas and Undercurrents in Organics	- Public Comment	- Livestock Subcommittee	- Deferred Items/Final Votes - NOSB Officer Elections - Subcommittee Work Plans - Other Business/ Closing Remarks - Adjourn
AFTERNOON	- Materials Update/ Process Overview - Public Comment	- Crops Subcommittee	- Compliance, Accreditation & Certification Subcommittee - Handling Subcommittee - Materials Subcommittee	

Meeting Format

- The USDA National Organic Program (NOP) National List Manager presents an overview of petitioned substances and Technical Reports in consistent format.
- The Board hears public comments, which are grouped by topic to facilitate review.
- NOSB members present and discuss Subcommittee proposals and discussion documents; NOSB votes on proposals. Final votes may be deferred to Friday May 2, 2014 if more deliberation is needed.
- NOTE: Agenda items may be withdrawn or votes may be postponed at the discretion of the Board.
- There will be two 15-minute breaks (mid-morning & mid-afternoon) and a 1 hr & 15-minute lunch break mid-day

Public Comments

****IMPORTANT NOTE REGARDING WRITTEN PUBLIC COMMENTS****

- Many of the proposals that would have been discussed at the cancelled October 2013 NOSB meeting will be discussed at the April 2014 meeting instead. If you submitted comments at that time, and the NOSB has not revised the proposal, you **DO NOT** need to resubmit your comments. If a document was revised, it is noted below by a "*****". If a proposal is new for spring 2014 it is marked with a "**+**". This is also noted on the Subcommittee proposals webpages, and at the top of each proposal.
- If you signed up for in-person oral comments for fall 2013, you **WILL** have to do so again for spring 2014.
- All persons wishing to comment at NOSB meetings during the public comment period must sign up in advance. Instructions are available at **www.ams.usda.gov/NOSBMeetings**. Speaking slots for walk-in commenters are not guaranteed. Walk-in commenters can sign up in person at the meeting if the schedule allows.
- Each commenter must state his/her name and affiliation for the record at the beginning of their comment.

- Each person may sign up for only one speaking slot, followed by time for questions from the Board. The amount of time provided for each commenter will be determined by the number of commenters and the time available.

Tuesday, April 29, 2014	8:30 AM	**Call to Order, Ground Rules, Agenda Overview** Miles McEvoy, AMS Deputy Administrator, Designated Federal Officer **Announcements, Introductions, NOSB Mission** Mac Stone, Chairperson and John Foster, Vice Chairperson **Secretary's Report, Acceptance of April 2013 Meeting Transcripts and Voting Results as Official Record** Dr. C. Reuben (Calvin) Walker, Secretary
		National Organic Program update, OFPA, FACA, NOSB Charter, NOSB Evaluation and Operating Guidelines Miles McEvoy, Deputy Administrator
		Policy Development Subcommittee Dr. Jean Richardson, Chairperson **Topics:** Update on status of PDS and fall 2013 documents
		Organic Agriculture at USDA Mark Lipson, USDA Organic Policy Coordinator/Chair of USDA's Organic Working Group
		Overview of USDA Natural Resource Conservation Service (NRCS) NRCS Staff
		Discussion: Overarching Ideas and Undercurrents in Organics/Outcomes from NOSB Training and NOSB Evaluation NOSB
		National Organic Program - Materials Update/Process Overview Dr. Melissa Bailey, Director, Standards Division; Dr. Lisa M. Brines, NOP National List Manager Summary of New and Outstanding Petitions Petition Process Rulemaking Process Sunset Review Process
	2:45 PM	**Public Comment**
	5:30 PM	**RECESS**

*** Fall 2013 document revised**

+ New for spring 2014

Lack of notation indicates no revisions to fall 2013 document

Wednesday, April 30	8:30 AM	**Public Comment**
	2:45 PM	**Crops Subcommittee** Zea Sonnabend, Chairperson Present Subcommittee proposals and summarize written comments **Topics:** *Proposal: Streptomycin - petitioned *Proposal: Magnesium Oxide - petitioned + Proposal: Vinasse - petitioned + Proposal: Laminarin - petitioned Verbal update: Inerts (no document) *Sunset 2015 Review List: Sulfurous Acid Sodium Carbonate Peroxyhydrate Aqueous Potassium Silicate
	5:30 PM	**RECESS**

Thursday, May 1	8:30 AM	**Livestock Subcommittee** Tracy Favre, Chairperson Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Methionine in Organic Poultry Feed (MET) - petitioned Proposal: Acidified Sodium Chlorite (ASC) - petitioned Verbal update: Vaccines from Excluded Methods (GMO Vaccines) (no document) *Proposal: Aquaculture - Chlorine (for aquatic animals) - petitioned *Proposal: Aquaculture - Tocopherols (for aquatic animals) - petitioned *Proposal: Aquaculture - Minerals (for aquatic animals) - petitioned Proposal: Aquaculture - Vitamins (for aquatic animals) - petitioned +Proposal: Aquaculture - Biologics: Vaccines (for aquatic animals) – petitioned +Proposal: Aquaculture - Micronutrients (for aquatic plants) - petitioned +Proposal: Aquaculture - CO_2 (for aquatic plants) - petitioned +Proposal: Aquaculture - Chlorine (for aquatic plants) - petitioned +Proposal: Aquaculture - Lignin Sulfonate (for aquatic plants) - petitioned +Proposal: Aquaculture - Vitamins B1, B12, H (for aquatic plants) - petitioned

	1:30 PM	**Compliance, Accreditation and Certification Subcommittee** Carmela Beck, Chairperson Present Subcommittee proposals and summarize written comments **Topics:** ***Proposal: Guidance on Retail Certification** Proposal: Clarifying Accredited Certifying Agents' Application of §205.206(e) Verbal Summary/Update: Sound and Sensible (no document)
	2:30 PM	**Handling Subcommittee** Harold Austin, Chairperson Present Subcommittee proposals and summarize written comments **Topics:** ***Proposal: Ammonium Hydroxide (boiler water additive) - petitioned** Proposal: Glycerin - petitioned for removal Discussion Document: Polyalkylene Glycol Monobutyl Ether (PGME) - petitioned Update: Ancillary Substances (no document) ***Sunset 2015 Review List:** Gellan Gum Tragacanth Gum Marsala Sherry
	4:15 PM	**Materials Subcommittee** Dr. C. Reuben (Calvin) Walker, Chairperson Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Update of Petition & Technical Review Process Proposal: Confidential Business Information in Petitions (CBI) Proposal: Fall 2013 Research Priorities **+** Written report: Seed Purity from GMOs
	5:30 PM	**RECESS**

Friday, May 2	8:30 AM	**Deferred Proposals/Final Votes**
		NOSB Officer Elections
		Subcommittee Workplans
		Other Business and Closing Remarks
	12:30 PM	**ADJOURN**

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Streptomycin

August 6, 2013
***Reviewed and revised February 18, 2014**

Discussion Summary:

The NOSB has been petitioned to remove the existing expiration date of October 21, 2014 for Streptomycin and replace it with a new one of Oct 21, 2017, for both apples and pears. The petitioner states that this would allow adequate time for the transition from strep over to non-antibiotic, biological alternatives for fire blight control.

There are two different positions on this subject: those that support the petition request for an extension and those that oppose an extension.

Both sides agree that it is time for a phase out for the allowed use of strep. The supporters believe that three additional years until October 2017 is reasonable, and opponents believe that yet another extension offers no assurance of phase out.

Proponents of an extension feel that:

- ~Because of the investment involved to establish an orchard (as well as the businesses established to handle this produce) in both time, money, and the need for completion of existing research of materials, that a slowdown (or extension) of the expiration date is needed, especially for pear growers.
- ~This slow down would benefit growers, processors, producers, handlers, and consumers alike.
- ~Alternative materials are still not readily showing consistent control and one material's registration (Previsto copper) has been delayed by EPA. Thus, the farmers still need some additional time in order to prepare for the transition to a non-antibiotic fire blight control period in time.

•Opponents feel that:

- ~Fire blight resistance to streptomycin is widespread in the U.S.
- ~Raise the question of essentiality, based on the significant percentage of growers selling to markets that do not allow antibiotic treatments.
- ~Organic integrity and sales are threatened because of consumer expectation that antibiotics are not used in organic production.

•Both sides agree that the "core" issue here is whether or not there is a risk of enhancing antibiotic resistance in human pathogens. There is science that supports both sides of this argument and the level of concerns that are raised by this particular use pattern. Supporters cite issues of use patterns and limits of residues as indicative of no evidence of harm. Opponents cite resistant human pathogens in strep treated orchards and horizontal gene transfer identified as leading to antibiotic resistance.

•While there has been a direct linkage shown to exist between infection and colonization of humans by antibiotic resistant bacteria in animals (Larsen et al 2010), supporters cite no direct linkage has been demonstrated between antibiotic resistant bacteria in humans and antibiotic sprays applied to plants (Stockwell and Duffy, 2012), such as the current use of strep in apples and pears for fire blight control. Lab results vary in their conclusions. Opponents cite evidence

that bacteria, including *Erwinia amylovora* and human pathogens, share a common genetic basis for resistance, transmitted by plasmids, to streptomycin in particular. (McGhee et al, 2010; Sundin, 2000; Sundin and Bender, 1996; Pezzella et al, 2004; Scherer et al, 2013; Foster et al, 2004.)

•Proponents state: there is no evidence that applications of antibiotics to orchards during bloom contributes to antibiotic resistance in human pathogens. The amount and timing of the use of strep in an orchard environment does not contribute to any human health concerns, especially in light of streptomycin being ineffective in humans when ingested orally.

•Opponents state: there is evidence that an application of strep leads to an increase in resistance to streptomycin in orchard bacteria, that human pathogens and fire blight bacteria share the same gene pool of genes resistant to streptomycin (i.e. that the same genes responsible for resistance in Erwinia amylovora are also responsible for resistance in human pathogens), that human pathogens do not need to be present in the orchard to obtain resistance genes acquired by and augmented in orchard bacteria, that strep residues are sometimes present in treated fruit, and that strep is still a critically important antimicrobial for use against human pathogens.

•The primary point of discussion here is whether to grant an extension or not to the current expiration date for streptomycin in October 2014. The points proponents say should be considered are: What impact does an extension/or non-extension have on the stakeholders that either use this material or have built their businesses around expanded crop availability; How will a decision impact the supply chain, How will a decision impact the consumer (all consumers, not just a select group(s)), What are the risks/if any for granting an extension or not, and would granting a short extension for allowed use knowing what the use patterns are pose any significant increases in human health concerns from resistance than currently exist today?

•The points opponents say should be considered are: What impact does yet another extension, which was first called for by the NOSB in 1995, have on the integrity of the organic label? What are the public health hazards of using antibiotics for nontherapeutic uses and why are infectious disease doctors concerned? What is the threat of low-level environmental exposure to antibiotics? What are the alternative strategies that are used to manage or prevent fire blight?

•Remember, according to proponents, this is not a new material, but one that has been on the National List of Approved Materials for a number of years as being allowed for use by organic growers to use on their organically grown and certified crops. Opponents point to long-standing NOSB attempts to phase out the use of antibiotics in organic apple and pear production, with votes by previous boards to phase-out, only to have subsequent boards issue extensions.

•One other point of discussion, proponents state that this would be a way to ensure a full expiration of strep from the National List, if an extension for use were to happen. They ask, how could we ensure all stakeholders that there would be an absolute point when this usage would truly expire? Opponents, who would like the 2014 antibiotic expiration date to take effect, believe that the debate on antibiotics and votes to phase them out by previous boards have resulted in only extended deadlines for too long, and organic should not in any way contribute to the worldwide crisis in antibiotic resistance, while ultimately threatening consumer confidence in the organic label.

New text:

Oral and written public comments (Docket AMS-NOP-13-0049) from pear growers noted that especially in the 2013 season, Blossom Protect did not work well in the Pacific Northwest and California. (The manufacturer of Blossom Protect does not agree with this statement and voiced

their disagreement during the written public comment period prior to the canceled fall 2013 NOSB meeting.) It was an unusually warm spring. The copper material that is very promising has been delayed in registration until at least 2014 nationwide and 2015 in California.

Summary of Proposed Action:

The Crops Subcommittee proposes to:
Remove the existing expiration date of October 21, 2014 for streptomycin and replace it with a new expiration date of October 21, 2017. This would be for use in both apples and pears for control of fire blight.

The Crops Subcommittee puts forward this resolution:

Resolution: The National Organic Standards Board is committed to the phase out of this material. Between now and the expiration date the Board urges growers and certifiers to include in organic systems plans an annual increase in the extent and/or number of alternative practices and materials that are trialed for controlling fire blight. In addition, the board strongly advocates to USDA a high priority for increased support for research into these alternative practices and materials.

Introduction

A Petition to the National Organic Standards Board (NOSB) was received for the Removal of the Expiration Date (October 21, 2014) for streptomycin and the establishment of October 21, 2017 as its sunset date, in order to allow for adequate time for the transition to proven effective non-antibiotic, i.e. biological alternatives for fire blight control in apples and pears.

Because this subject is complex and there are two different positions to be represented, this recommendation is organized to present two separate positions - those for and those against an extension. These are designed to supplement the points raised in the checklist. Most of the same background presented in the spring 2013 Recommendation for Oxytetracycline is relevant to Streptomycin, except for the 2007 and 2008 actions.

The subcommittee acknowledges the concerns of consumers and previous NOSB members who feel that it is time to phase this material out from organic agriculture. The two positions represented in the discussion section of this document differ on the timing of the phase-out. Additional concerns are being put forward in a separate resolution on the subject.

Points of Agreement and Disagreement

This section focusses on how the material is used in the context of both plant and human health. Because much of the general information was covered in the proposal for Oxytetracycline, this review focusses on the differences and similarities between the two materials. Specific portions address Checklist categories as noted.

1. Fire blight control
Proponents of both positions agree that orchard establishment requires a large investment of time and money, that apples and pears are grown in a variety of locations that require different management plans, and that more research is needed into systems for preventing fire blight damage.

Proponents of extending the expiration date of streptomycin say:

- Because of the very large investment of time and money that establishing an orchard entails, the variety of locations that apples and pears are grown, and the very rudimentary state of research on alternatives to this material in that variety of locations, we are supporting slowing down the removal of streptomycin from the National List.

- Since the organic pear industry is more at risk to fire blight than apples there is concern that pear research and control measures are lagging behind and that an expanded time frame will be needed. Streptomycin is still fairly widely used in pears, especially those grown in areas with high humidity and warm springs.

- A slightly extended date of 2017 will benefit consumers and growers alike. The few more seasons of research will enable new products to be tested in both apples and pears in a variety of weather conditions.

- In 2009, about 15% of the total apple area and 40% of the pears (organic and conventional) were treated with streptomycin or oxytetracycline for control of Fireblight, the disease caused by the bacteria *Erwinia amylovora*.[1]

- Experience of pear growers especially in the 2013 season has shown that Blossom Protect has not worked well in the Pacific Northwest or California. It was an unusually warm spring. The copper material that is very promising has been delayed in registration until at least 2014 nationwide and 2015 in California.

Opponents to extending the expiration date of streptomycin say:

- Like most challenges in organic production systems, with fire blight there is no one material and no one practice that will eliminate the problem. Fire blight must be met with a truly organic systems approach that is sensitive to the potential adverse health and environmental effects of inputs and consumer expectations.[2]

- Fire blight resistance to streptomycin is widespread in the United States. Streptomycin-resistant strains of fire blight have been found in California, Oregon, Washington, Michigan, New York,[3] Missouri,[4] and Utah.[5] Plasmid-borne genes have been found to confer resistance in California, Michigan,[6] and New York.[7]

- With regard to the “essentiality” of streptomycin, not all organic apple and pear growers depend on antibiotics. In fact, there is a sizeable proportion of growers of both apples and pears who do not use antibiotics.

- As of March 10, 2011, there were 96 businesses certified as EU-compliant organic producers of apples and/or pears in the state of Washington alone, representing about one third of the state’s organic apple and one fourth of the state’s organic pear production. EU-compliant organic apple and pear growers cannot use antibiotics, and face a three-year ban from selling in the EU if they do.[8] In addition, cultural changes in the orchard environment have contributed to epidemics of fire blight.[9]

2. Need for phase out of streptomycin

The sub-committee acknowledges the concerns of consumers and previous NOSB members who feel that it is time to phase this material out from organic agriculture. The two positions represented in the discussion section of this document differ on the timing of the phase-out.

Proponents of an extension for streptomycin say:
Because of the need to make sure that this material is phased out, a resolution motion has been added to affirm the commitment by the NOSB to all organic stakeholders. The NOSB must ensure that the decisions made reflect due consideration of the various needs and concerns of the vast array of all our organic stakeholders, especially when dealing with complicated issues, such as this one.

Additionally, in spite of the claims below about the threat of spreading resistance to streptomycin, most of the research on this subject has been conducted with antibiotics used in livestock and very little in orchard environments. Some very recent research specifically for an orchard situation noted that more streptomycin-resistant isolates were cultured from non-sprayed orchards compared to sprayed orchards.[10]

Opponents of an extension for streptomycin say:
Streptomycin is an antibiotic considered by the World Health Organization to be of critical importance to human medicine.[11] Streptomycin is used in a way that exposes bacteria in the orchard to the antibiotic.[12] Current science shows that environmental exposure to antibiotic use in the environment is the major cause of development and spread of antibiotic resistance in human pathogens.[13]The spread of antibiotic resistance does not require contact between the antibiotic and human pathogens because the major means of spreading antibiotic resistance is through the transfer of genes between different bacteria. Uses resulting in low residues (subtherapeutic or subinhibitory levels) can create a high health risk.[14] Streptomycin resistance is evident and expected to grow if urgent use precaution is not exercised.[15] Organic production should not be contributing to the problem of antibiotic resistance.

3. Antibiotic Resistance
Proponents and opponents of extending the expiration date of streptomycin agree that the core issue here is whether there is a risk of enhancing antibiotic resistance in human pathogens. The most astute and experienced scientists in this area realize that science and medicine have to find a way to co-exist with resistance, including managing reservoirs of resistance in the environment and preventing development of new forms of resistance. (Am. Academy of Microbiology, 2009).

Proponents of extending the expiration date of streptomycin say:

- Antibiotic-resistant bacteria that are competent phyllosphere colonisers can persist in the environment, evidently independent of antibiotic use, as shown by Yashiro and McManus (2012). They demonstrated that long-term applications of streptomycin alone did not alter the bacterial communities on apple leaves. They sampled leaves from four orchards that were treated with spring-time applications of streptomycin over 10 years and from four orchards that were not sprayed with antibiotics. The bacterial genera *Massilia*, *Methylobacterium*, *Pantoea*, *Pseudomonas*, and *Sphingomonas* were detected from all orchards, regardless of spray history. More streptomycin-resistant isolates (65%) were cultured from non-sprayed orchards compared to sprayed orchards (50%). They concluded that factors other than streptomycin influence both the proportion of streptomycin-resistant bacteria and phylogenetic makeup of bacterial communities on apple leaves (Yashiro and McManus, 2012).

- There are numerous reports that the use of antibiotics in animal production is associated with increase of antibiotic-resistant bacteria in animals, waste-water, and manure (for some examples see Larsen 2010, Wright 2010). A direct linkage was reported between infection and colonization of humans by antibiotic resistant bacteria from farm animals (Larsen et al 2010). No direct linkage has been demonstrated between antibiotic resistant bacteria in humans and antibiotic sprays on plants (Stockwell and Duffy, 2012).

Opponents of extending the expiration date of streptomycin say:

- Application of streptomycin leads to an increase of streptomycin resistance in the fireblight organism and other bacteria in the orchard.

Selection of bacteria resistant to streptomycin occurs at extremely low antibiotic concentrations.[16] It is accepted that reliance on streptomycin for fireblight control resulted in the development and spread of resistance to streptomycin in *E. amylovora.*[17] Resistance genes are prevalent in treated soils,[18] and researchers have concluded that resistance is often acquired through gene transfer.[19] Some researchers found the highest concentration of streptomycin-resistant bacteria in the phylloplane of treated crops,[20] but Yashiro and McManus (2012)[21] found a higher percentage of cultured phyllosphere bacteria resistant to streptomycin at non-sprayed orchards than at sprayed orchards. But they stated,

> However, our conclusion does not absolve streptomycin of all risk associated with its use. For example, it is possible that streptomycin could select for novel resistance genes in apple orchards, even if the overall frequency of resistant bacteria is not increased. A greater diversity of mobile resistance genes in apple orchards could lead to horizontal transfer of resistance among a greater range of bacteria, which in turn could be consumed on fresh produce.

- Streptomycin resistance genes from the orchard are transferable to other bacteria.

Streptomycin resistance in *E. amylovora* may come from a chromosomal or two known streptomycin resistance genes carried on plasmids.[22] "The carriage of *strA-strB* within an integron, a transposon, and on broad-host-range plasmids has facilitated the world-wide dissemination of this determinant among at least 21 bacterial genera."[23] The streptomycin resistance genes (*strA-strB*) are known to be carried on transposons and spread by horizontal gene transfer, but are unlikely to have been transferred directly –it is more likely that they are spread through intermediate bacteria. "The distribution of the *strA-strB* genes in the environment clearly illustrates the expansiveness of a common microbial gene pool and the rapid dissemination of Ab^r determinants in bacterial populations." [24] This has been confirmed by a several researchers.[25]

- Streptomycin is a critically important antimicrobial.

Streptomycin is classified as a critically important antimicrobial by the World Health Organization. It is a limited therapy as part of treatment of enterococcal endocarditis and Multi-Drug Resistant (MDR) tuberculosis.[26] It is also effective in treating Brucella (brucellosis), Calymmatobacterium granulomatis (donovanosis, granuloma inguinale), Escherichia coli, Proteus spp., Aerobacter aerogenes, Klebsiella pneumoniae, and Enterococcus faecalis in urinary tract infections, Francisella tularensis, Haemophilus ducreyi (chancroid), Haemophilus influenzae (in respiratory, endocardial, and meningeal infections - concomitantly with another antibacterial agent), Klebsiella pneumoniae pneumonia (concomitantly with another antibacterial agent), Mycobacterium tuberculosis, Pasteurella pestis, Streptococcus viridans, Enterococcus faecalis (in endocardial infections - concomitantly with penicillin).[27]

4. Ecological Impacts

Opponents of extending the use of streptomycin say:

- Streptomycin use may have unforeseen ecological impacts.

Since resistance to antibiotics is more prevalent in some groups of microorganisms than others, the dispersal of streptomycin in the environment can disrupt the microbial ecology. For instance, blue-green algae, which are important in sequestering carbon dioxide and releasing oxygen gas, are as a group susceptible to antibiotics.[28]

<u>Differences between Streptomycin and Oxytetracycline</u>

•• Use: While tetracycline is only used during bloom and will only be present on fruit that set early in the bloom period while the late blooms are being sprayed, streptomycin is registered for use from early bloom until 45 days before harvest.

•• Mode of Action: Streptomycin binds irreversibly to bacterial ribosomes and block synthesis of proteins (51). Oxytetracycline binds reversibly to these proteins (McManus et al., 2002). (Category 1, Question 9]

•• Mechanism of Resistance: There are 2 mechanisms of resistance to streptomycin in fire blight bacteria: spontaneous mutation of a chromosomal gene which encodes production of ribosomal protein, thus strep cannot bind to ribosome and bacteria become immune to antibiotic. This is most common in the US. Acquired resistance has been detected occasionally in MI and CA. The pathogen acquired plasmids that contained genes encoding an enzyme that inactivates strep. These resistant isolates of fire blight were detected in an orchard ten years after applications were stopped (34). The fire blight bacteria have not been known to develop resistance to tetracycline in the laboratory, and little is known about the mechanisms for resistance to tetracycline in that bacteria.

** Genetics of Resistance: The genes for resistance to streptomycin that are transferred by plasmid are the same genes known to confer resistance to streptomycin in human pathogens.[29] This is a step in the chain of causation that is not known for tetracycline.

•• Residue on Fruit: While there were not specific studies besides EPA data that set ADI limits that showed residue of tetracycline on fruit, one study in Austrian orchards showed detection of streptomycin residues (33) in apples, with the highest concentrations in the apple core. Apple fruit were collected about three months after bloom and tested for streptomycin. The level of detection was 2 µg/kg (0.002 ppm or 2 ppb) and the limit of quantification was identified as 7 µg/kg (0.007 ppm or 7 ppb). They reported that the highest concentration of streptomycin detected was 18 µg/kg (0.018 ppm), well below the EPA tolerance of 250 µg/kg (0.25 ppm). The Austrian ADI for streptomycin is 0.03 mg per kg of body mass per day (0.03 ppm). The study did not report on exactly what spray practices led to this result.)[Category 1, Question 9]

•• Use in medicine: Both tetracycline and streptomycin are classified as critically important antimicrobials by the World Health Organization. Tetracycline is one of a limited number of therapies for infections due to *Brucella, Chlamydia* spp. and *Rickettsia* spp. Streptomycin is a Limited therapy as part of treatment of enterococcal endocarditis and Multi-Drug Resistant (MDR) tuberculosis. Tetracycline has a higher priority because it is used more frequently for specific uses, which could lead to faster spread of resistance. Tetracycline is administered orally, while streptomycin is administered by injection.[30] It is unclear what link there may be between oral ingestion and the build-up of resistance to injected streptomycin.

Conclusions

Those supporting an extension of streptomycin use say:
There is no evidence that applications of antibiotics to orchards during bloom contributes to antibiotic-resistance in human pathogens. Human pathogens have not been found in orchards and would have to be present for the resistance genes to transfer. Naturally occurring streptomycin resistant bacteria may be minor components of the overall bacterial communities found on apple flowers and in soils, but their presence is independent of the antibiotic application. The amount and timing of the use of this material in an orchard environment does

not contribute to any human health concerns, especially in light of streptomycin being ineffective in humans when ingested orally.

Those opposing an extension of streptomycin use say:
There is evidence that application of streptomycin leads to increase resistance to streptomycin in orchard bacteria, that human pathogens and the fire blight bacteria share the same gene pool of genes resistant to streptomycin (i.e., that the same genes responsible for resistance in *Erwinia amylovora* are also responsible for resistance in human pathogens), that human pathogens do not need to be present in the orchard to obtain resistance genes acquired by and augmented in orchard bacteria, that streptomycin residues are sometimes present in treated fruit, and that streptomycin is still a critically important antimicrobial for use against human pathogens. In light of the crisis of antibiotic resistance, we cannot allow streptomycin use to be extended in organic production.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: NA

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Streptomycin is synthetic and is already classified as such on the National List so there is no need to make a motion to that effect.

Listing Motion
Motion to remove the existing expiration date of October 21, 2014 for streptomycin at §205.601(i)(11), and replace it with an expiration date of October 21, 2017, so that the listing reads: (11) Streptomycin, for fire blight control in apples and pears only until October 21, 2017

Motion by: Harold Austin
Seconded by: Zea Sonnabend
Yes: 5 No: 3 Absent: 0 Abstain: 0 Recuse: 0

Additional Motion: **Resolution:** The National Organic Standards Board is committed to the phase out of this material. Between now and the expiration date the Board urges growers and certifiers to include in organic systems plans an annual increase in the extent and/or number of alternative practices and materials that are trialed for controlling fire blight. In addition, the board strongly advocates to USDA a high priority for increased support for research into these alternative practices and materials.

Motion by: Harold Austin
Seconded by: Zea Sonnabend
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Jay Feldman, Subcommittee Chair, to transmit to NOSB August 6, 2013

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Streptomycin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		The petition claims the manufacturing process as CBI. However, the 2011 TR (lines 314-315) states, "Dzhedzhev et al. (1975) reported that the manufacture of streptomycin resulted in high atmospheric concentrations of the solvents butyl alcohol and butyl acetate in the workplace." The TR also says (lines 315-332) Streptomycin is produced using fermentation, a process that usually involves the use of solvents and gases that may be discharged into water or air, subject to EPA permits. The TR concludes (lines 326-328) that assuming streptomycin manufacturers comply with applicable water and air regulations; it is unlikely that environmental contamination will result from the fermentation process. (March 8, 2011 TR – lines 326-328) also in that same TR, lines 334-341 states that no surface residue can be found on pear or apple trees after four to six weeks following a spray application(Gardan and Manceau (1984)). Also in this same section the EPA (1988) states streptomycin residues are non-detectable (<0.5ppm) on crops when treated according to label use rates and directions. TR lines 414-415 states that the RED for streptomycin concluded that agricultural streptomycin products, labeled and used according to EPA regulations, will not pose unreasonable risks or adverse effects to the environment (EPA 1992). There is an EPA registration review of streptomycin underway that is scheduled to be completed in 2014.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		See above for detailed explanation
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	X			Streptomycin should not be applied following an application of a Bordeaux mixture and it is incompatible with lime sulfur (according to the 2002 HSDB) (March 8, 2011 TR lines 357 & 358).

5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		March 8, 2011 TR (lines 338) states that strep breakdowns into products that include methylamine, carbon dioxide, and urea, all of which occur naturally in the environment. (EPA 1988, 1992) EPA cited data that showed that streptomycin biodegrades relatively quickly in soil and water. Streptomycin can be phytotoxic to plants; therefore it is sprayed on the surface of plants rather than injected (McManus and Stockwell, 2000). Most apple and pear producers are prudent in their use of streptomycin sprays to reduce costs and to prevent the development of streptomycin-resistant strains of *Erwinia amylovora.* Disease risk models help producers optimize the timing of antibiotic sprays and reduce the total number of applications. These measures can help reduce the development of antibiotic resistance. (March 8, 2011 TR lines 111-115) There is a high probability that streptomycin resistant bacteria are present in the environment as a consequence of pesticidal use of streptomycin (EPA, 2006a). (TR lines 429-431) The HED Chapter of the TRED states that there have been reports of adverse effects resulting from use of streptomycin as a pesticide (EPA, 2006a). (TR lines 449-450) Because of the risk to workers, personal protective equipment is advised to prevent skin contact with streptomycin, and workers are not permitted re-entry into treated areas for at least 12 hours. (TR lines 454-456)
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X	X		A certain background level of streptomycin is expected in soil due to the natural presence of the bacterium *Streptomyces griseus* (Brosche, 2010). EPA (1988, 1992) cited data that show that streptomycin biodegrades relatively quickly in soil and water. (TR lines 207-210). The breakdown products include methylamine, carbon dioxide, and urea, all of which occur naturally in the environment. Therefore, the application of streptomycin for control of fire blight in apples and in pears in accordance with labeled instructions is unlikely to contaminate the environment. (TR lines 337-341). According to EPA, streptomycin is moderately persistent in aerobic soil (a single value of t1/2= 17.5 days was determined). EPI Suite estimated a shorter aerobic soil half-life (t1/2= 25 days) and a longer sediment half-life (t1/2= 100 days). Given the moderate

				persistence/high mobility and solubility of streptomycin, the chemical is expected to dissipate relatively slowly and at the same time be vulnerable to leaching/run-off. (TR lines 217-225) Gardan and Manceau (1984) reported that no surface residue of streptomycin was detectable on pear or apple trees after four to six weeks following spray application. However, Mayerhofer et al. (2009) showed that the use of streptomycin sprays can lead to detectable concentrations of streptomycin in apples. Streptomycin was detected in 20 of 41 samples from orchards that were treated one to three times with streptomycin sprays. The concentration of streptomycin was highest in the apple cores and skin and ranged from 1.9 to 18.4 µg/kg (equivalent to 0.0019 to 0.0184 ppm, well below the EPA's established tolerance of 0.25 ppm). (TR lines 238-244)
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]	X	X		The TRED for streptomycin concluded that "there is reasonable certainty that no harm to any population subgroup will result from exposure to streptomycin (EPA, 2006b). (March 8, 2011 TR lines 438 – 439) Also, in the TR lines 441-444 states that "Current tolerances (maximum residue limits) for streptomycin on or in apples and pears is 0.25ppm. Assuming that the maximum amount of streptomycin residues are present in all types of food which may contain residues, EPA determined that chronic aggregate dietary exposure from streptomycin residues in food and water is not considered to be a human health concern (EPA, 2006a). Bacterial resistance to streptomycin as a result of pesticidal use has the potential to cause adverse public health consequences if human bacterial pathogens are present in orchards and develop resistance or if non-pathogenic bacteria in orchards develop resistance and later transfer the resistance to human bacterial pathogens. EPA's assessment concluded that "the possibility of antibiotic resistance resulting in adverse human health consequences was of medium concern following occupational application and was of high concern following application by residential users" (EPA, 2006a, pg. 3). (TR lines 645-650) Streptomycin remains important in modern medicine, and an increase in streptomycin-resistant bacteria in

				the environment and in humans may lead to adverse human health consequences. Streptomycin is used today in medicine in combination therapy to treat tuberculosis (due to increasing resistance to other anti-tubercular drugs) and enterococcal endocarditis (when there is resistance to gentamicin). It is also used to treat the plague and tularemia. (TR lines 634-638) See also question #5. Streptomycin is toxic to algae (Qian *et al.,* 2012) and therefore the EPA requires a warning on any streptomycin label include a warning not to apply directly to water or in areas where surface water is present, and to not contaminate water during cleaning of equipment or disposal of wastes. TR lines 414-415 states that the RED for streptomycin concluded that agricultural streptomycin products, labeled and used according to EPA regulations, will not pose unreasonable risks or adverse effects to the environment (EPA 1992). There is an EPA registration review of streptomycin underway that is scheduled to be completed in 2014.
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]	X			Toxic to bacteria and algae. See question #7. The ammonium-Nitrogen concentration was significantly increased following application of streptomycin, possibly indicating that nitrifying bacteria were susceptible to this bactericide. This study also found that application of streptomycin at a rate of 3 mg/g soil caused a continuing reduction in the total bacterial population which lasted longer than the study (22 days). Streptomycin applied at 3 mg/g soil also reduced active hyphae only on the first day following application. A broad-spectrum antibiotic like streptomycin would be expected to inhibit the nitrification process in soil. The presence of streptomycin in three different types of soils affected the ecological balance in the soil, causing the elimination of some bacterial populations. The eliminated species were described as beneficial bacteria involved in various metabolic processes, mineralization of organic compounds, degradation of toxic compounds, or creating soil structure. This study also isolated from the soils many strains of bacteria demonstrating resistance to streptomycin, including opportunistic pathogens of humans and/or animals. (2011 TR lines 377-378, 379-382, 386-387, 389-391, 395-398)

				Based on the limited data available, it is still unclear if the use of streptomycin for control of fire blight has significant negative effects on interactions in the agro-ecosystem, including soil organisms. There are no studies available in the field and the studies in the laboratory with soil bacterial populations appear to be contradictory. (TR lines 404-407)
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]	X			Toxic to algae. (TR line 347) Algae are present in most of the soils where moisture and sunlight are available, mostly blue-green (Cyanophyta) and green (Chlorophyta). Soil algae are important in maintaining fertility, building soil organic matter, building soil structure, increasing water holding capacity, and aerating soils.[31]

Category 2. Is the Substance Essential for Organic Production? Streptomycin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Streptomycin is a naturally occurring compound which is produced by the soil bacterium *Streptomyces griseus.* Agricultural streptomycin is produced on a large scale by aerobic fermentation of *Streptomyces griseus* followed by isolation and purification by ion exchange (HSDB, 2002; EPA, 1992) March 8, 2011 TR lines 172-174. Also, TR lines 199-200 states that Streptomycin is produced through a naturally occurring process (aerobic fermentation), but the processes used to isolate and purify the substance are not naturally occurring. The forms of streptomycin currently on the National List as approved are listed as synthetic substances.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X	X		Streptomycin is a naturally occurring compound which is produced by the soil bacterium *Streptomyces griseus.* Commercially, streptomycin is produced through a naturally occurring process (aerobic fermentation), but the processes used to isolate and purify the substance are not naturally occurring. (TR lines 199-201)

5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		There are several biological control agents (such as bacteria or yeast) that are used to try to outcompete the fire blight pathogen where it occurs on the blossom. These materials are used for fire blight suppression. Two strains of beneficial bacterium, *Pantoea agglomerans,* are: Bloomtime Biological and Blight Ban C9-1. The bacterium Pseudomonas fluorescens A506 is marketed as Blight Ban A506. There are two strains of yeast *Aureobasidium pullulans* that are used to make up the product Blossom Protect (Bio-ferm, Germany) which has recently been introduced into the market to help in controlling fire blight. TR 2011 lines 468-486. In this same TR, Blight Ban A506 is rated as being poor to fair for effectiveness, lines 493-505 (Johnson et al.,2009) in inoculated trials and slightly better in field trials (Johnson 2010). Johnson further states that Bloomtime and Blight Ban C9-1 both performed slightly better with about 50% reduction in disease incidence observed in the inoculated field tests. He rates Bloomtime Biological as poor to good and the effectiveness of Serenade Max and Blossom Protect as fair to good for effectiveness for fire blight suppression. By comparison, the antibiotic treatment oxytetracycline is described as fair to very good, and treatment with streptomycin is poor to excellent (the poor rating is due to widespread pathogen resistance to streptomycin within the western states). (TR lines 493-507) Disease control was more consistent in field trials conducted with compatible mixtures of antagonistic organisms than with single strains –up to 68 and 71% disease reduction on average, compared to 39% and 81% on average, for oxytetracycline and streptomycin, respectively. (TR lines 517-532) In Germany, treatment with Blossom Protect resulted in an average efficiency of 82% reduction in fire blight incidence (results from six different trials). (TR lines 547-548) Johnson (2010) reports that he and his colleagues evaluated Blossom Protect in an

				inoculated fire blight trial in 2008 (also using four applications during bloom). They found this product to be nearly as effective as streptomycin (Agri-Mycin) in an orchard with high disease pressure. (TR lines 552-555) A large amount of public comment received in written form to FR Docket AMS-NOP-12-0070 and verbally at the Spring 2013 meeting indicated that the above "substitute products" did not work well in certain regions or agricultural systems and therefore were not true substitutes.
8. Are there any alternative substances? [§6518(m)(6)]	X			Besides the biologicals, there are alternative substances that are listed as having some control of fire blight and of these oxytetracycline is by far the best alternative substance. Other materials listed are various copper mixtures (a couple of new products currently being looked at by researchers), lime-sulfur, and Peracetic acid (which is as a disinfectant and not as a spray replacement material).
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X	X		No one practice can eliminate fire blight, including the use of antibiotics. There are practices that can help in reducing fire blight potential in an orchard as part of a systems approach. Some of these would include using fire blight prediction models to assist in proper timing of materials applications, monitoring and removal of infected plant tissue, planting of resistant root stocks (this would only protect the root system and not the fruit producing portion of the tree), ground cover and water management to help reduce humidity levels within an orchard, and also planting of more fire blight resistant cultivars. (TR lines 601-617, 671-701)

Category 3. Is the substance compatible with organic production practices? Streptomycin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		It is currently included on the National List of Allowed and Prohibited Substances, as a synthetic substance allowed in organic crop production for fire blight control in apples and pears only [7 CFR 205.601 (i)(11)] as previously /currently approved by the NOSB and implemented into policy by the NOP. Contrary to consumer expectations. Inconsistent with prohibition on antibiotics in livestock. Inconsistent with European requirements.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X	X		If it is used as part of an organic systems plan in a rotational manner, to enhance resistance management in an effort to minimize the potential for resistance to fire blight to develop. Increases likelihood of antibiotic resistance in pathogenic organisms. It is not sustainable because the fire blight organism will develop resistance.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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		X		
toxins derived from bacteria	X			
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

[1] Stockwell, V.O., and Duffy, B., 2012. Use of antibiotics in plant agriculture. Rev. Sci. Tech. Off. Int. Epiz., 31:199-210.
[2] As reported in Ostenson, H.T. 2010. Organic pome and cherry production and marketing issues: Past, present and future. Acta Hort. (ISHS) 873:137-144, and presented to IFOAM, "Over the last ten years, the Hartman Group (Bellevue, Washington, USA) has studied changes in consumer attitudes, backgrounds, and buying characteristics related to the organic market. The Hartman Group surveyed about two thousand household consumers across four regions of the USA. They found that the 'traditional' properties suggested by 'organic' were no longer the same properties held by the new organic consumer. The survey indicated that traditional properties such as 'locally-grown,' Fair Trade, 'tastes better,' and sustainable production ranked at the bottom. The new organic consumers made it clear that they want, plain and simple, a product centered around the 'absence of all health concerns,' and the absence of pesticides, growth hormones, GMO's, antibiotics, and BSE."
[3] McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W., 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182- 191.
[4] Russo, N. L., Burr, T. J., Breth, D. I., and Aldwinckle, H. S., 2008. Isolation of streptomycin resistant isolates of *Erwinia amylovora* in New York. Plant Dis. 92:714-718.
[5] Claudia Nischwitz, Christine Dhiman, 2012. Streptomycin resistance of *Erwinia amylovora*, causal agent of fire blight. Utah State University Extension and Utah Plant Pest Diagnostic Laboratory, PLP-018.
[6] McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182- 191.
[7] Russo, N. L., Burr, T. J., Breth, D. I., and Aldwinckle, H. S., 2008. Isolation of streptomycin resistant isolates of *Erwinia amylovora* in New York. Plant Dis. 92:714-718.
[8]Instead, these growers rely on a number of other practices, allowing them to avoid fire blight damage to susceptible varieties. Balancing nutrients and avoiding over-application of nitrogen fertilizers, especially on susceptible varieties of apples or pears; avoidance of over-pruning in the dormant season; use of pre-bloom foliar nutrient sprays even though there is no foliage; use of copper materials on the trees between delayed dormant and tight cluster sages as preventive measures against overwintering FB; use of lime sulfur during bloom to thin apples; and, use of Serenade MAX (in the future, perhaps Blossom Protect) post-bloom and at petal-fall, with good spray coverage. (With some differences for pears.)
[9] In response, the following is suggested: Increase species diversity; decrease tree density; use resistant cultivars and rootstocks; plant a variety of cultivars on a variety of rootstocks.
[10] Yashiro, E & McManus, P. 2012 Effect of streptomycin treatment on bacterial community structure in the apple phyllosphere. PLoS ONE 7(5): e37131. doi:10.1371/journal.pone.0037131
[11] WHO, 2009. Critically Important Antimicrobials for Human Medicine, http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf See Table 1.
[12] Streptomycin TR, 2011. Lines 423-431.
[13] American Academy of Microbiology, 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem. http://academy.asm.org/images/stories/documents/antibioticresistance.pdf (pp.1-5, 10.)
[14] American Academy of Microbiology, 2009. (p.8.)
[15] Streptomycin TR, 2011. Lines 632-633. American Academy of Microbiology, 2009. (p.2.)
[16] Gullberg E, Cao S, Berg OG, Ilbäck C, Sandegren L, et al., 2011. Selection of Resistant Bacteria at Very Low Antibiotic Concentrations. PLoS Pathog 7(7)**:** 1-9.
[17] McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182-191. Alan L. Jones and Elise L. Schnabel, 2000. The Development of Streptomycin-resistant Strains of *Erwinia amylovora*, in J.L. Vanneste (ed.), *Fire Blight The Disease and its Causative Agent, Erwinia amylovora*, CAB International, UK. Pp. 235-254.
[18] S. Tolba et al., 2002. Distribution of streptomycin resistance and biosynthesis genes in streptomycetes recovered from different soil sites. FEMS Microbiology Ecology 42: 269-276

[19] Egan, S., Wiener, P., Kallio¢das, D. and Wellington, E.M.H. (2001) Phylogeny of Streptomyces species and evidence of horizontal transfer of entire and partial antibiotic gene clusters. Antonie Van Leeuwenhoek 79, 127-133. Wiener, P., Egan, S. and Wellington, E.M.H. (1998) Evidence of transfer of antibiotic-resistance genes in soil populations of streptomycetes. Mol. Ecol. 7, 1205-1216.
[20] George W. Sundin, Dave E. Monks, Carol L. Bender, 1995. Distribution of the streptomycin-resistance transposon Tn*5393* among phylloplane and soil bacteria from managed agricultural habitats. Canadian Journal of Microbiology, 41(9): 792-799.
[21] Yashiro E, McManus PS, 2012. Effect of Streptomycin Treatment on Bacterial Community Structure in the Apple Phyllosphere. PLoS ONE 7(5): e37131
[22] McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182- 191.
[23] Sundin, G. W. 2002. Distinct recent lineages of the *strA-strB* streptomycin-resistance genes in clinical and environmental bacteria. Curr.Microbiol. 45:63-69.
[24] GW Sundin and CL Bender, 1996. Dissemination of the *strA-strB* streptomycin-resistance genes among commensal and pathogenic bacteria from humans, animals, and plants, Molecular Ecology 5, 133-143
[25] See for example, Cristina Pezzella, Antonia Ricci, Elisabetta DiGiannatale, Ida Luzzi, and Alessandra Carattoli, 2004. Tetracycline and Streptomycin Resistance Genes, Transposons, and Plasmids in *Salmonella enterica* Isolates from Animals in Italy. Antimicrobial Agents and Chemotherapy, 48 (3): 903–908. Alexandre Scherer, Hans-Rudolf Vogt, Edy M. Vilei, Joachim Frey, and Vincent Perreten, 2013. Enhanced antibiotic multi-resistance in nasal and faecal bacteria after agricultural use of streptomycin, Environmental Microbiology 15(1), 297–304. ("This study shows that the application of low concentrations of streptomycin on grass, as occurs during the spraying of orchards, selects for multidrug-resistant nasal and enteric bacterial flora, including extended-spectrum beta-lactamase-producing *E. coli*.") Foster, G. C., McGhee, G. C., Jones, A. L., and Sundin, G. W. 2004. Nucleotide sequences, genetic organization, and distribution of pEU30 and pEL60 from *Erwinia amylovora*. Appl. Environ. Microbiol. 70:7539-7544.
[26] WHO, 2009. Critically Important Antimicrobials for Human Medicine, http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf See Table 1. Tuberculosis is rapidly developing resistance to all known antimicrobials. Phillip Trollip, 2013. Emergence and Spread of Extensively and Totally Drug-Resistant Tuberculosis, South Africa. Emerging Infectious Diseases, 19 (3): 449-455 www.cdc.gov/eid
[27] http://www.drugs.com/pro/streptomycin.html
[28] Jose Luis Martinez, 2009. Environmental pollution by antibiotics and by antibiotic resistance determinants. Environmental Pollution 157: 2893–2902.
[29] See, for example, the following articles. C.-S. Chiou and A. L. Jones, 1993. Nucleotide Sequence Analysis of a Transposon (Tn5393) Carrying Streptomycin Resistance Genes in Erwinia amylovora and Other Gram-Negative Bacteria. Journal of Bacteriology, Vol. 175, (3): 732-740. GW Sundin and CL Bender, 1996. Dissemination of the *strA-strB* streptomycin-resistance genes among commensal and pathogenic bacteria from humans, animals, and plants, Molecular Ecology 5, 133-143. McGhee, G. C., and Sundin, G. W. 2011. Evaluation of kasugamycin for fire blight management, effect on nontarget bacteria, and assessment of kasugamycin resistance potential in *Erwinia amylovora*. Phytopathology 101:192-204. Cristina Pezzella, Antonia Ricci, Elisabetta DiGiannatale, Ida Luzzi, and Alessandra Carattoli, 2004. Tetracycline and Streptomycin Resistance Genes, Transposons, and Plasmids in *Salmonella enterica* Isolates from Animals in Italy. Antimicrobial Agents and Chemotherapy, 48 (3): 903–908. Alexandre Scherer, Hans-Rudolf Vogt, Edy M. Vilei, Joachim Frey, and Vincent Perreten, 2013. Enhanced antibiotic multi-resistance in nasal and faecal bacteria after agricultural use of streptomycin, Environmental Microbiology 15(1), 297–304.
[30] WHO, 2009. Critically Important Antimicrobials for Human Medicine, http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf See Table 1.
[31] "Soil microorganism—algae" My Agriculture Information Bank http://agriinfo.in/?page=topic&superid=5&topicid=150
Zancan, S., Trevisan, R., & Paoletti, M. G. (2006). Soil algae composition under different agro-ecosystems in North-Eastern Italy. *Agriculture, ecosystems & environment*, *112*(1), 1-12.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Magnesium Oxide

August 6, 2013
***Revised February 26, 2014 - Minority opinion added**

Summary of Proposed Action:

Magnesium oxide (MgO) has been petitioned for use under §205.601 Synthetic substances allowed for use in organic crop production. Specifically, the petition states "Magnesium oxide is intended to be used to control the viscosity of a clay suspension agent to prevent settling of materials suspended in water or other liquids." The petitioner indicates they wish to use MgO for the application of finely ground humates, but the petition is written more broadly: "The substance is intended to be used in combination with other organic inputs applied as a liquid foliar on a wide variety of different agricultural, vegetable, fruit, and horticultural crops."

The petitioner indicates they would use MgO at a very low level: at 0.074% of the humate suspension being applied, which would equate to 0.0007 to 0.0014 pounds of MgO applied per acre.

Magnesium oxide occurs as the mineral magnesia, and in its hydrated form – magnesium hydroxide -- is the naturally occurring mineral periclase. Magnesium oxide appears to be a fairly benign compound that has a wide range of uses, including as an antacid and laxative (milk of magnesia), and in lots of industrial processes such as in producing cement, abrasive materials and furnace linings.

There are several manufacturing processes used to produce MgO. It is commonly made from sea water or salt brines, but can also be made by heating $MgCO_3$ limestone to drive off CO_2 and produce MgO. (To produce MgO from sea water or salt brine uses the following procedure: The raw materials are lime and salt water -- either sea water or brine from salty wells. The lime is heated to produce calcium oxide. Fresh water is then added to the calcium oxide to produce calcium hydroxide. Sea water or salt brine from a well -- treated with a small amount of sulfuric or hydrochloric acid -- is then added to the calcium hydroxide, causing the magnesium chloride in the salt water to react with calcium hydroxide to produce magnesium hydroxide and calcium chloride. The magnesium hydroxide is then heated to produce magnesium oxide.)

The MgO manufactured using sea water or salt brine (and some acid) produces a purer and more refined form of MgO than that produced by heating magnesium carbonate limestone, and so is preferred by the petitioner.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A

Subcommittee Action & Vote:

Classification Motion:
Motion to classify Magnesium Oxide as petitioned as synthetic.
Motion by: Francis Thicke
Seconded by: Colehour Bondera
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion:
Motion to list Magnesium Oxide at §205.601 with the following annotation: For use only to control the viscosity of a clay suspension agent for humates.
Motion by: Francis Thicke
Seconded by: Zea Sonnabend
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Basis for annotation: ☒ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Approved by Jay Feldman, Subcommittee Chair, to transmit to NOSB August 6, 2013

Minority position: During Subcommittee discussions in January and February 2014, a member of the Crops Subcommittee made a motion for the following: To list Magnesium Oxide at §205.601 with the following annotation: Until May 1, 2019 [or 5 years after the date it is first allowed]. The motion did not pass. The justification for the minority opinion is as follows: A synthetic material used in organic production, even if used in small quantities, must meet all of the OFPA criteria. Current consideration of the material has raised issues relating to environmental impacts and alternatives. (1) The review in 5 years must be performed with the same standard for allowing continued use as is used to approve use in the first place; (2) the need for liquid humates and hence MgO should be re-evaluated; (3) the possibility of using nonsynthetic acids in place of synthetic sulfuric acid must be re-evaluated.

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 26, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Magnesium Oxide

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		X		When MgO is produced using sea water or salt brine, a small amount of acid is used to lower the pH of the salt solution to prevent the formation of carbonates. When MgO is produced using magnesium carbonate limestone, carbon dioxide is released into the atmosphere. Additional carbon dioxide is produced through the burning of fossil fuels used to achieve the high heat required to decompose the limestone.
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 2. Is the Substance Essential for Organic Production? Magnesium Oxide

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	.
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]		X		None that have the desired functional properties, according to the petitioner.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			MgO is not absolutely essential for the materials application it is petitioned for, but it makes application easier, and perhaps safer for the person applying the materials (reduces dust).

Category 3. Is the substance compatible with organic production practices? Magnesium Oxide

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]			X	

5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Vinasse

+February 25, 2014

Introduction

The NOSB received a petition for Vinasse as a synthetic soil amendment and plant nutrient (fertilizer) for organic crop production. In effect, the petition seeks to have the NOSB classify vinasse as a non-synthetic (natural).Petitioning as a synthetic is the only way to achieve a vote from the NOSB on this matter.

A limited scope Technical Review was conducted solely on the manufacturing process and whether vinasse is synthetic or non-synthetic.

Background

The path to vinasse production is complex, starting with sugar refining, passing through molasses fermentation, and ending with multiple distillations. Both sugar and molasses have historically been considered non-synthetic and allowed in organic production. From the TR:

> 44-45. Vinasse is generally obtained through distillation of fermented cane and beet molasses, which is a byproduct of cane and beet juice processing for the production of pure or refined sugar.
> 48. Sulfur dioxide is sometimes added during the processing of beet juice prior to crystallization to decolorize the cane juice.
> 51. The resulting byproduct, molasses, is then mixed with yeast or other microorganisms and fermented.
> 54-57. In the case of ethanol production, small amounts of sulfuric acid may be added prior to fermentation to reduce the populations and activity of undesired bacterial species by adjusting the pH to between 4 and 5. Distillation of the resulting fermentation broth separates the desired organic compounds (e.g., ethanol) from the mother liquor. Vinasse is the byproduct of the distillation procedure.

The TR goes on to describe in detail the processes for removing the sugar from sugar cane and beets, separating the molasses, and then fermenting it to make ethanol with vinasse as a by-product. Further information from the TR states:

> 365-377. Molasses is generally less contaminated with bacterial flora than cane juice, as a large portion of the non-sporulated bacteria is destroyed during sugar production. Notwithstanding, most components are frequently subjected to bacteriostatic or sterilizing thermal (steam) treatments to control any bacterial flora that may otherwise excrete undesired organic compounds into the fermentation medium (Fahrasmane, 1998). The molasses-based fermentation medium may also be treated with small quantities (~0.3 mg/L) of antibiotics, such as penicillin (Borzani, 1957) and tetracycline (Aquarone, 1960). However, the extent of this practice in current rum-making operations is uncertain. If added, it is possible that these antibiotics will not be fully degraded during the fermentation and ethanol distillation processes; a certain amount could remain in vinasse derived from antibiotic-treated fermentation mediums. Bacteriosides such as chlorine dioxide (Sumner 2011), ammonium bifluoride or quaternary ammonium compounds may also be used to control bacterial contamination (Murtagh, 1999). With the exception of chlorine dioxide, residues of these compounds may persist in vinasse. Finally, acidification of the media to a lower pH (i.e., pH = 4–5) using sulfuric acid generally precedes the fermentation step as a protective measure (Fahrasmane, 1998).

Discussion
The Crops subcommittee reviewed the manufacturing process against the draft guidance on classification of materials (NOP 5033). Some of the relevant considerations from the draft guidance are:

1) whether the manufacturing process for vinasse is a synthetic or a biological process
2) whether vinasse contains a synthetic substance, not on the National List, at a significant level.
3) whether vinasse is the result of a chemical change
4) whether all non-allowed synthetics have been removed to the degree that they have no technical or functional effect in the final product.

It is apparent although not explicitly stated in the TR that vinasse production is decentralized in many countries and with many different approaches to the substance during and after fermentation. Some vinasse is generated without synthetic materials added during and after fermentation, while some may have additional acid, synthetic anti-microbial agents, or even synthetic sources of nitrogen added after fermentation. Therefore the subcommittee has concluded that since not all vinasse is synthetic, it does not belong on the National List.

However, the subcommittee also believes that vinasse with synthetic materials added to it after fermentation should not be permitted in organic cropping systems. Therefore we are proposing specific language for a listing of vinasse in the Guidance on Materials for Organic Crops Production (NOP 5034-1). This annotation in the guidance would enable materials review organizations to determine those sources that would not be allowed. This annotation is similar, but slightly different from, the one on the molasses listing:

> **Vinasse** - may not contain prohibited additives, such as but not limited to, pH adjusters, sanitizers, ammonium compounds, antibiotics or chlorine materials that are not provided for at §205.601. Nitrogen levels may not be fortified.

Minority Opinion
Identifying the allowed and prohibited formulations of vinasse through the National List process is the appropriate action for the NOSB. The minority proposes to create a hybrid listing on both 601 and 602, explaining in the recommendation that vinasse is available in both synthetic and nonsynthetic forms, but the restrictions that the NOSB recommends is placed on its use apply to both forms.

On 601, list vinasse as synthetic with the following annotation:" *Vinasse is only allowed when its manufacturing process does not result in synthetic additives, such as, but not limited to, pH adjusters, sanitizers, ammonium compounds, antibiotics or chlorine materials, in the formulation that are not specifically provided for at 205.601. Nitrogen levels may not be fortified. Vinasse may not be produced using genetically engineered microorganisms, sugar beets, or other substrate. If the condition on genetically engineered organisms is covered by a general policy adopted by the NOSB and codified into regulations, then that language will supersede this restriction.*" See nonsynthetic versions of vinasse manufactured without synthetic chemical change and above substances in 602. The recommendation should explain that the annotation is added because there are numerous formulations of vinasse that are synthetic and incompatible with organic production.

On 602: List vinasse with the following annotation: "*Vinasse may not be manufactured with a process that effects synthetic chemical change or utilizes in synthetic additives, such as, but not limited to, pH adjusters, sanitizers, ammonium compounds, antibiotics or chlorine materials, in the formulation that are not specifically provided for at 205.601. Nitrogen levels may not be fortified. Vinasse may not be produced using genetically engineered microorganisms, sugar beets, or other substrate. If the condition on genetically engineered organisms is covered by a general policy adopted by the NOSB and codified into regulations, then that language will supersede this restriction."*

Subcommittee Action & Vote

Classification Motion:
Motion to classify Vinasse as non-synthetic
Motion by: Zea Sonnabend
Seconded by: John Foster
Yes: 4 No: 3 Absent: 0 Abstain: 0 Recuse: 0

Motion:
Motion to add the following specific language to the listing of vinasse in the Guidance on Materials for Organic Crops Production (NOP 5034-1). **Vinasse** - may not contain prohibited additives, such as but not limited to, pH adjusters, sanitizers, ammonium compounds, antibiotics or chlorine materials that are not provided for at §205.601. Nitrogen levels may not be fortified
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 4 No: 3 Absent: 0 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 26, 2014

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Laminarin

+February 26, 2014

Introduction

The NOSB received a petition for Laminarin, a seaweed extract for disease control that is allowed by EPA for that purpose.

Background

From the Laminarin petition:

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

Stage 1: Fresh *Laminaria digitata* seaweed, harvested on the North Brittany coast of France, undergoes extraction in tap water that has a pH adjusted to 2 by addition of sulfuric acid. At this stage sulphuric acid is a processing aid. Laminarin can be extracted at neutral pH or in acidic conditions. The described acidic conditions do not modify the chemical structure of laminarin. The addition of sulfuric acid avoids the co-extraction of other compounds such as alginates (which occurs at neutral pH). When alginates are extracted, the solution has a higher viscosity; purification and filtration steps for laminarin then become much more difficult. This is the reason why sulphuric acid is used to lower the pH and to facilitate the manufacturing process.
Stage 2: The extract is then filtered using a Seitz filter.
Stage 3: The solution then undergoes tangential filtration (membrane technology – physical process) to remove impurities from the solution. The filtrate containing laminarin is kept for the next purification step and the retentate is removed.
Stage 4: The filtrate (see above) then undergoes a second tangential filtration to remove any remaining impurities (filtrate), thereby resulting in a purified solution of laminarin in water (retentate).
Stage 5: The pH is adjusted between 6 and 7 by adding sodium hydroxide to neutralize the acidic solution, resulting in a solution of laminarin at neutral pH for formulation purposes (i.e., Vacciplant formulation). The addition of dilute sodium hydroxide does not modify the chemical structure of laminarin.

From the note from NOP to Crops Subcommittee, 6/3/13:

In NOP's review of the eligibility of this petitioned substance for the National List, we reviewed the manufacturing process against the draft guidance on classification of materials (NOP 5033). Based on our preliminary review, this substance may be classified as nonsynthetic. We have moved this petition forward for NOSB review and final determination on the classification status for the following reasons:

- The classification guidance is currently in draft form
- Other aquatic plant extracts are classified as synthetic for crop production at 205.601(j)(1)
- At this time, NOP is not aware of any products containing laminarin as an active ingredient that are approved by certifying agents or third-party material review organizations, such as EPA or OMRI

Discussion

The Crops subcommittee also reviewed the manufacturing process against the draft guidance on classification of materials (NOP 5033, section 4.6):

> **4.6 Extraction of Nonorganic Materials**
> Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).
>
> For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:
>
> • At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
> • The material has not been altered into a form that does not occur in nature; and
> • Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

The majority of the subcommittee has determined that Laminarin is extracted by an acid-base extraction and meets the criteria in section 4.6 above.

In regards to the third bullet point above the subcommittee majority believes that the acid-base reaction itself neutralizes any of the sulfuric acid starting material to the degree that it has no technical or functional effect. The minority opinion tries to draw parallels between laminarin which is extracted and then used to boost the plant's immune defenses against disease with sulfuric acid used to stabilize manure (a petition that was rejected) or acids used to stabilize fish products listed on §205.601. The majority feels these comparisons are not relevant because of the acid being used in substantially greater quantities in manure and fish, and the fact that they are both fertilizers means that the residual sulfates or phosphates would have a functional effect in the fertilizers. Laminarin is used for disease control at a rate of 0.52 - 1.04 fl. oz. per acre (as stated in the petition) which would not provide a functional effect from some parts per million of that rate being sulfate.

Because of a determination that it is non-synthetic, the subcommittee has not filled out a checklist as it does not need to be added to the National List.

Minority Opinion
A minority of the Subcommittee supported the view that laminarin is synthetic because sulfuric acid is added but not removed. Sodium hydroxide is added to neutralize sulfuric acid, but the sodium sulfate produced by the neutralization reaction (which does not chemically change laminarin) is not removed.

The minority agrees that laminarin does not undergo chemical change in the extraction process. Unfortunately, however, the NOP decision tree is incomplete –it does not cover all of the criteria in the guidance document NOP 5033. The guidance document states, “Some materials may be considered synthetic due to chemical changes which occur during manufacturing, while others substances may be classified as synthetic due to addition of small amounts of synthetic ingredients.”

In the case of laminarin, we need to look at the synthetic ingredients that are added. The section on extraction in the NOP guidance states that in order for a material to by classified as nonsynthetic, “Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.”

The extraction of laminarin involves the addition of sulfuric acid, as described in the petition. The sulfuric acid is not removed. Sodium hydroxide is added to neutralize the acid, but the sulfate remains. While there is no definition of “technical or functional effect” in the NOP regulations or the guidance, our calculations suggest that the amount of sulfate and sodium added to laminarin in the extraction process is significant.

The minority does not claim that the sulfate in laminarin constitutes a synthetic plant nutrient because it is not used in quantities that would be significant nutritionally to plants. Rather, the claim is that the sulfate is a significant residue within the laminarin that is not removed.

Some relevant points that we considered:

1. Sulfuric acid is added during the extraction of laminarin to reduce the pH to 2. Later, it is neutralized with the addition of the base sodium hydroxide. Although the sulfuric acid is neutralized, it is not removed. We calculate that altogether, 624 parts per million (ppm) sulfate and 299 ppm of sodium are added.[1] Because the kelp provides some (unknown) buffering capacity, the quantities are probably somewhat higher than this calculation indicates.
2. The NOSB has previously found (in 2006 and 2012, for anaerobic digestion of livestock and poultry manure) that the addition of sulfuric acid, even when followed by a step that neutralizes the acid, leaves behind a significant synthetic residue that has a functional effect in the agricultural system.
3. OMRI regards sulfuric acid and sulfate as prohibited, with limited specific exceptions.
4. The listing of liquid fish products is an instructive precedent indicating that when pH is adjusted with a synthetic, the product should be classified as synthetic.

Subcommittee Action & Vote

Classification Motion:
Motion to classify Laminarin as nonsynthetic
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 5 No: 2 Absent: 0 Abstain: 0 Recuse: 0

Because laminarin was classified as non-synthetic, no further action by the Crops Subcommittee is necessary.

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 26, 2014

[1] Compare this concentration to the Secondary Maximum Contaminant Level of sulfate in drinking water and the EU standard for drinking water --both 250 ppm.

Sunset 2015 Review List - Request for Public Comment
Crops Substances

*Reviewed and revised: February 26, 2014.

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 NOP before their sunset dates in 2015. This list provides the substance's current status, 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 2014 public meeting, the NOP is requesting that the public provide comments about these substances as part of the spring 2014 NOSB public meeting. These comments should be provided through www.regulations.gov by April 8, 2014 as explained in the meeting notice published in the Federal Register on March 10, 2014

The Crops Subcommittee has posed specific questions to solicit public comments regarding the substances due for sunset review by 2015. These questions are included in the listing for each substance below.

It is important for the public to engage in the Sunset Process early. We strongly encourage submission of comments on these substances in advance of or at the spring 2014 meeting. Providing your comments early is important to: 1) ensure that the NOSB has adequate time and information to develop any proposals to remove substances based on this information before its Fall 2014 meeting; and, as such 2) provide stakeholders adequate opportunity to comment on any proposals to remove substances before NOSB votes and makes a recommendation at its fall 2014 meeting.

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 substances currently on the National List were originally recommended by the NOSB based on evidence available at the time of their last review that 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.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on continuing the allowance of substances on this 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 <u>Support</u> Substances Under Review*:**
If you provide comments in support of an allowance of a substance on the National List, you should provide <u>new</u> 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 production.

For Comments That <u>Do Not Support</u> 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 <u>new</u> 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 organic 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. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

<u>Table 1. Guidance on submitting comments for alternatives to substances on the National List.</u>

If the currently listed substance is used in…	And is a…	Then the recommended alternative should be a (an)…
Crop Production	Synthetic substance	- Another currently listed synthetic substance; - Nonsynthetic substance; or - Management practice.

Written public comments will be accepted through April 8, 2014 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

SUNSET 2015: CROPS SUBSTANCES

Aqueous potassium silicate (Listing 1 of 2 – 205.601(e))

Synthetic

Use – As an insecticide (including acaricides or mite control).

Listing: Aqueous potassium silicate (CAS # 1312-76-1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

Technical Reports: 2003 (PDF); 2014 (PDF)

Petition(s): Potassium Silicate (PDF) (2004), Potassium Silicate Supplemental (PDF) (2006)

Past NOSB Actions: NOSB review and recommendation for addition to the National List - 11/30/07.

Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521).

Sunset Date: 12/14/2015

Specific Questions from Subcommittee

1. Potassium silicate makes plants more resistant to disease and herbivory, at least in part by concentrating silica. Humans and livestock are herbivores who might be consuming the treated plants. The 2014 Technical Report (TR) discusses how the foliar application of silicate can affect availability of micronutrients (TR 471-473), make plant tissues less tender and less digestible to humans and livestock (477-481 & 497-502), and lead to other morphological changes (487-490). Does the foliar application of potassium silicate in the quantity and frequency needed for insect and disease control have impacts on the nutritive value of treated foods that would exceed the impacts of silica obtained by the plant from natural soils? Are users employing mitigation strategies in consideration of these impacts? How should the NOSB weigh this impact on the nutritive value of treated plants?

2. Can organic management systems conserve and build available silicon in the soil in a ways that can be alternatives to potassium silicate? The 2014 TR suggests the following alternative practices: soilscaping, choice of variety and planting time, balancing silica accumulators and non-accumulators, moisture management, choice of mulch and ground cover, and scouting (661-689). Other forms of silica are also suggested as alternative materials (592-605). The subcommittee is interested in comments concerning nonsynthetic materials and practices being used in the field that would build comparable resistance to insects and fungi, while precluding the need for synthetic potassium silicate.

Reference: 7 CFR 205.601(e)

Aqueous potassium silicate (Listing 2 of 2 – 205.601(i))

Synthetic

Use – As plant disease control.

Listing: Aqueous potassium silicate (CAS # 1312-76-1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

Technical Reports: 2003 (PDF); 2014 (PDF)

Petition(s): Potassium Silicate (PDF) (2004), Potassium Silicate Supplemental (PDF) (2006)

Past NOSB Actions: Recommended for addition to the National List on 11/30/07.

Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591).

Added to National List 12/13/2010 (75 FR 77521).
Sunset Date: 12/14/2015
Reference: 7 CFR 205.601(i)

Sodium carbonate peroxyhydrate

Synthetic

Use – As an algaecide.
Listing: Sodium carbonate peroxyhydrate (CAS # 15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
Technical Reports: 2006 (PDF); 2014 (PDF)
Original Petition: Sodium Carbonate Peroxyhydrate (PDF) (2005)
Past NOSB Actions: Recommended for addition to the National List on 11/30/07.
Regulatory Background: Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521).
Sunset Date: 12/14/2015
Specific Questions from Subcommittee

1. The subcommittee is seeking input on the comparison of this material to copper sulfate for control of algal scum in rice production and whether it can replace copper sulfate for that use.

Reference: 7 CFR 205.601(a)

Sulfurous acid

Synthetic

Use – As plant or soil amendment.
Listing: Sulfurous acid (CAS # 7782-99-2)—for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.
Technical Reports: 2010 (PDF); 2014 (PDF)
Original Petition: Sulfurous Acid (PDF) (2008)
Past NOSB Actions: Recommended for addition to the National List on 5/09
Regulatory Background: Proposed rule (including justification) published 1/12/2010 (75 FR 1555). Added to National List 7/6/2010 (75 FR 38693).
Sunset Date: 7/7/2015
Specific Questions from Subcommittee

1. The Crops Subcommittee is interested in the conditions under which sulfurous acid undergoes the transformation to sulfate, and conditions under which that sulfate is available as a plant nutrient. The 2014 TR describes the chemistry of sulfurous acid in the soil at lines 64-67, 140-149, and 261-264. The subcommittee seeks comments that address the following questions: Are there specific soil and ecological (e.g., moisture) conditions under which the transformation to sulfate would be made and the sulfate made available? On the other hand, are there soil and ecological conditions that would result in the build-up of hydrogen sulfite, sulfate, or other products of sulfurous acid? Are there management practices that can be used by the grower to affect whether the transformation occurs and the sulfate is available to crops? Are there evaluation tools that can be used by farmers and certifiers to determine

which of the above soil conditions are present?

2. The subcommittee would like public input on whether sulfurous acid is used to remedy conditions resulting from unsustainable agricultural practices. If so, how can this be evaluated by the NOSB in the sunset review of this material?

Reference: 7 CFR 205.601(j)

National Organic Standards Board
Livestock Subcommittee
Synthetic Methionine (MET) in Organic Poultry Feed Proposal

August 20, 2013
Reviewed February 3, 2014 - No revisions

Summary of Proposed Action

The Livestock Subcommittee proposes to revise the current allowance of synthetic methionine (MET) to read:

> 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 average pounds per? ton of 100% synthetic methionine in the diet over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds.

The Livestock Subcommittee would also like to propose NOP Guidance for Certifying Agents and Industry on how to calculate and verify the use and allowance of synthetic MET expressed as a maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the bird.

Introduction

The current organic standards allow for the use of synthetic MET for use only in organic poultry production at the following maximum levels of synthetic MET per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The allowed rates represent “step down” levels that were recommended by NOSB in April 2010, codified in a final rule on September 19, 2012, and went into effect on October 2, 2012.

NOSB recommended the step down rates in order to balance various interests including: (i) Providing for the basic maintenance requirements of organic poultry; (ii) satisfying consumer preference to reduce the use of synthetic MET in organic poultry production; and (iii) motivating the organic poultry industry to continue the pursuit of commercially sufficient sources of allowable natural sources of MET.

However, in the attempt to balance interests, the 2010 NOSB recommendation included an allowance for synthetic methionine expressed as a total maximum limit of pounds of MET per ton of feed, while the Methionine Task Force (MTF) July 2009 petition requested that methionine rates be expressed as an average over the life of the flock. The rates expressed as a maximum limit do not address MET demands when laying chicks first come into production.

In the NOP Proposed Rule published in the Federal Register on February 6, 2012, the NOP recognized that on April 8, 2011, the MTF submitted a new petition for revised maximum allowable levels of synthetic MET expressed as an average per ton of feed over the life of the bird as originally requested in the 2009 petition. As stated in the preamble to the Proposed Rule:

> “The NOP anticipates that the NOSB will consider this petition at a future meeting. In the meantime, the NOP believes it is necessary to move forward issuing this proposed rule to

address the April 2010 NOSB recommendation. This is necessary to prevent any gap in the allowance of synthetic methionine in the diets of organic poultry due to the current expiration date of October 1, 2012." – (Federal Register/Vol. 77, No. 24/Monday, February 6, 2012 pg. 5719).

This NOSB proposal addresses the petition submitted by the MTF on April 8, 2011.

Background

MET is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability. MET is required for proper cell development and feathering in poultry. Natural feed sources with a high percentage of MET include blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal. Synthetic MET is also used in poultry feed. This substance is a colorless or white crystalline powder that is soluble in water. It is regulated as an animal feed nutritional supplement by the Food and Drug Administration (21 CFR 582.5475).

The NOSB initiated a review of this substance in 1999, as a result of a petition requesting to add synthetic Met to the National List for poultry. In 2001, the NOSB evaluated a technical advisory panel analysis of MET against the criteria provided in the OFPA (7 U.S.C. 6517–6518), and determined that the use of synthetic MET feed supplementation is compatible with a system of organic poultry production. Consistent with the NOSB's recommendation, the Secretary amended § 205.603 of the National List on October 31, 2003, to allow MET as a synthetic substance for use in organic poultry production until October 21, 2005 (68 FR 61987).

Based upon subsequent NOSB recommendations in March 2005 and May 2008, the Secretary amended the listing for MET to continue the use through October 21, 2008 (70 FR 61217), and again through October 1, 2010 (73 FR 54057). The 2005 and 2008 NOSB recommendations to continue the allowance for MET were informed by updates on the development of allowable natural alternatives, none of which had attained commercial viability. While expressing a strong preference for supplementation with allowable natural sources of MET, the NOSB concluded that terminating the allowance for synthetic MET would disrupt the well-established organic poultry market, and cause substantial economic harm to organic poultry producers. The NOSB and stakeholders agreed that the organic feed sector would continue to research and develop sufficient supplies of allowable organic and natural sources.

On July 31, 2009, the MTF, which is comprised of organic poultry producers, submitted a new petition requesting to extend the allowance for synthetic MET for five years until October 2014. In addition, the MTF proposed that the total amount of synthetic MET in the diet remain below the following levels, calculated as the average pounds per ton of 100% synthetic MET over the life of the bird:

> Laying chickens—4 pounds; broiler chickens— 5 pounds; and, turkey and all other poultry—6 pounds.

In consideration of the July 2009 petition and public comments, the NOSB issued two recommendations on April 29, 2010. These recommendations acknowledged a need for the continued allowance of synthetic MET, and conveyed the intent to decrease the amount of synthetic MET allowed in organic poultry production and encourage development of natural alternatives. One recommendation proposed to allow synthetic MET in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed:

> Laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds.

The NOP codified this recommendation through a National List amendment published in the **Federal Register** on August 24, 2010 (75 FR 51919), and reaffirmed on March 14, 2011 (76 FR 13501).

The second NOSB recommendation from April 2010 proposed reduced maximum levels of synthetic MET after October 1, 2015. The NOSB recommended that the annotation or synthetic MET be revised to read:

> For use only in organic poultry after October 1, 2012, at the following maximum levels per ton: laying and broiler chickens—2 pounds per ton; turkeys and all other poultry—3 pounds per ton.

The NOP issued a proposed rule in the Federal Register to amend the National List to reflect the 2010 recommendation on February 6, 2012 followed by a final rule published in the Federal Register on September 19, 2012:

> 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

The amended listing removed the expiration date of 2012 and subjected synthetic MET at rates listed above to review within five years in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C 6517(e)). Synthetic MET is now subject to a sunset review by the NOSB by 2017.

Relevant areas in the Rule

7 CFR §205.603(d)(1) - Synthetic substances allowed for use in organic livestock production. As feed additives.

Discussion

Much is known about the nutritional needs of poultry and the feedstuffs available to poultry producers. The dietary demand for total MET declines with age for broilers and turkeys, while there is a decline during the early stages of pullet development, it increases just before laying begins and trails off as the birds age. The current proposal is somewhat of an estimate of the average demand for each class of birds based on the demand charts. Producers are feeding additional levels of protein, commonly soybean meal, to their birds in an attempt to meet the MET needs of the birds. This in effect is over feeding numerous amino acids in order to get enough MET into the birds. During the winter months, the birds would consume enough feed to meet their needs, but the additional protein in the feed was excreted into the barns causing ammonia levels to rise and blisters on the bird's feet. During the summer months, the birds naturally consume less feed as their nutritional maintenance requirement is lower, they cannot consume enough feed to meet the necessary level of MET. Producers and certifiers are seeing an increase in feather pecking which can lead to cannibalism, agitation and nervousness and

other behavioral issues. This behavior change is an animal welfare issue and the organic producers fail to understand why a logical solution cannot be adopted. If the rations could be tailored to the needs of the animal, why would the organic regulations prevent them from doing the right thing for the bird, especially if the overall intake would be at or below the allowed maximum over the course of its life.

Previous NOSB deliberations have discussed alternative sources for synthetic MET. The MTF has invested lots of time and money seeking viable alternatives for their industry in an effort to meet consumer expectations. High MET corn has production and yield issues. Corn variety trials are ongoing with the hopes this breeding work will be able to develop varieties that supply the appropriate amount of necessary amino acids. Pasture may provide some supplementation during the right conditions, but is certainly not a dependable solution. Other feed grains may have higher MET levels than corn, but have lower overall protein or may be limiting in other amino acids which makes them improbable solutions. The EU uses corn gluten meal to balance the MET demand since synthetic MET is not allowed, but 5% of their rations do not have to be organic. Organic corn gluten meal is not available to US producers. Fish meal and crab meal are used by some organic producers, while others are concerned about off flavors, and the availability is very low as most of these products are stabilized for transport with non-compliant stabilizers. Many organic consumers are looking for vegetarian based production systems as well. The NOSB Livestock Subcommittee put forth a discussion document on feeding animal byproducts to poultry as an alternative source of MET and while there was a minority that agreed with the proposal, the majority deemed that organic principles would be compromised. Because there is so much interest to find an alternative to synthetic MET for organic producers, numerous projects around the world are evaluating herbal and insect based sources. Because of the need for U.S. Food and Drug Administration (FDA) approval, these will be many years out if determined to be suitable alternatives.

Under this proposal, producers will have an increased liability to document feeding rates to document compliance with the regulation. Certifiers will have to develop tracking systems with producers and their feed mills to verify compliance. Larger poultry operations change the rations frequently to keep cost down by only feeding to meet the bird's needs. These operations will have detailed records on flock age, size, and feed rations fed on a daily basis. It will be somewhat complicated if a pullet flock is transferred to another farmer for egg production, who is with another certifier. All the feed documentation will have to follow as well. Smaller operations often feed the same ration throughout the life cycle of the bird and therefore would never feed more than the average. Certifiers have indicated that mechanisms can be developed with their clients, suitable to verify compliance with the regulation. They are in part motivated by the behavioral issues being reported by their inspectors during this first season under the new cap. The NOP may need to issue Guidance Documents or Instructions to certifiers to clarify how verification can be obtained. Certifiers affiliated with the Accredited Certifiers Association (ACA) often work together and help each other gain consistency in areas like this. This could also be a part of the annual training for certifiers conducted by the NOP and ACA.

The NOSB Livestock Subcommittee is unsure of how certifiers will handle a situation if the flock goes out of production prior to the average being below the regulatory cap. We are uncertain as to whether this would be a noncompliance that must not be repeated or a willful violation indicating civil penalties.

Calculating MET allowances average over the life of the flock, will result in the following:

- Feed rations can better adjust to the naturally changing demands of the bird. Poultry farmers will have more flexibility to appropriate adjust diets for stage of life, seasonality,

breed, etc.;

- Overall usage of MET will be lowered. Producers can only add MET to the average cap, not consistently add MET at the maximum rate;
- Farmers and nutritionists will still be only marginally capable of meeting the bird's basic needs. The organic poultry industry will continue to have a tremendous incentive to actively evaluate novel sources of MET. With continued research and the development of effective alternatives proven to meet the demands of the organic poultry sector, the NOSB Livestock Subcommittee believes that MET can eventually be eliminated from organic production.

Current listing on the National List:

> 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.

The regulations currently express a total maximum limit of pounds of MET per ton of feed. Consistent with the petition from July 2009 and April 2011, this proposal requests that MET rates be expressed as an average per ton of feed over the life of the flock.

Recommended Committee Action & Vote

Motion to accept the following amendment at §205.603(d): 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 average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds.

Motion by: Mac Stone
Seconded by: Francis Thicke

Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Further Clarification of the Proposed Amendment

Under this recommendation, producers would be able to exceed the above levels on a particular formulation, provided that there was an offsetting formulation below the level, such that the average inclusion rate of 100% synthetic MET over the entire life cycle of the flock was below the allowed maximum level.

Reference is specifically made to 100% synthetic MET, as some forms of synthetic MET (e.g. the liquid form Alimet) are not 100% MET. The maximum pounds as shown above is based on the 100% synthetic MET equivalent so that a consistent standard can be applied to all organic operations, irrespective of the form of MET they are using (e.g. wet vs. dry).

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 20, 2013

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Acidified Sodium Chlorite (ASC)

August 20, 2013
Reviewed January 7, 2014 - No revisions

Summary of Proposed Action:

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x Yes	☐No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	x No	☐ N/A
3. Compatibility & Consistency	x Yes	☐ No	☐ N/A

Substance Fails Criteria Category: 2

Comments:

Acidified Sodium Chlorite (ASC) was petitioned for use as a pre and post teat dip treatment in organic livestock production. ASC is currently allowed on the national list as a disinfectant for direct food contact under 205.605(b). After carefully reviewing the petition, along with the Technical Evaluation Report prepared for the committee in 2013, we have found that this material generally satisfies the criteria related to impact on humans and the environment, along with general compatibility and consistency with organic principles. However, the TR notes that a number of functional alternative substances are available, and the committee's research and outreach to producers confirms that many substances are already used as mastitis-preventing teat dips. Accordingly, the essentiality criteria are not met, and the committee does not recommend the addition of ASC to the national list as a teat dip.

Subcommittee Action & Vote

Classification Motion: Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic.
Motion by: Joe Dickson
Seconded by: Colehour Bondera
Yes: 8 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Motion to list Acidified Sodium Chlorite(CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) at §205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, Allowed for use on organic livestock as a pre and post teat dip treatment, acidified with lactic acid or other GRAS acid.
Motion by: Joe Dickson
Seconded by: Colehour Bondera
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

Basis for annotation: x To meet criteria above ☐ Other regulatory criteria ☐ Citation

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 20, 2013

NOSB Evaluation Criteria for Substances Added To the National List :Livestock

Category 1. Adverse impacts on humans or the environment? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse,? [§6518(m)(3)]		x		Risk is minimal. TR page 9, lines 359-369.
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		x		TR page 9, lines 359-390.
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		x		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		Breakdown products are citric acid, salt and water (2009 handling recommendation).
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		When used as petitioned, SCA and its components exhibit minimal likelihood of persistence in the environment. TR page 7 lines 296-298.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		"When used as petitioned, acidified sodium chlorite and its component chemicals exhibit minimal likelihood of persistence or accumulation in the environment." TR page 10, lines 436-428. The material is both GRAS and on the USDA National List for handling.
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
9. Are there detrimental physiological effects on soil organisms, crop- s, or livestock? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 2. Is the Substance Essential for Organic Production: Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		TR page 7, lines 280-293.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR page 6, lines 222-279
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		TR page 7.
6. Is there an organic substitute? [§205.600(b)(1)]		x		There are a limited number of organic or natural substances that are appropriate substitutes. Nisin, a natural material that may be a substitute, is not authorized for use as a teat dip due to earlier rejection by NOSB as an antibiotic . A number of essential oils and organic acids may also be used as teat dips. TR page 11, lines 542-547
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x	x		See above.
8. Are there any alternative substances? [§6518(m)(6)]	x			The TR also suggests that a number of alternative substances, including iodine, alcohols, chlorine materials, hydrogen peroxide, chlorhexadine and certain essential oils may function as alternatives.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		Teat dips are critical in commercial dairy production to prevent mastitis. TR page 12.

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 3. Is the substance compatible with organic production practices? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			TR, petition. Substance is already allowed for use in handling in direct food contact.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			x	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			x	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			x	
6. 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		x		TR page 6, lines 210-221
toxins derived from bacteria		x		TR page 6, lines 210-221
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		x		TR page 6, lines 210-221
livestock parasiticides and medicines		x		TR page 6, lines 210-221
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		x		TR page 6, lines 210-221

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Chlorine Materials in aquatic livestock production

August 20, 2013
***Reviewed and revised January 21, 2014**

Summary of Proposed Action:
Chlorine Materials are petitioned for use in aquatic livestock production, to be added to *205.611 - Synthetic substances allowed for use in organic aquatic animal production* as follows:

> (x) Chlorine materials—residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
>
> (i) Calcium hypochlorite.
> (ii) Chlorine dioxide
> (iii) Sodium hypochlorite

Synthetic Chlorine is proposed to be added to the National list at 205.611 for use in aquatic animal production. Section 205.611 of the National List will contain the list of synthetic substances allowed in organic aquatic animal production.

Chlorine materials are widely used for their disinfectant properties, and are currently approved for such uses in crop, livestock and processed organic product production. The annotations on the National List for livestock and handling limit the use of chlorine materials to disinfection and sanitation, and require that residual chlorine levels be consistent with Safe Drinking Water Act levels. The NOP has also clarified the use of chlorine in production and handling in a guidance document, NOP 5026.

The Livestock Subcommittee has received a petition for the use of Chlorine Materials in aquatic livestock production. These materials are used in aquatic animal production for the disinfecting hard surfaces and culture water in nurseries, grow-out operations with tanks, harvest and slaughter equipment, and in processing facilities. Given that the materials' use in aquaculture applications is identical to existing uses in other production categories, the committee has not requested a new Technical Evaluation Report, but it is instead relying on recent TR's developed for Handling and Crops uses of this group of materials.

Evaluation Criteria	**Criteria Satisfied?**
1. Impact on Humans and Environment	X Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	X Yes ☐ No ☐ N/A
3. Compatibility & Consistency	X Yes ☐ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No X N/A

Substance Fails Criteria Category: N/A

Recommended Committee Action & Vote

Classification Motion: Chlorine Materials (Calcium hypochlorite – CAS 7778-54-3; chlorine dioxide – CAS 10049-04-4; and sodium hypochlorite – CAS 7681-52-9) are synthetic.

Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 5 No: 1 Absent: 0 Abstain: 1 Recuse: 0

Listing Motion: Motion to list Chlorine Materials (Calcium hypochlorite- CAS 7778-54-3; chlorine dioxide- CAS 10049-04; and sodium hypochlorite – CAS 7681-52-9) at § 205.611 with the following annotation : Chlorine materials - Disinfecting and sanitizing facilities and equipment. Residual levels in the water shall not exceed the maximum residual disinfecting limit under the Safe Drinking Water Act.

Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 5 No: 1 Absent: 0 Abstain: 1 Recuse: 0

Basis for annotation: X To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes: This annotation is consistent with other listings of Chlorine on the NL, and ensures that any environmental impact is effectively mitigated.

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 21, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		2006 Crops TR lines 212-266. The TR identities several areas of potential environmental impact, but notes that existing EPA regulations and the annotation restricting effluent to the levels of the Safe Drinking Water Act are sufficient to mitigate any environmental impact. The petitioner and a number of producers have confirmed that chlorine materials are not used in direct contact with the environment (e.g. ponds and net pens) and the restrictive annotation would prohibit such uses regardless.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See Question 1
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No. [2006 Crops TR]

4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water. Any presence of the substance in the overall agroecosytem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		No. The substance degrades rapidly to naturally occurring compounds in the presence of air and sunlight [2006 Crops TR 417-432] This TR also confirms (in lines 384 –402) that these materials are not persistent in the environment in general, and that in water and soil, sodium and calcium hypochlorite separate into sodium, calcium and hypochlorite ions. Chlorine dioxide is also reactive and breaks down quickly. While the TER does not directly address its fate in aquatic environments, again, the annotation would limit the extent to which any chlorine material could be discharged into sea water or any other part of the environment.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See Q # 1
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		Any presence of the substance in the overall agroecosytem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		The substance is not used in direct contact with soil or terrestrial livestock. It is only used in contact with hard surfaces and equipment, or culture water. [2006 Crops TR 322-327, petition]

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 2. Is the Substance Essential for Organic Production? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Yes. 2006 TR Lines 149-171
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]			X	This process does not involve the chemical transformation of a natural substance; the starting materials are synthetic. 2006 TR Lines 177-178
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		2006 TR Lines 183-184
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	2006 TR Lines 183-184
6. Is there an organic substitute? [§205.600(b)(1)]			X	2006 TR Lines 183-184
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		Petition page 7-8 (notes the limitations on alternative materials) and 2011 Crops TER page 12.
8. Are there any alternative substances? [§6518(m)(6)]		X		
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 3. Is the substance compatible with organic production practices? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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			X	
toxins derived from bacteria			X	
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals			X	
livestock parasiticides and medicines			X	
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers			X	

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Tocopherols in aquatic animal production

August 22, 2013
***Reviewed and revised January 21, 2014**

Summary of Proposed Action:
Synthetic Tocopherols are proposed to be added to the National List at 205.611 for use in aquatic animal production as an anti-oxidant added to feed. Section 205.611 of the National List will contain the list of synthetic substances allowed in organic aquatic animal production.

Tocopherols were petitioned in 2012 by the Aquaculture Working Group for use in aquaculture livestock production. Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term "tocopherols" refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from plant products are often referred to as "mixed tocopherols" because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41). Tocopherols are mixed with fish oil, fishmeal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish (Hardy and Roley, 2000). Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E. Finally, oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000). Tocopherols are considered essential for the health of aquatic animals

Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). 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])(TR lines 26-32).

Tocopherols are also affirmed as GRAS by the FDA when used as chemical preservatives (21 CFR 582.3890) and nutrients and/or dietary supplements (21 CFR 582.5890) in animal feeds in accordance with good manufacturing or feeding practice. No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. TR lines 464-466. "Tocopherols are currently permitted by Canadian, European, and Japanese Organic Standards, IFOAM and CODEX, although they may not specifically be permitted as antioxidants in livestock feed production.

In reviewing whether use of synthetic tocopherols is compatible with or essential to organic agriculture the subcommittee took into consideration the Organic Foods Production Act (OFP) which limits use of synthetics. Tocopherols are in the vitamin group listed at section 6517(c)(1)(B)(i).

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production, and this proposal is based on the NOSB Recommendations of standards voted in 2007, 2008, and 2009. Therefore the livestock subcommittee recommends reassessment of this material when regulations for open and closed systems are in place.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	X Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	X Yes	☐ No	☐ N/A
3. Compatibility & Consistency	X Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Subcommittee Action & Vote

Classification Motion: Motion to classify tocopherols, as petitioned, as synthetic.
Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list tocopherols at §205.611 of the National List for use in aquatic livestock production as an antioxidant added to aquatic animal feed with the following annotation: Tocopherols derived from vegetable oils are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative.

Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): Tocopherols derived from vegetable oils are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative.

Basis for annotation: x☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 21, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Tocopherols (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during, use or misuse? [§6518(m)(3)]		X		If solvents used in the manufacturing are released into the environment through waste streams, environmental contamination could occur. However, no sources were identified that discussed environmental contamination resulting from the manufacturing of tocopherols. (TR lines 498-501)
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		The extraction of tocopherols from vegetable oil byproducts may include one or more of the following chemical processes: esterification, saponification, solvent extraction, and/or crystallization using a solvent (TR 281-314). Physical separation methods may also be used during the extraction of tocopherols, and these include various distillation steps. Solvents used include: hexane, ethanol, isopropanol, acetone, isopentane, isohexane, and trichloroethylene (TR lines 282-284). Can also be made from a byproduct of vegetable oil refining (oils of soybean, canola, sunflower, corn, and cottonseed, some of which may be genetically engineered) (TR lines 289-292).
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		TR lines 451-450.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X			Excessive intake of tocopherols above the vitamin E requirement of fish could result in hypervitaminosis E, a condition of high storage levels of the vitamin in the fish which could result in toxic symptoms such as poor growth, toxic liver reaction, and death (De Silva et al., 2012; Halver, 2002) (TR lines 480-483).

6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Tocopherols exert their antioxidant properties by reacting with free radicals, so they are unlikely to persist. Oxidized tocopherols can be recycled in the presence of other antioxidants, however, and some of the metabolites of tocopherols can be toxic.[1]
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See TR lines 393-439. The tocopherol level found in the flesh of a fish is related to the fish's total dietary intake of tocopherols (Sargent et al., 2002). The use of tocopherols as an antioxidant or vitamin supplement in aquatic animal feed will possibly increase tocopherol levels in those fish that consume the feed, with unknown effects on the human consumer (TR lines 522-524). No sources were identified that discuss adverse effects upon human health from the use of tocopherols as an antioxidant in aquatic or terrestrial animal feed. It is unlikely that the use of tocopherols as an antioxidant in aquatic animal feed would be harmful to human health. (TR lines 509-511)
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. (TR lines 464-466.)
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]			X	

Category 2. Is the Substance Essential for Organic Production? Tocopherols (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			TR lines 276-369. The 1995 Technical Advisory Panel (TAP) Report for Tocopherols, which

[1] Aalt Bast and Guido R.M.M. Haenen, 2002. The toxicity of antioxidants and their metabolites. Environmental Toxicology and Pharmacology 11 (2002) 251–258.

				reviewed the use of tocopherols as a food antioxidant, states that tocopherols are made via vacuum steam distillation of edible vegetable oil products (NOSB, 1995). (TR lines 285-287)
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			(TR lines 276-369.) Synthetics are added in extraction process. All of the methods found in the literature involve chemical processes. At the end of the process used to extract and purify tocopherols, the compounds remain in the same form as in the naturally occurring source materials. (TR lines 320-322) The petitioner provided a material safety data sheet (MSDS) for a product called Naturox® IPO Liquid (Kemin Industries, Inc.) which lists organic sunflower oil, lecithin, and rosemary extract as components of the mixed tocopherols formulation (Kemin Industries, Inc., 2008). The Joint Expert Committee on Food Additives (JECFA) specification for the food additive "mixed tocopherols concentrate" states that it may contain an edible vegetable oil added to adjust the required amount of total tocopherols (JECFA, 2006). Powdered forms of mixed tocopherols contain a carrier such as tapioca starch, gum acacia, and/or maltodextrin (Organic Technologies, 2009; NOSB, 1995). No additional sources were found that discuss possible additives to commercially-produced tocopherols for use as antioxidants in food or feed, including aquaculture feed products. (TR lines 55-63)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X	X		Naturally occurring tocopherols exist. But the petition is for synthetic tocopherols.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term "tocopherols" refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from

				plant products are often referred to as “mixed tocopherols” because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41)
6. Is there an organic substitute? [§205.600(b)(1)]	X			Organic Rosemary oil may work in some applications.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Rosemary extract, lecithin, vitamin C, natural sources of vitamin E (eg, wheat germ oil), and others (TR lines 531-583).
8. Are there any alternative substances? [§6518(m)(6)]	X			See 7 above.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			No sources were identified that discussed alternative practices that would make the use of an antioxidant unnecessary in aquatic animal feed (TR 595-597).

Category 3. Is the substance compatible with organic production practices? Tocopherols (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Synthetic tocopherols are currently permitted for specific uses in organic livestock production and organic handling. Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). 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])(TR lines 26-32).
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			Tocopherols are mixed with fish oil, fish meal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and

				thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish (Hardy and Roley, 2000). (TR lines 99-105) Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E.
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]	X			Oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000). (TR lines 107-109) Tocopherols are used to stabilize fishmeal and are required under law if fishmeal is to be transported.
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		See comments at Item 3 above.
6. 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		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			Tocopherols are in the vitamin group
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion - Tocopherols in aquatic animal production
February 21, 2014

Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB needs to reconsider the approval in five (5) years. The minority believes that there should be a five-year expiration date as an annotation. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to those relating to extractants, as well as alterative natural materials. The review in five (5) years provides an opportunity for the Board to monitor the use of the material, update its scientific and essentiality review, incentivize alternatives and continuous improvement, and vote on continued or modified use of the material under the same standard of review that is used to approve the material during its petition review, pending the receipt of a petition requesting the use be extended.

The minority also has concerns about the unnecessary presence of volatile synthetic solvents in tocopherols. The Livestock Subcommittee received a letter from Oh Oh Organics supporting the consistent availability of natural tocopherols extracted without synthetic solvents. The letter states,

> I have sold Non-GMO, non-solvent extracted tocopherol since 2005. Both BASF, an international ingredient manufacturer out of Germany and BTSA, a company specializing in non-GMO Tocopherols supply this material. It is consistently available and is broadly used in the food, cosmetic and household cleaning business. Additionally I have seen ISO certified documents for a supplier in China...so, I believe it available around the world.

The minority believes that the use of synthetic tocopherols is incompatible with organic agriculture because:

- It is inconsistent with use of vitamins in terrestrial animals, where they are restricted to use for, “enrichment or fortification when FDA approved.”
- It is a synthetic preservative.

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Minerals in aquatic animal production

August 6, 2013
***Reviewed and revised February 3, 2014**

Summary of Proposed Action:
Synthetic minerals are proposed to be added to the National List at 205.611 for use in production of aquatic animals. Section 205.611 of the National List will contain the list of synthetic substances allowed in organic aquatic animal production.

Synthetic Trace Minerals are presently approved at 205.603(d)(2) for use in livestock production, used for "enrichment and fortification when FDA approved".

Minerals are essential for production of healthy animals. In the case of nutrient requirements for fish and shrimp, the National Research Council (NRC) defines essential trace minerals as "required". Petitioner requests addition to the National List of trace minerals without specific notation to include but not to be limited to the following: Cobalt Chloride, Copper, Potassium iodide, Ethanediamine dihydroiodide, Ferric Sulfate, Ferric citrate, Manganese sulfate, Sodium Selanate, Sodium Selanite Sodium Chloride, and Zinc Sulfate.

Minerals are produced using chemical synthesis and extraction from either natural or reclaimed sources and while a range of potential environmental impacts may occur from excess and improper disposal during manufacture, under normal animal feeding the risks to the environment are low, and human health effects specifically related to trace minerals in aquatic animal feeds have not been reported.

Minerals are included as ingredients in feed pellets at approximately 0.1% to o.2% of feed pellet mass. The dietary importance of a given trace mineral is conditional on the animal species being grown.

In considering alternative sources for trace minerals as petitioned it should be noted that feeding wild caught fish, fish meal, other animal based meals, together with plant based feeds such as soy, corn, cottonseed etc. could provide a balanced diet without the fortification of feed with synthetic trace minerals.

In reviewing whether minerals are compatible with organic agriculture the subcommittee took into consideration the Organic Food Production Act (OFPA) which limits the use of synthetics to various categories, one of which is "pheromones, soaps, horticultural oils, fish emulsions, treated seeds, vitamins and minerals".

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on NOSB Recommendations voted in 2007, 2008, and 2009

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: N/A

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Motion to classify Minerals as synthetic:

Motion by: Francis Thicke
Seconded by: C. Reuben Walker
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0#

Listing Motion: Motion to list Minerals at §**205.611** of the National List.

Motion by: Francis Thicke
Seconded by: C. Reuben Walker
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): None

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 3, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Minerals (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		When used as petitioned trace minerals from unconsumed feed pellets have the potential to persist in treated bodies of water, ground water, sediments and bioaccumulate in animal tissues. Data regarding persistence of trace minerals resulting from uses in aquaculture are limited. (TR 657-659). Overall the risk of lethal effects from bioconcentration is considered low (TR685-686)
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		Industrial effluents consisting of trace minerals may contribute to deleterious growth algal blooms as found in India (TR810-811), but under normal regulated operation risks are low
3. Are there any adverse impacts on		X		When used as petitioned trace minerals

biodiversity? (§205.200)				in the minute amounts used (.01-0.2% in feed) adverse impact on biodiversity is low risk
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No (TR 548)
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		No direct interactions between trace minerals and other aquatic animal feed additives were identified (TR 825) The petitioned trace minerals are chemically equivalent to trace minerals used in fortification of organic livestock feed for terrestrial animals.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		There is a wide range of toxicities associated with the range of trace minerals especially at excessive levels (TR 697-821) However a negligible potential for toxicity exists under the prescribed use. (TR 738-740)
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Data on persistence in aquatic systems is limited (TR 658) Overall the risk of lethal effects from bioconcentration of the petitioned trace elements is considered low. (TR 685-686)
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		Environmental concentrations of trace minerals are unlikely to cause adverse health effects in humans except during improper disposal (TR 920-926) and human health effects specifically related to trace minerals in aquatic animal feeds have not been reported (TR 927-928)
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		No reported toxicity has been observed in non-target wildlife or livestock and toxicity in the ago-ecosystem is unlikely. Accidental release of industrial effluent may lead to ecological impairment.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		Trace elements are required by soil organisms, crops and livestock, so if the usage rates are kept within requirements for aquatic animals there should be no detrimental effects.

Category 2. Is the Substance Essential for Organic Production? Minerals (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X	X		Trace minerals are produced using chemical synthesis and extraction from either natural or reclaimed sources. (TR 556-557)
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			See 2 above
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See 2 above
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		There are no direct substitutes for trace minerals (TR 993) There are natural sources- fish meal being the best source, but availability and resource demands to use them widely make them an unrealistic source. Many trace minerals can be found in vegetable oils, kelp, raw animal meat and so forth (TR 994-1044) Further the fish industry is working to mitigate demand for wild fish as fish feed.(TR 1068-1076) In the early years of aquaculture raw horsemeat was used (TR 403-404)
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		See 5 above A combination of plant based and animal based feeds may meet dietary requirements thereby precluding supplementation by synthetic trace minerals (TR 1109-1118)
8. Are there any alternative substances? [§6518(m)(6)]	X			See 5 above
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			There is debate as to whether vitamin or trace minerals are necessary to meet nutritional requirements of farmed fish. (TR 1052-1054) (TR 1096) However when fish are reared in high density indoor system or other closed systems they need to be provided with complete, fortified diets (TR 1096-1098)

Category 3. Is the substance compatible with organic production practices? Minerals (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Minerals are presently on the National List at 205.603(d)(3) and Minerals are listed in the OFPA at 6517 (c) (1)(B)(i)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			Trace minerals enrich and fortify feed
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]		X		
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		
6. 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	X			Some trace minerals include sulfur and copper compounds (TR 540-544)
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			Trace minerals
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion - Minerals for aquatic animals
February 21, 2014

Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB needs to reconsider the approval in five (5) years. The minority believes that there should be a five-year expiration date as an annotation. Current consideration of the material has raised issues relating to health or environmental impacts, because of the broad coverage of the term "minerals;" alternative natural materials and management methods; and compatibility with organic practices. The review in five (5) years provides an opportunity for the NOSB to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

The minority also has the following concerns:

- The listing for "minerals" without qualification of either specific synthetic substance or specific use or application, is inconsistent with (§6517(b) of OFPA: "The list established under subsection (a) of this section shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) of this section or each natural substance prohibited under subsection (c)(2) of this section.")
- The listing for "minerals" includes many substances that should not be allowed in organic production (e.g., arsenic compounds), or used in aquatic situations (e.g., copper sulfate).
- The listing for "minerals" without qualification or specific identification does not allow an informed vote on either classification or other OFPA criteria. It is impossible to judge the health and environmental impacts of or the need for unspecified minerals.
- The petitioner has not made a case for a need for synthetic "trace minerals" in general, and certainly not for synthetic "minerals."
- It is incompatible with organic agriculture to allow the routine use of synthetic materials to fulfill essential system functions.

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Vitamins in aquatic animal production

June 17 2013
Reviewed January 21, 2014 - Minor formatting revisions only

Summary of Proposed Action:
Synthetic vitamins are proposed to be added to the National List at 205.611 for use in production of aquatic animals. Synthetic vitamins are presently approved at 205.603(d) (3) for use in organic, soil based, livestock production as "Vitamins for enrichment or fortification when FDA approved." Vitamins are listed in the OFPA at 6517 (c) (1) (B)(i).

Vitamins are essential for production of animals, and although feed consisting of fish meal, or ingredients such as soy, corn, or vegetable oils could be used to supply vitamins. Currently, synthetic vitamin forms provide a more readily available and consistent source of vitamins to ensure good health for organic livestock. In the case of nutrient requirements for fish and shrimp, the National Research Council (NRC) defines essential vitamin compounds as "required", and it is this group of 15 synthetic vitamins which are proposed for addition to the National List: Vitamin A; B1 (Thiamine); B2 (Riboflavin); B3 (Niacin); B5 (Pantothenic Acid); B6 (Pyridoxine); B7 (Biotin); B8 Choline; B9 (Folic Acid); B12 (Cobalamin); Inositol; Vitamin C; Vitamin D3; Vitamin E Tocopherols; and Vitamin K.

Manufacture of vitamins can be by chemical processes, fermentation or extraction depending on the specific vitamin. Fermentation can be synthetic or non-synthetic. Typically chemical processes are used to achieve consistent and balanced feed pre-mixes. While large spills during manufacture may result in algal blooms, the typical feeding of vitamins for fish production is not considered to pose environmental harm. Vitamins should not be considered persistent in marine environments. Adverse effects due to persistence are more likely to be seen in closed systems.

In considering alternative sources for the 15 vitamins petitioned, Vitamin E can be extracted from vegetable oils and a diet comprised of forage and fish oils is the most natural means of providing vitamins to carnivorous and omnivorous fish. However, the aquaculture industry is working to mitigate use of and possible depletion of wild fish if it continues to be used in large amounts as a feed source in aquaculture. Extraction from natural sources is widely considered inefficient and low yielding.

In reviewing whether vitamins are compatible with organic agriculture the subcommittee took into consideration the Organic Food Production Act (OFPA) which limits the use of synthetics to various categories, one of which is "pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins, and minerals.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on NOSB Recommendations of Standards voted in 2007, 2008, and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:** N/A

Subcommittee Action & Vote,

Classification Motion: Motion to classify vitamins, as petitioned, as synthetic: Vitamin A, CAS #127-47-9; B1 (Thiamine), CAS # 59-43-8; B2 (Riboflavin), CAS # 83-88-5; B3 (Niacin), CAS # 59 67-6; B5 (Pantothenic Acid), CAS #137-08-6; B6 (Pyridoxine), CAS # 58-56-0; B7 (Biotin), CAS # 58-85-5; B8 (Inositol), CAS # 87-89-8; B9 (Folic Acid), CAS # 59-30-3; B12, (Cobalamin), CAS # 68-19-9; Choline, CAS # 67-48-1; Vitamin C, CAS # 50-81-7; Vitamin D, CAS # 67-97-0; Vitamin E, Tocopherols CAS # 59-02-9; and Vitamin K, CAS # 130-37-0.

Motion by: C. Reuben Walker
Seconded by: Jean Richardson
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list vitamins as listed above at §205.611 of the National List

Motion by: C. Reuben Walker
Seconded by: Jean Richardson
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation: None

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 21, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Vitamins (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		Vitamin pre-mixes are incorporated into feed at a rate of approximately 0.5%-1.5% (Petition page 3) and releases are assumed to pose no risk (TR 982-983). Large amounts of vitamins released into open waters may result in promotion of algal blooms and red-tides (TR 986-987) and perhaps eutrophication (TR 1075-1079). It is unlikely that vitamins use or misuse will result in environmental impairment due to their short half lives in aquatic systems. (TR 972-973 and 807-829). Overall, accidental release of small amounts of vitamins into the environment

				is not assumed to pose any significant risk (TR 982-983).
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See 1 above. Industrial production of synthetic vitamins includes use of reagents and fermentation waste which can have negative environmental impacts, but no specific examples of such contamination are cited in TR (TR 945-987).
3. Are there any adverse impacts on biodiversity? (§205.200)		X		See 1 above.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No (TR 541-548).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Overall vitamins should not be considered persistent in marine environments as these compounds readily decompose in oxic (oxygen rich) environments (TR 827-829). No direct interactions of vitamins and other aquatic animal feed additives have been identified (TR 991).
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		See 5 above and 7 below.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		See 5 above. The potential for toxicity is generally dependent on the vitamin's solubility properties. Water soluble vitamins (thiamine, riboflavin, pyridoxine, pantothenic acid, niacin, biotin, folic acid, choline, inositol, and ascorbic acid) are rapidly depleted and these vitamins do not bioaccumulate in animal fatty tissue. Lipid-soluble vitamins A, D, E, and K bioaccumulate in fatty tissue (TR 847-876). Literature on bioaccumulation or persistence of vitamins in aquatic environments is limited. In general lipid soluble vitamins are more likely to bioaccumulate in fatty tissues (TR 830-836). Adverse effects due to persistence will be more severe in closed systems (TR 805-806).

8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See 1, 5, and 7 above. Limited information is available regarding potential for environmental or human health toxicity at the small levels used (TR 1045-1050).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		It is unlikely that vitamins used in aquatic animal feed would enter a terrestrial agro-ecosystem (TR 1027-1028). No studies have been found indicating toxic effects of vitamins in soil dwelling organisms (TR 1030-1033). Vitamin D3 is used in a rodenticide (TR1071-1072). Overloading aquatic ecosystems with nutrients could potentially reduce BOD but this would negatively impact fish production and thus with good management can be avoided (TR1075-1079).
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See 1, 7, and 9 above. No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms (TR 1033).

Category 2. Is the Substance Essential for Organic Production? Vitamins (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X	X		There are 15 Vitamins petitioned and the production methods vary. Some can be produced by fermentation or extraction from natural sources, but are typically commercially produced by chemical processes (TR 553-554). Fermentation can be considered synthetic or non-synthetic (TR 785-786).
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X	X		See 1 above. Of the 15 synthetic vitamins petitioned Vitamins A, D, E, and K are lipid (TR 852-853). Vitamin E, tocopherols is typically extracted from natural materials, i.e. vegetable oils (TR 779).

				Extraction from natural sources in widely considered inefficient and low yielding (TR 574-773).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See 1 above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		See 1 and 3 above and 9 below.
6. Is there an organic substitute? [§205.600(b)(1)]	X	X		Vegetable oil for Vitamin E, but not for the others petitioned.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		For some of the vitamins vegetable oils or fish oils can be used.
8. Are there any alternative substances? [§6518(m)(6)]	X	X		See 1 and 8 above and 9 below.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		When possible a diet comprised of forage fish is the most natural means of incorporating proteins and vitamins into diets of carnivorous and omnivorous fish (TR 1247-1249) but the fish industry is working to mitigate demand for wild fish as fish feed (TR 1277-1285).

Category 3. Is the substance compatible with organic production practices? Vitamins (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Vitamins are presently on the National List at 205.603(d) (3). Vitamins are listed in the OFPA at 6517 (c) (1)(B)(i)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			Vitamins enrich and fortify feed.
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]		X		
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		

6. 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	X	X		Thiamine and biotin and vitamin K are sulfur containing. The other vitamins listed do not contain sulfur (TR 537-539).
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Biologics - Vaccines in aquatic animal production

[+]February 18, 2014

Summary of Proposed Action:
Biologics – Vaccines, except for those produced by excluded methods, are proposed to be added to the National List at 205.611 for use in production of aquatic animals. Section 205.611 of the National List will contain a list of synthetic substances allowed in aquatic animal production.

The petitioner requests vaccines (including vaccines made with excluded methods) for the medical treatment of aquatic animals under a new Section 205.611: Synthetic substances allowed for use in organic aquatic animal production (x) As ….medical treatments as applicable, Biologics-Vaccines.

Section 6509(d)(1)(C) of the Organic Food Production Act (OFPA) authorizes the use of vaccinations as an allowed healthcare practice in the production of organic livestock.

Section 205.238(a)(6) requires that producers of land based livestock must establish and maintain preventive healthcare practices, including administration of vaccines and other veterinary biologics. At the present time organic livestock producers are allowed to use vaccines as provided in Section 205.603(a)(4) Biologics-vaccines. However, vaccines made with excluded methods (GMO) are prohibited as provided in Section 205.105 (e) However there is a specific reference at 205.105(e) providing an allowance for vaccines made with excluded methods if the vaccines are reviewed and recommended for addition to the National List by the NOSB. Such review needs to be conducted in accordance with section 205.600(a), using criteria specified in the Act at 6517 and 6518.

Products containing biologics are regulated by the USDA/APHIS Center for Veterinary biologics.

Most vaccines are injected intramuscularly or orally, although the fish can also be immersed or sprayed. Vaccines are composed of either weakened live or killed pathogens or antigenic components (molecular subunits) of pathogens. The production process begins when the virus/bacteria are replicated from “reference” organisms and grown in a protein growth medium in the laboratory. Vaccines made from excluded methods differ in that their production may be by altering, deleting, adding or otherwise genetically modifying the bacteria or virus.

The Technical Report (TR) differentiates between inactivated and modified live vaccines. Inactivated vaccines contain microorganisms and viruses rendered non-infectious by inactivation. When the inactivated microorganism is bacterial the resulting vaccine is called a bacterin. Inactivated vaccines produced from the supernatant of a bacterial culture or from an inactivated toxin are called toxoids. Formaldehyde is the most widely used agent for inactivating viral, bacterial and parasitic pathogens. Addition of necessary adjuvants which are produced from a wide range of substances including oil water emulsions, aluminum containing compounds and various proteins. Modified live vaccines are produced in a number of ways and can be immunosuppressive. (TR 146-168).

Vaccines are useful in preventing or significantly reducing clinical signs and chronic conditions and preventing spread of disease. They are best administered in the early stage of life. If

injected the fish may need to be sedated somewhat first as this is stressful on the fish and the person administering the vaccination.

Farmed fish, for example fish in net pens or tanks, are living in crowded conditions and vaccination is an excellent preventive for disease control, reducing disease spread into wild fish in the geographic area around.

Internationally vaccines are allowed in aquaculture in the UK , Canada, Japan, Sweden, except for GMO vaccines; The European Union allows GMO vaccines in aquaculture as an exception to their Rule.

Fish breeding, as with land based livestock, can be used to select highly disease resistant breeding lines for farming. Alternative substances and practices can be used to reduce or, in some cases, eliminate the need for vaccines. In the past antibiotics were administered after disease was noted. Fish can be fed herbal remedies or probiotics and other materials to stimulate their natural immune systems. Fish crowding in tanks or net pens can be reduced to avoid disease. Fish can be farmed in more complex multispecies environments. Constant monitoring of fish behavior and general health and "good husbandry" can reduce the likelihood of disease. Fish health in farmed facilities will be largely determined by required standards for organic aquaculture.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on the NOSB Recommendations of standards voted in 2007, 2008 and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	☐ No	☐ N/A

Subcommittee Action & Vote:

Classification Motion: Motion to classify Biologics – Vaccines for Aquatic Animals, as petitioned as synthetic.
Motion by: Jean Richardson
Seconded by: C. Reuben Walker
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list Biologics: Vaccines for Aquatic Animals at §205.611 with the following annotation: except those produced with excluded methods
Motion by: Jean Richardson
Seconded by: Joe Dickson
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Basis for annotation: x☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair to transmit to NOSB February 18, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Biologics-Vaccines (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		In the case of killed and modified live vaccines there is potential for incomplete inactivation for a particular vaccine lot leaving live pathogen and the reversion to virulence of the modified vaccine inadvertently precipitating a new epizootic through vaccination. But the vaccines themselves contain mostly organic material that rapidly degrades in the environment.(TR 656-659) All vaccines under USDA license are manufactured under strictly controlled facilities and stringently regulated under EPA, thus environmentally detrimental waste is unlikely (TR 660-666) Modified live vaccines are desirable and highly effective in closed systems. However the virus is still capable of infection. These vaccines have not usually been considered acceptable due to the environmental risk that non-virulent viruses could revert to virulent forms or that attenuated viruses that are not virulent in vaccinated species could prove virulent to other species in open systems (TR 296-299) Host density plays a critical role in spread of fish disease in the environment among wild and farmed fish. Low host density reduces rate of encounter between susceptible hosts and pathogens. (TR 748-754) and thus much will depend on the scope and detail provided in the yet to be promulgated Standards for Aquaculture.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See 1 above.
3. Are there any adverse impacts on biodiversity? (§205.200)	X			Because live vaccines have a short life span outside the host, environmental damage is not expected from accidental release or shedding from animals (Petition p. 10) and see 1 above.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		The substance falls into the category of a medicine (TR 504)

5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Many chemicals are used in producing fish vaccines. Formaldehyde and ethyleneimine for example are not on the National List, yet they are presently used in production of approved vaccines. Adjuvants are added to vaccines to promote antigenicity and are not considered excipients Polyvalent vaccines should always be used under veterinary supervision as adverse events could occur between vaccines from different sources.(TR 337-353)
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		See 1 and 5 above Some reports have described autoimmune disease development in farmed salmon after vaccination with oil adjuvated vaccines. There is possibility of increased infection with unvaccinated pathogens as a result of vaccine induced autoimmunity. Vaccines can largely reduce risks for large scale animal suffering caused by disease in fish farming.(TR 620-636)
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		See 1 above
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		The aim of vaccines is to prevent mass destruction of large numbers of infected or potentially contagious animals, prevent transmission of diseases to humans, promote good health of animals farmed and wild, and protect the environment. (TR 300-302) Self injection appears to be the most important human health risk from use of fish vaccines. (TR 760-761). All vaccines are rigorously tested in the USA. See also 1 above
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		Vaccination is aimed to imitate natural processes in fish and have been found to be effective. (TR 684-712) Much depends on management of host density farmed in tanks or net pens (TR748) There is one DNA vaccine to control an infectious virus (hematopoietic necrosis) but little is known about impacts of this in net pens or tanks (TR 713-727) Ongoing research will be needed to evaluate impacts after regulations are promulgated. (TR 728-738)
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See 1 and 9 above

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 2. Is the Substance Essential for Organic Production? Biologics-Vaccines (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X	X		Vaccines are created by naturally occurring biological processes including cell culture and fermentation. (TR548-585). However, some vaccines are produced with formaldehyde inactivation, or chemical bonding with adjuvants
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			See 1 above Most of the vaccines approved for use by the USDA for fish are produced by conventional methods starting from natural pathogens gown in culture. (TR 73-86)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			Host density increases the spread of aquatic pathogens in to and within farmed fish populations, and from farmed fish to wild fish. (TR 778-780) There are some alternative substances, but probably not as effective as vaccines. In the past farmed fish were treated with antibiotics when sick. Today the goal is prevention. Use of probiotics and feed additives, herbal extracts etc. can be fed to stimulate natural immune systems (TR 781-806)
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			See 8 above Vaccines should only be administered to healthy fish. Healthy Fish populations for farming can be selected from certain breeding lines. Management and good husbandry can reduce possibility of infection both in open and closed systems. Disease surveillance must be a rigorous aspect of fish farming to avoid disease as far as possible.(TR 25-259)

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 3. Is the substance compatible with organic production practices? Biologics-Vaccines (aquatic animals)

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Biologics-vaccines are allowed in land based livestock production 7 U.S.C.Section 6509(d)(1)(C)) 7 CFR 205. 238(a)(6) Section 205.603(a)(4) Section 205.103(e) excludes vaccines made with excluded methods except as provided in 205.600(a), using criteria at 7 U.S.C Section 6517 and 6518 NOTE that this proposal does NOT propose to add to the National List any vaccine made with excluded methods (GMO)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]		X		
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		
6. 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		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines	X			The substances fall into the category of a medicine (TR 504)
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion – Biologics - Vaccines in aquatic animal production
February 21, 2014

Annotation motion for aquaculture vaccines: Add annotation, "Until May 1, 2019 [or sunset date]."
Justification: Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB needs to reconsider the approval in five (5) years. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to those in water receiving discharges or open water systems; and alterative natural materials and management methods. The review in five (5) years provides an opportunity for the Board to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

In addition, the minority makes the following comments:
The answers (yes/no) checked often do not conform to the evidence presented in the comments/documentation column.

With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:

- The following statements in response to the question, "Is there a probability of environmental contamination during use or misuse?" suggest that the answer should be *yes* instead of *no*:
    - In the case of killed and modified live vaccines there is potential for incomplete inactivation for a particular vaccine lot leaving live pathogen and the reversion to virulence of the modified vaccine inadvertently precipitating a new epizootic through vaccination. (TR 656-659)
    - Modified live vaccines are desirable and highly effective in closed systems. However the virus is still capable of infection. These vaccines have not usually been considered acceptable due to the environmental risk that non-virulent viruses could revert to virulent forms or that attenuated viruses that are not virulent in vaccinated species could prove virulent to other species in open systems. (TR 296-299)
- The following responses to, "Is there potential for detrimental chemical interaction with other materials used in organic farming systems?" suggest that the answer should be *yes* instead of *no*:
    - Many chemicals are used in producing fish vaccines. Formaldehyde and ethyleneimine for example are not on the National List, yet they are presently used in production of approved vaccines. Adjuvants are added to vaccines to promote antigenicity and are not considered excipients. (TR 338-348)
    - Polyvalent vaccines should always be used under veterinary supervision as adverse events could occur between vaccines from different sources. (TR 349-354)
- The following response to, "Is there a toxic or other adverse action of the material or its breakdown products?" suggests that the answer should be *yes* instead of *no*:
    - Some reports have described autoimmune disease development in farmed salmon after vaccination with oil adjuvated vaccines. There is possibility of increased infection with unvaccinated pathogens as a result of vaccine induced autoimmunity. (TR 630-634)
- The following responses to, "Are there adverse biological and chemical interactions in the agro-ecosystem?" indicate that not enough is known to justify the *no* answer:

- There is one DNA vaccine to control an infectious virus (hematopoietic necrosis) but little is known about impacts of this in net pens or tanks. (TR 714-728; 642-656)
- Ongoing research will be needed to evaluate impacts after regulations are promulgated. (TR 728-738)

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Checklist
Micronutrients for use in aquatic plant production

+February 3, 2014

Summary of Proposed Action:
Micronutrients are proposed to be added to the National List at 205.609 for use in aquatic plant production. Section 205.609 of the National List will contain the list of synthetic substances allowed in organic aquatic plant production.

There are 18 to 21 elements (depending on the plant) considered essential for plants to properly grow and develop. Three come from air and water (C, H, O) and the rest must be otherwise supplied. Three are considered primary nutrients (N, P, K), three are considered secondary nutrients (Ca, Mg, S) and the other 12 are considered micronutrients: Fe, B, Cu, Cl, Mn, Mo, Zn, Co, Ni, Na, Se and Cr. Micronutrients are needed by plants at 10 to 100,000 times lower concentrations than primary nutrients.

Previous to the development of micronutrient media for plant aquaculture systems, it was common practice to add aqueous extracts of soil to culture water to supply micronutrients. Today, there are available micronutrient mixtures – such as the Guillard f/2 media – that are commonly added to culture water to supply micronutrients for plant aquaculture. These micronutrient mixtures generally supply six micronutrients: Fe, Cu, Zn, Co, Mn and Mo. However, "deficiencies of one or more additional micronutrients may develop depending upon the source of growing water and the species of aquatic plant in culture" (petition, p.2).

All micronutrients are allowed for use in terrestrial organic crop production with the exception of those containing nitrate or chloride. In terrestrial agriculture, chloride is avoided to avoid salt buildup in the soil. However, in aquaculture, "most water sources, including marine, brackish and fresh water contain much larger amounts of chloride salts than would be added by these nutrients at the very low levels employed" (petition, p. 6). None of the micronutrient formulations listed in the 2010 Micronutrient Technical Report for crop production (lines 59-95) contain nitrate, although several of them contain ammonium (a nitrogen-containing ion). However, at the low levels trace minerals are used at, the amount of nitrogen added with nitrogen-containing micronutrient supplements would be very small.

In terrestrial organic crop production, soil testing is required to document deficiencies before micronutrients can be applied. In aquatic plant production, micronutrients are generally added to culture media at the outset and supplemented occasionally, and "testing of dissolved ionic forms of micronutrients at very low concentrations, other than ferric ions, is extremely difficult or prohibitively expensive" (petition, p.4).

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on the NOSB Recommendations voted in 2007, 2008 and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:** NA

Subcommittee Action & Vote,

Classification Motion: Move to classify micronutrients as petitioned for aquatic plants as synthetic
Motion by: Francis Thicke
Seconded by: C. Reuben Walker
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list micronutrients at §205.609 with the following **annotation**: For non-vascular plants only.

Motion by: Francis Thicke
Seconded by: C. Reuben Walker
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Basis for annotation: x☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 3, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Micronutrients for use in aquatic plant production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		Because micronutrients are used at very low concentrations there is little probability of environmental contamination. Petition (pg.4): “any residual trace elements released into environment will be extremely low concentrations below any physiologically significant level, & will be rapidly absorbed by microorganisms.”

2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		Little specific information is available on micronutrient manufacturing in either the petition or TR, other than that micronutrients are manufactured in many different ways. TR line 323: “Commercial micronutrients are generally manufactured as by-products or intermediate products of metal mining and processing industries.” Petition, page 3: “various trace minerals are obtained from sources in a number of countries, including China. Manufacturing processes are proprietary.”
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Crops TR line 534: “Micronutrients are essential for normal plant growth, but levels above that required for good growth can be toxic and suppress plant growth, and may cause adverse biological or chemical interactions in the agro-ecosystem.” However, there would be no incentive to add micronutrients at higher-than-needed levels for aquatic plant production.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		TR 504-508: reactivity of micronutrients is low towards other chemicals/substances, these components exist naturally in soil; must follow application rates. As noted above, there would be no incentive to apply at rates higher than necessary.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		TR 656-659: micronutrients may be applied as different compounds-most applied micronutrients are simple ionic forms & will not breakdown any further.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		As noted above, micronutrients are simple ions that will not break down further, and they are applied at very low levels, which should be expected to be mostly consumed by the plants.
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		The micronutrients used in aquatic plant production are also essential elements in humane nutrition, so at the levels used they will not be harmful to human health.

9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		TR 545: toxicity could occur if micronutrients are applied in excess. However, in aquatic plant systems they are used at very low levels
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See #9 above.

Category 2. Is the Substance Essential for Organic Production? Micronutrients for use in aquatic plant production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			TR line 323: "Commercial micronutrients are generally manufactured as by-products or intermediate products of metal mining and processing industries."
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Micronutrients are manufactured in a wide variety of ways, generally involving chemical change of mineral sources.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See #2 above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		TR line 867: Most naturally available minerals of micronutrient components not soluble or are only very slowly soluble in water.
6. Is there an organic substitute? [§205.600(b)(1)]		X		Minerals are inorganic
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		See #5.
8. Are there any alternative substances? [§6518(m)(6)]		X		Micronutrients are essential elements for plant growth. There are no alternatives
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		In some cases, recirculating water from other ecological systems could make adding micronutrients unnecessary.

NOSB Evaluation Criteria for Substances Added To the National List: Crops/Livestock

Category 3. Is the substance compatible with organic production practices? Micronutrients for use in aquatic plant production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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	X			
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers	X			

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Carbon Dioxide (CO_2) for Use in Aquatic Plant Production

[+]February 3, 2014

Summary of Proposed Action:

Synthetic carbon dioxide is proposed to be added to the National List at 205.609. Section 205.609 will contain a list of synthetic substances allowed in organic aquatic plant production.

Carbon dioxide is an inorganic compound composed of one carbon atom and two oxygen atoms. In nature, carbon dioxide occurs as a gas and comprises 0.03% of the Earth's atmosphere. It is utilized by plants during photosynthesis and is produced by respiration by animals and plants. It is an important component of the carbon cycle and is also a well-known greenhouse gas.

The petition is for the use of carbon dioxide to grow algae within contained systems such as ponds and tanks. Petitioned use is for synthetic carbon dioxide due to the difficulty in buyers determining the source of CO_2. However there are naturally occurring sources of CO_2 available in some parts of the country.

CO_2 gas is used in the culture of aquatic plants as a production aid for alkalinity adjustment and maintaining pH at levels essential for rapid and healthy growth of the algae. Most, if not all, algae species are sensitive to pH levels. Carbon dioxide is used to maintain desired pH levels in water. The addition of CO_2 to water drives the pH value lower. Carbon dioxide is consumed by algae as cultures grow and can drive the pH level above the desired optimum. Since aquatic animals eliminate carbon dioxide as a metabolic product, the presence of aquatic animals in an algal culture reduces demand for carbon dioxide.

Carbon dioxide is available from natural sources and as a byproduct of various artificial sources. The most common operations from which commercially produced carbon dioxide is recovered are industrial plants which produce hydrogen or ammonia from natural gas, coal, or other hydrocarbon feedstock, and large-volume fermentation operations in which plant products are made into ethanol for human consumption, automotive fuel or industrial use. Breweries producing beer from various grain products are a traditional source. Corn-to-ethanol plants have been the most rapidly growing source of feed gas for CO_2 recovery.

Carbon dioxide is allowed for use under all international organic standards that were researched in an August 2006 technical report including Canadian, CODEX, EEC Council and IFOAM. However, it should be noted that at the time of that technical report, organic standards were not in place for organic aquatic plant production, and the allowed uses of carbon dioxide were for processing aids, pest control and terrestrial plant production.

While the petition is for synthetic carbon dioxide, the petitioner has made it clear that the reason for the request to include synthetic CO_2 is because of the variable availability around the country, rather than because synthetic is the only source.

Per the 1995 NOSB TAP review, CO_2 poses little risk to the environment and was unanimously determined to be consistent with a system of sustainable agriculture. At that time, the petitioned use was for addition to the National List at 205.605 for use in organic handling. The present petition is for use in aquatic plant production and therefore should be evaluated with different considerations. It could be argued that production methods that require continued external inputs may not be sustainable.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on NOSB recommendations of standards voted in 2007, 2008, and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	X Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	X Yes	☐ No	☐ N/A
3. Compatibility & Consistency	X Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Motion to classify Carbon Dioxide, CAS # 124-38-9, as synthetic
Motion by: Tracy Favre
Seconded by: Joe Dickson
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Listing Motion: Motion to list CO_2 at §205.609 with the following **annotation**: for use in contained systems such as tanks and ponds.
Motion by: Tracy Favre
Seconded by: Calvin Walker
Yes: 4 No: 1 Absent: 2 Abstain: 0 Recuse: 0

Basis for annotation: **X** To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 3, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Carbon Dioxide for use in Aquatic Plant Production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		Carbon dioxide can be classified as either synthetic or non-synthetic depending upon source, and is a naturally occurring component of air. High concentrations can lower the pH of water, which could adversely affect the environment. However, good management practices would mitigate this possibility. (Petition 2012).
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X.			Production of carbon dioxide is a by-product of processes that have adverse effects on the environment. However, because CO_2 is a by-product of these processes, these affects would occur regardless of CO_2 production. (Aug 2006 TR, lines 296-299).
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Under good management practice carbon dioxide for use in aquatic plant production is self-limiting, as too much CO_2 decreases plant production and lowers water pH. (Petition, 2012) So impacts to biodiversity are unlikely.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		CO_2 can exist in gaseous, liquid or solid forms but does not contain inerts. All manufacturing processes require purification (Aug 2006 TR, lines 188-189)
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		High concentrations of CO_2 will decrease water pH and make some nutrients bio-unavailable, but under normal good management practices, it is unlikely there would be detrimental chemical interactions. (Petitioner) See #3 above regarding self-limiting.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		CO_2 can be long-lived in the environment and therefore could contribute to climate change but otherwise poses no adverse action upon breakdown.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Carbon dioxide is a greenhouse gas (Aug 2006 TR, line 299), however, under proper management for aquatic plant production, CO_2 would be metabolized by aquatic plants. (Petitioner)

8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		At levels proposed for use by the petitioner, under normal good management practice, there is no demonstration of harmful effects to human health or the environment. In high concentrations in closed systems, there is a possibility of atmospheres dangerous for humans, but good management practices are likely to mitigate this possibility. Up to .05% is considered not harmful to humans. However, higher concentrations can be harmful. (Aug 2006 TR, lines 306-307) No evidence was found indicating that carbon dioxide leaves residues on food. (Aug 2006 TR, lines 354-356). Carbon dioxide is on the list of FDA confirmed GRAS substances. (Aug 2006 TR, lines 348-349)
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		On the contrary, good management of CO_2 levels leads to increased plant production and biodiversity. Only at high concentrations could CO_2 potentially have a negative impact. (Petitioner)
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See comment above.

Category 2. Is the Substance Essential for Organic Production? Carbon Dioxide for Use in Aquatic Plant Production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		Carbon dioxide is an inorganic compound composed of one carbon atom and two oxygen atoms. In nature, carbon dioxide occurs as a gas and comprises 0.03% of the Earth's atmosphere. It is utilized by plants during photosynthesis and is produced by respiration by animals and plants. It is an important component of the carbon cycle and is also a well known greenhouse gas. (Aug 2006 TR, lines 17-21) Petitioned use is for synthetic Carbon Dioxide due to the difficulty in buyers determining the source of CO_2. However, while non-agricultural, there are naturally occurring sources of CO_2 available in some parts of the country. (Aug 2006 TR, lines 240-252)

2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			There are numerous methods by which CO_2 can be produced, including fermentation and as a by-product of oil and gas production. (Aug 2006 TR, lines 226-229)
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			In some cases, CO_2 production is a result of manufacturing processes, such as ethanol or oil and gas refining processes. (Aug 2006 TR, lines 178-201)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X			CO_2 can result from metabolic process of plants and animals and from some fermentation processes. (Aug 2006 TR, lines 203-207, 234-238)
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			Naturally occurring CO_2 does exist in deposits located in Mississippi, Colorado, and New Mexico, Utah, Wyoming and Washington, but transport of pressurized gas over long distances is not advised, and therefore may not be available in some parts of the country. (Aug 2006 TR, lines 178-201)
6. Is there an organic substitute? [§205.600(b)(1)]		X		Citric acid can be used in soil based operations but for aquatic environments, there is no known substitute. (Petitioner)
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Naturally occurring as a result of biological processes of animals, additionally natural sources of CO_2 are available on a regional basis. (Petitioner)
8. Are there any alternative substances? [§6518(m)(6)]		X		There are no known substitutes. While there are non-synthetic forms of carbonate such as sodium bicarbonate and sodium carbonate that can lower pH values in water, these substances do not lower pH to values below 8.5 that are necessary for most species of algae. For aquatic plant production, CO_2 is essential for proper plant health and productivity. When aquatic plant production is paired with animal production, the requirement for additional CO_2 is reduced. (Petitioner)
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		See comment #8 above, however it is difficult to properly maintain water pH in aquatic plant production without the use of CO_2 . Alkalinity and pH control is essential in the culture of aquatic systems. All, or virtually all, aquatic plants require carbon dioxide for healthy and rapid growth. There are no substitute substances, nor are there alternative culture methods. (Petitioner)

Category 3. Is the substance compatible with organic production practices? Carbon Dioxide for Use in Aquatic Plant Production

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Per a 2005 TAP review, CO_2 is consistent with organic farming and handling. CO_2 is already listed on the National List for use in organic handling at 205.605. Carbon dioxide is allowed for use under all international organic standards that were researched including Canadian, CODEX, EEC Council and IFOAM. However, it should be noted that at the time of the technical report, organic standards were not in place for organic aquatic plant production, and the allowed uses of carbon dioxide were for processing aids, pest control and terrestrial plant production (Aug 2006 TR, lines 127-171)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X	X		Per the 1995 NOSB TAP review, CO_2 poses little risk to the environment and was unanimously determined to be consistent with a system of sustainable agriculture. At that time, the petitioned use for or addition to the National List at 205.605(b) for use in organic handling. The present petition is for use in aquatic plant production and therefore should be evaluated with different considerations. While the petition is for synthetic Carbon Dioxide, the petitioner has made it clear that the reason for the request to include synthetic CO_2 is because of the variable availability around the country, rather than because synthetic is the only source. It could be argued that production methods that require continued external inputs may not be sustainable.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	

5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion - Carbon Dioxide for Use in Aquatic Plant Production
February 23, 2014

A minority of the subcommittee suggests that it is appropriate to adopt an annotation for carbon dioxide in aquaculture, with a justification explaining the that the specific time frame of five (5) years for an expiration date allows the Board to monitor the use of the material, incentivize alternatives, update its scientific and essentiality review, and vote on the continuation of use pending the receipt of a petition requesting that use be continued.

Support for the annotation is based on the following justification: Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time. Therefore, the NOSB needs to reconsider the approval in five (5) years at the least. Current consideration of the material has raised issues relating to health or environmental impacts; alternatives derived from natural sources; and compatibility with organic and sustainable agriculture.. The review in five (5) years provides an opportunity for the Board to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

The NOSB Principles of Organic Production and Handling (adopted October 17, 2001) begin:

Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible,

through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

To provide a major component necessary for aquatic plant growth in the form of a synthetic chemical is inconsistent with organic principles.

The Crops Subcommittee received information that indicates that additions of synthetic carbon dioxide are not essential. An NOP survey of certifiers who certify organic aquatic plant production found that very few inputs were used. Sometimes natural alkali, carbon dioxide, and sodium bicarbonate were used. Integrated systems[1] control pH and alkalinity, as well as other parameters, by balancing the organic components of the system.

While carbon dioxide may not seem very hazardous, the atmospheric concentration has reached the all-time high of 400ppm, elevating to extreme levels the threat of global climate change. Organic production may not be a large contributor, but the use of synthetic carbon dioxide, which is not captured, as opposed to using carbon dioxide produced by animals in the system, does contribute to the problem.

Finally, lacking an organic aquaculture policy for plant production introduces a further difficulty in creating the parameters necessary to establish systems that are compatible with the Organic Foods Production Act and resulting organic methods. Evaluating the use patterns of synthetic materials permitted on the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which no synthetics are added.

The petitioner has indicated that carbon dioxide for use in organic production of aquatic plants would be used only in closed systems. We believe that use of this substance in closed systems with no discharge to natural water bodies is vital to be added to the motion for the carbon dioxide proposed recommendation.

[1] See, for example, Siew-Moi Phang, 1992. Role of algae in livestock-fish integrated farming systems. Proceedings of the FAO/IPT Workshop on Integrated Livestock-Fish Production Systems, 16–20 December 1991, Institute of Advanced Studies, University of Malaya, Kuala Lumpur, Malaysia.

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Chlorine Materials in Aquatic Plant Production

[+]February 18, 2014

Summary of Proposed Action:
Chlorine Materials are petitioned for use in aquatic plant production, to be added to *205.609 - Synthetic substances allowed for use in organic aquatic plant production* as follows:

§ 205.609 Synthetic substances allowed for use in organic aquatic plant production.
(a) As disinfectants and sanitizers.
(x) Chlorine materials— Except, That, residual chlorine levels in water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act
(i) Calcium hypochlorite
(ii) Chlorine dioxide
(iii) Sodium hypochlorite

Chlorine materials are widely used for their disinfectant properties, and are currently approved for such uses in crop, livestock and processed organic product production. The annotations on the National List for livestock and handling limit the use of chlorine materials to disinfection and sanitation, and require that residual chlorine levels be consistent with Safe Drinking Water Act levels. The current listing for use in crops at 205.601(a) states:

(2) Chlorine materials—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

The NOP has also clarified the use of chlorine in production and handling in a guidance document, NOP 5026.

The Livestock and Crops Subcommittees have received a petition for the use of Chlorine Materials in aquatic livestock and plant production. This checklist and proposal relate to the proposed use in aquatic *plant* production; a separate checklist evaluates the petitioned use in aquatic animal production. These materials are used in aquatic plant production for the disinfecting hard surfaces and culture water in nurseries, growout operations with tanks, harvest equipment, and in processing facilities. Because the petitioned uses of chlorine are identical for aquatic plants and animals, this checklist follows the same logic as the Livestock Subcomittee's proposal for chlorine in aquatic animal production. Given that the materials' use in aquaculture applications is identical to existing uses in other production categories, the Livestock committee did not requested a new Technical Evaluation Report for the petitioned use in aquatic animal production, but instead relied upon recent TR's developed for Handling and Crops uses of this group of materials. The crops committee did request a TR for chlorine as part of the 2012 sunset review of the material, and that 2011 TR has be utilized in the preparation of this checklist.

During the subcommittee discussion and vote, several members raised concerns as to whether the petition and technical review adequately address the question of whether this material is essential in aquatic plant production, or whether functional and commercially viable alternative disinfectants and sanitizers exist. The subcommittee specifically requests public comment from any knowledgeable stakeholders in this particular area.

It should also be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on the NOSB Recommendations of standards voted in 2007, 2008 and 2009.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied?**		
1. Impact on Humans and Environment	X Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	X Yes	☐ No	☐ N/A
3. Compatibility & Consistency as Organic (only for § 205.606)	X Yes	☐ No	☐ N/A

Proposed Annotation (if any): see listing motion below

Basis for annotation: X To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes: This annotation is consistent with other listings of Chlorine on the NL, and ensures that any environmental impact is effectively mitigated.

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Chlorine Materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) are synthetic.

Motion by: Joe Dickson
Seconded by: Colehour Bondera
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list chlorine materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) at §205.609 with the following annotation: Chlorine materials - Disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

Motion by: Joe Dickson
Seconded by: Jean Richardson
Yes: 6 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to Transmit to NOSB February 23, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		2006 Crops TR lines 212-266. The TR identities several areas of potential environmental impact, but notes that existing EPA regulations and the annotation restricting effluent to the levels of the Safe Drinking Water Act are sufficient to mitigate any environmental impact. The petitioner and a number of producers have confirmed that chlorine materials are not used in direct contact with the environment (e.g. ponds and net pens) and the restrictive annotation would prohibit such uses regardless. The 2011 Crops TR (lines 225-306) is consistent with the 2006 TR.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See Question 1
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No. [2006 Crops TR; 2011 Crops TR]
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water. Any presence of the substance in the overall agroecosytem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.

6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		No. The substance degrades rapidly to naturally occurring compounds in the presence of air and sunlight [2006 Crops TR 417-432] This TR also confirms (in lines 384 –402) that these materials are not persistent in the environment in general, and that in water and soil, sodium and calcium hypochlorite separate into sodium, calcium and hypochlorite ions. Chlorine dioxide is also reactive and breaks down quickly. While the TER does not directly address its fate in aquatic environments, again, the annotation would limit the extent to which any chlorine material could be discharged into sea water or any other part of the environment. The 2011 Crops TR (lines 381-390) is consistent with the 2006 TR.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See Q # 1
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		Any presence of the substance in the overall agroecosytem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		The substance is not used in direct contact with soil or terrestrial livestock. It is only used in contact with hard surfaces and equipment, or culture water. [2006 Crops TR 322-327, petition]

Category 2. Is the Substance Essential for Organic Production? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Yes. 2006 TR Lines 149-171. 2011 TR Lines 183-211.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]			X	This process does not involve the chemical transformation of a natural substance; the starting materials are synthetic. 2006 TR Lines 177-178. 2011 TR Lines 216-217.

4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		2006 TR Lines 183-184. 2011 TR Lines 222-223.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	2006 TR Lines 183-184. 2011 TR Lines 222-223.
6. Is there an organic substitute? [§205.600(b)(1)]			X	2006 TR Lines 183-184. 2011 TR Lines 222-223.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		While the 2011 TR does list a number of potential alternatives (lines 519-530), the petition (pages 7-8) describes compelling limitations of the alternatives.
8. Are there any alternative substances? [§6518(m)(6)]		X		See #7
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		2011 TR Lines 611-628. None of the alternatives are effective for cleaning irrigations systems.

Category 3. Is the substance compatible with organic production practices? Chlorine Materials

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			The evaluation criteria above shows that the material is essential in organic aquatic plant production and, as petitioned, does not present adverse effects on humans or the environment.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See #1
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	

6. 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			X	
toxins derived from bacteria			X	
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals			X	
livestock parasiticides and medicines			X	
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers			X	

Minority Opinion - Chlorine Materials in Aquatic Plant Production
February 20, 2014

A minority of the subcommittee suggested that the subcommittee adopt an annotation motion for chlorine use in aquaculture for plants that set a 5-year expiration date on the listing, with a justification explaining that the specific time frame for an expiration date allows the Board to monitor the use of the material, update its scientific and essentiality review, incentivize alternatives and continuous improvement, and vote on the continuation of use pending the receipt of a petition requesting that use be extended.

Support for the annotation motion is based on the following justification: Since the petition for chlorine use in aquaculture certified organic is being considered in the absence of regulations defining acceptable defined practices in organic aquaculture, essentiality in particular cannot be judged at this time. Therefore, the NOSB needs to reconsider the approval in five years at the least. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to chlorine manufacture; alternatives under consideration by EPA's Design for the Environment and the Toxics Use Reduction Institute; and compatibility with organic and sustainable agriculture. The review in 5 years provides an opportunity for the Board to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material during its petition review.

In addition, the minority makes the following comments and additions to the majority checklist, which it believes does not provide a full assessment of environmental and health standards review required under the Organic Foods Production Act (OFPA): There are two separate uses covered by the petition – (1) disinfection of hard surfaces, and (2) disinfection of culture water. These two uses are distinct, and the distinction is blurred by the motion of the subcommittee.

The use for disinfecting hard surfaces is similar to the allowed use in terrestrial crop production. It is specifically mentioned as a use included as a "production aid" in OFPA. Such use results in limited effluent, and the major difference between it and the current §601 listing is that aquaculture facilities are likely to be closer to water that could be contaminated by effluent. The use for disinfecting culture water, on the other hand, involves much greater quantities of water,

potentially larger discharges, and the possibility for spills into waterbodies. It is not a "production aid" use. The Technical Review (TR) does not address hazards associated with such a use in questions #4-8. Alternatives for the water disinfection use are not discussed in questions #12-14. We cannot be sure what such a use would be in the aquaculture setting until we have aquaculture standards (for example, what is the agro-ecosystem in question?)

With regard to alternatives, there are now resources associated with "Green Chemistry" programs, such as the Toxics Use Reduction Institute at the University of Massachusetts in Lowell, and the Design for the Environment program at EPA that address chemical alternatives to chlorine as a disinfectant when such nonchemical approaches as steam are not appropriate. These need to be considered in evaluating alternatives. See, for example, the following websites: The Presidential Green Chemistry Challenge Awards Program p. 30 (p. 34 of pdf); Overview of Design for the Environment, disinfectants p. 20; Green Product Certification and Labeling: Quick Reference.

Further, the petitioner has indicated that all materials petitioned for use in organic production of aquatic plants would be used only in closed systems. Therefore, an annotation should be added restricting the use of chlorine to closed systems with no discharge into natural waterbodies.

With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:

- Effluent standards are set under the Clean Water Act (CWA), so there is a disconnect between allowances under the SDWA and impacts on wildlife under the CWA. The SDWA standard of 4 mg/L is 363 times as high as the aquatic life protection criterion of 11 ug/L set under the CWA.[1] Neither, however, equates to the OFPA criterion of "no harm" and the fact that aquaculture systems are closer to water that could be contaminated by effluent than terrestrial agricultural systems raises unique concerns that require close scrutiny and not reliance on other standards for terrestrial production.
- Misuse can kill plants and soil organisms and raise soil pH and kill fish and invertebrates (2011 Crops TR lines 386-390; 270-271)
- TRI data includes 5.7 million pounds of chlorine per year released by facilities making and using chlorine. (ATSDR Tox Profile p. 162)
- When mixed with organic materials (e.g., algae, dirt), hypochlorite produces trihalomethanes (THMs), which are carcinogenic. Currently, the maximum contaminant level (MCL) for total THMs is 0.080 mg/L (EPA 2009). (2011 Crops TR lines 277-280) Depending on the source of water, this could result in the presence of THMs in culture water and its concentration in algae when used to disinfect water. (Chloroform MSDS http://datasheets.scbt.com/sc-239527.pdf)
- Due to high reactivity, the petitioned substances do not persist in the environment. But many products are possible from reactions, and some may be persistent. This is particularly an issue for water disinfection. (2011 Crops TR lines 476-491)
- Human health effects of chlorine include burning, pain, inflammation, irritation to respiratory system, etc. (2011 Crops TR lines 496-514)
- Chlorine may harm the beneficials inherent in an aquaculture system when used to disinfect water, or when discharged. (2011 Crops TR, lines 270-271)
- Chlorine compounds are used to kill algae, an important part of the aquatic ecosystem. (2011 Crops TR, lines 62, 87)

[1] EPA Ambient Water Quality Criteria for Chlorine, http://water.epa.gov/scitech/swguidance/standards/upload/2001_10_12_criteria_ambientwqc_chlorine1984.pdf

With regard to checklist Category 2, Essentiality, the minority believes the following need to be considered:

- "[T]he following non-synthetic materials are allowed as drip irrigation cleaners and could be used on hard surfaces: acetic acid, vinegar, citric acid, and other naturally occurring acids." (2011 Crops TR 519-520)
- The petition does not describe any limitations of alternative substances. It simply states that the alternatives are not used. The petition also does not distinguish between the disinfection of equipment and water. Some alternatives may be useful for one and some the other.
- Other alternative substances are hydrogen peroxide, electrolyzed water, alcohols, peracetic acid, copper sulfate, and soap algaecides for hard surfaces. Ozone for water disinfection (2011 Crops TR 535-606) See EPA Green Chemistry award for alternatives.[2]
- For other practices, see Toxics Use Reduction Institute CleanerSolutions Database.[3]

Under Category 3, Compatibility, the minority points out the following:

- Chlorine does not enhance water life and properties; is not from renewable resources; and has negative impacts on biodiversity. (2011 Crops TR 270-271, 278-279, 349-352).
- Natural alternatives exist. (2011 Crops TR 270-271, 278-279, 349-352, 519-530)
- The use for culture water disinfection is not included in any of the OFPA categories of §6517(c)(1)(B)(i).

[2] The Presidential Green Chemistry Challenge Awards Program Summary of 2005 Award Entries and Recipients, p. 30. http://www.epa.gov/greenchemistry/pubs/docs/award_entries_and_recipients2005.pdf Almost all traditional, widely used disinfecting and sanitizing products contain ingredients that are toxic or potentially toxic, are environmentally hazardous, or have a high potential for accidents. For example, oxidizing chemicals, such as hypochlorite, peracetic acid, hydrogen peroxide, ozone, and chlorine dioxide, kill microorganisms by indiscriminate oxidation of organic matter, potentially destroying antioxidants, nutrients, and vitamins while forming unknown or toxic byproducts, including cancer-causing free radicals. The non-oxidizing microbicidal quaternary ammonium compounds (QACs; other traditional disinfectants) inhibit butyl cholinesterase in blood plasma, liver, pancreas, and the white matter and are unsafe for use on fruits and vegetables because they leave large residues.

Microcide uses ingredients listed by the FDA and EPA in volumes 21 and 40 of the Code of Federal Regulations (CFR) as biodegradable, generally recognized as safe (GRAS), food additives, safe, and/or nonpolluting. With these ingredients, Microcide develops broad-spectrum microbicidal products as alternatives to toxic and oxidizing chemicals for the food processing, personal care, and health industries. Their products use surface-active agents at low pH. Raising the pH diminishes the microbicidal properties, allowing safe environmental disposal and biodegradation of the products after use. These products selectively kill microorganisms on food-contact surfaces, on fresh fruits and vegetables, and on body parts (including mucosal and skin surfaces) without covalent chemical reactions. The technology presents alternative products safe for manufacturing, transportation, and use without accident potential. Two of Microcide's products, PRO-SAN and PRO-SAN L, are EPA-registered pesticides.

[3] http://www.turi.org/Our_Work/Cleaning_Laboratory/Does_It_Clean/CleanerSolutions_Database

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Lignin Sulfonate in aquatic plant production

[+]January 21, 2014

Summary of Proposed Action:

Synthetic lignin sulfonate is proposed to be added to the National List at 205.609 for use only as a chelating agent for micronutrients used in aquatic plant production. Section 205.609 of the National List will contain the list of synthetic substances allowed in organic aquatic plant production.

Synthetic lignin sulfonate is presently approved for use in organic (soil based) crop production as a plant or soil amendment (chelating agent), and as a dust suppressant 205.601(j)(4), and as a floating agent in post-harvest handling (205.601(l)(1)).

Chelating agents are water soluble compounds that have the ability to bind with metal nutrients. The soluble nature of the chelate molecule facilitates root and cell uptake of metal nutrients. Because most micronutrients are metals (e.g., iron, cobalt, zinc, etc.), many fertilizers with micronutrients contain some form of chelating agent.

Micronutrients are essential nutrients to maintain growth, maturation and disease resistance. Micronutrients must be chelated to become available for aquatic plants. Mineral deficiencies result from inadequate intake and lead to poor plant growth.

Lignin sulfonate is a by-product of the wood pulping industry. It is a derivative of lignin, where lignin has been sulfonated in the wood pulping process. There are a number of methods for pulping wood, such as sulfite chemical pulping, the acidic sulfite process, and the Kraft pulping process. Typically the process consists of cooking softwood chips under pressure in sulfur dioxide–containing liquors. Sulfonated lignin is the liquid by-product in the spent liquor when the pulping process is complete.

Although “Lignin Sulfonate” is the petitioned material it actually complexes into several salts, each with a separate CAS number, namely: sodium lignosulfonate; magnesium lignosulfonate; ammonium lignosulfonate; and calcium lignosulfonate. The Organic Materials Review Institute (OMRI) places restriction on use of ammonium lignosulfonate, but otherwise lignin sulfonate can be used with any allowed micronutrient. Petitioner requests addition to National List of sodium lignosulfonate with CAS numbers 8061-51-6 and 9009-75-0, and lignin sulfonic acid, CAS 8062-15-5 which forms a “sulfonate” when chelated to a metal.

Lignin sulfonate salts are soluble in water. Due to their high biological demand (BOD) during breakdown in water, lignosulfonates will remove dissolved oxygen from waterways, and decreased pH may result from lignin sulfonate decomposition in water. Lower pH levels can increase the level of some metals, such as mercury, in aquatic systems leading to higher exposures in fish. However, when lignin sulfonates are used as chelating agents to bind micronutrients for production of algae the amounts used are extremely small, with chelated micronutrients maintained at levels of microgram moles per litre, parts per billion. Further, such use occurs in completely closed systems such as glass flasks, containers, on-shore tanks and ponds, and not in open water. For these reasons, the environmental impact of using lignin sulfonate in these kinds of systems is expected to be minimal or negligible

In reviewing whether use of synthetic lignin sulfonate is compatible with organic agriculture the subcommittee took into consideration the Organic Foods Production Act (OFPA) which limits use of synthetics to various categories one of which is “copper and sulfur compounds” and lignin sulfonate is listed by inference as part of that group.

In determining if the petitioned substance is essential to organic agriculture the subcommittee reviewed availability of any natural, non synthetic alternative material given that OFPA states that “To be sold or labeled as an organically produced agricultural product under this title, an agricultural product shall (1) Have been produced and handled without the use of synthetic chemicals except as otherwise provided in this title;……” (6504 (1)). Nonsynthetic chelating agents include citric acid. However citric acid is also a nutrient source for algae and when used as a trace mineral chelator it can cause high levels of trace minerals to accumulate in the plant tissue. Nonsynthetic amino acids, humates, fulvates and organic root exudates can be used in soil environments, but presently it is not known if these soil substances would work in aquatic conditions. Therefore there are presently no known alternatives to synthetic lignin sulfonate as a chelating agent which would permit adequate nutrient uptake by micro and macro algae in aquatic containers.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on NOSB Recommendations of standards voted in 2007, 2008 and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	No	☐ N/A

Substance Fails Criteria Category: Comments: N/A

Subcommittee Action & Vote

Classification Motion: Move to classify Lignin Sulfonate CAS numbers: 8062-15-5 (lignin sulfonic acid), 8061-51-6 (sodium lignosulfonate/ lignin sulfonic acid sodium salt) and 9009-75-0 (sodium lignosulfonate), as synthetic.

Motion by: C. Reuben Walker
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list Lignin Sulfonate (CAS #s: 8062-15-5 (lignin sulfonic acid), 8061-51-6 (sodium sulfonate/lignin sulfonic acid sodium salt), and 9009-75-0 (sodium lignosulfonate), as chelating agents at §**205.609** of the National List

Motion by: C. Reuben Walker
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): none

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 21, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Lignin Sulfonate for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse,? [§6518(m)(3)]		x		Lignin sulfonates are soluble in water with potential for decrease in BOD and pH (TR 332-226), but with chelated micronutrients maintained at levels of microgram moles per litre, parts per billion, (Petition p. 3) and used in completely closed tanks, or containers for algae production, environmental damage through use or misuse is unlikely.
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		x		Lignin sulfonates are bi-products of the Paper Industry. There are several processes used for production of lignin sulfonates: sulfite chemical pulping, the Kraft process, acid sulfite pulping (TR 239-258). While there may be adverse impacts from high levels of lignin sulfonates, normal use indicates no evidence of toxicity. (TR 300-330). Concerns about presence of dioxins and furans in lignin sulfonates produced by the Kraft process have largely been put to rest, with tests indicating non-detect levels (TR 339-348). Large spills of paper mill effluent could negatively impact nearby waterways and environmentally sensitive area (TR 366-368). Production of chelated micronutrients may require that dump water containing lignosulfonates be processed in a treatment system.
3. Are there any adverse impacts on biodiversity? (§205.200)		X		See 1 and 2 above

4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		x		Lignin sulfonate is listed by inference as part of the group "copper and sulfur compounds" in the OFPA Section 6517 c)1) B) i) and Lignin sulfonate is a synthetic inert ingredient that is not classified by EPA as an inert of biological concern. And it is exempt from requirement of tolerance under 40 CFR parts 180.910 and 180.930 (TR 227-232)
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		x		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		As noted in 1 and 2 above. Lignin sulfonates are water soluble so it is possible for dissolved lignosulfonates to enter waterways through direct contamination or run off from land surfaces, and lignosulfonates may be toxic to fish (TR 332-337) However, in the ppb amounts and enclosed containers/tanks to be used no concerns are raised in the TR
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		As noted in 1 and 2 and 5 above. Little information is available on bioaccumulation of lignosulfonates (TR 276-278) Lignosulfonates break down in soil in about a year
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		There is no research indicating any negative human health impacts (TR 491-496) Environmental impacts are noted in 1, 2, & 8

9. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		x		Lignosulfonates discharged into water bodies may cause foaming and discoloration (TR 274-276) and may contaminate waterways following rain events (TR 370-373). Due to their high biological oxygen demand (BOD) during breakdown in water, lignosulfonates increase acidity, lower oxygen and can lead to benthic changes, and decreased biodiversity unless properly monitored and regulated with the goal of increasing biodiversity in open systems and can corrode aluminum in absence of calcium. (TR 452-454). However, chelated micronutrients for micro and macro-algal production will be used in completely closed containers and there should be no ecosystem or biodiversity impact .
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		x		See 6 and 8 above. Lignosulfonates used as chelating agents in aquatic plant production are used in entirely enclosed containers and should not run off onto soils.

Category 2. Is the Substance Essential for Organic Production: Lignin Sulfonate for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		See 3 below
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR 239-258, and Petition p. 5
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	x			Lignin sulfonate is a by-product of paper pulping and thus has already been chemically altered prior to use as a chelating agent in production of micronutrients for algae production
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		See 3 above
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		Lignin occurs naturally in wood, but lignin sulfonate does not have a natural source.
6. Is there an organic substitute? [§205.600(b)(1)]		x		

7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		x		Nonsynthetic amino acids and nonsynthetic citric acid are allowed for use as chelating agents (TR 544-547) However, Citric acid is non-functional in aquatic environments and could lead to micronutrient toxicity due to uptake of excess citric acid and attached metals. Naturally occurring chelates include humates, fulvates and organic root exudates in soils (TR 585-590), but are not available and cannot be used in aquatic substrate.
8. Are there any alternative substances? [§6518(m)(6)]		x		See 7 above
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		None provided in Petition or TR for aquatic production. Further, it should be noted that micronutrients are essential for aquatic plant growth, and can only be taken up by plants if chelated.

Category 3. Is the substance compatible with organic production practices? Lignin Sulfonate for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			Lignin sulfonate is presently on the National List as chelating agent in plant or soil amendments. At present there are no federal standards for aquatic plant production
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			As in 1 above and 6 below
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			x	
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]			x	
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			x	

6. 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	x			Lignin sulfonate is listed by inference as part of the group “copper and sulfur compounds” in the OFPA section 6517(c)(1)(B)(i)
toxins derived from bacteria		x		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		x		
livestock parasiticides and medicines		x		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		x		

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Vitamins in aquatic plant production (B1, B12, and H)

[+]February 18, 2014

Summary of Proposed Action:

Synthetic vitamins B1, B12 and H are proposed to be added to the National List at 205.609 for use in production of aquatic plants. Section 205.609 of the National List will contain a list of synthetic substances for use in the production of aquatic plants.

Healthy plant growth in water and on land depends on the level of nutrients available in plant environment. Synthetic vitamins (B1, C and E) are presently on the National List at 205.601(j)(8) as plant or soil amendments. Vitamins B1 (Thiamine), Vitamin B12 (Choline), and Vitamin H are the only vitamins being petitioned and for use in organic aquatic plant production, and only for use in closed systems.

The manufacture of vitamins can be by chemical processes, fermentation or extraction depending on the specific vitamin. Fermentation can be synthetic or non-synthetic. Vitamins should not be considered persistent in marine environments. Adverse effects due to persistence are more likely to be seen in closed systems.

Synthetic vitamins are not specifically manufactured for use in aquatic plant production. However, the vitamins proposed for use in aquatic plants production are produced from the same type of processes and manufacturers of vitamins for organic livestock.

In reviewing whether vitamins are compatible with organic farming the subcommittee took into consideration the Organic Food Production Act (OFPA) which limits the use of synthetics to various categories, one of which is “pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins, and minerals.” Vitamins are listed in the OFPA at 6517(c)(1)(B)(i).

The NOP received the petition for the use of synthetic vitamins in aquatic plants on August 3, 2012. The Crops subcommittee deemed the petition sufficient on June 16, 2013; no technical review (TR) was requested. In October, 2013, the aquatic petitions were transferred to the Livestock Subcommittee to be considered as a group. The crops subcommittee did not request a TR because vitamins are already allowed at §205.603(d)(3) for livestock feed, and specific ones (B1, C, and E) are allowed for crops at §205.601(j)(8).TR references in this Checklist are from the TR dated April 29, 2013 requested by the livestock subcommittee for vitamin use in production of aquatic animals.

The NOSB seeks public input on the essentiality of the use of vitamins in aquatic plant production.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic or animal production and this proposal is based on NOSB Recommendations of Standards voted in 2007, 2008, and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:** N/A

Subcommittee Action & Vote.

Classification Motion: Motion to classify vitamins (B1, B12, and H), as petitioned, as synthetic:

Motion by: Jean Richardson
Seconded by: Colehour Bondera
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list vitamins (B1, B12 and H) at §205.609 of the National List

Motion by: C. Reuben Walker
Seconded by: Jean Richardson
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation: None proposed

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 18, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		Vitamins are dissolved in growing media for aquatic plants in very dilute solutions ranging from 0.4-0.02 ppm. Media and plant cultures are in containers, such as on-shore tanks and ponds. The petitioner does NOT seek allowance for synthetic vitamins for production of aquatic plants in public waters. (Petition page 2). It is unlikely that vitamin use or misuse will result in environmental impairment due to their short half lives in aquatic systems. (TR 972-973 and 807-829). Large amounts of vitamins released into open waters may result in promotion of algal blooms and red-tides (TR 986-987) and perhaps eutrophication (TR 1075-1079). Overall, accidental release of small amounts of vitamins into the environment is not assumed to pose any significant risk (TR 982-983).
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See 1 above. Industrial production of synthetic vitamins includes use of reagents and fermentation waste which can have negative environmental impacts, but no specific examples of such contamination are cited in TR (TR 945-987).
3. Are there any adverse impacts on biodiversity? (§205.200)		X		See 1 above.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No (TR 541-548).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Overall vitamins should not be considered persistent in marine environments as these compounds readily decompose in oxic (oxygen rich) environments (TR 827-829).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		See 5 above and 7 below.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		See 5 above. The vitamins petitioned , Thiamine, Choline and Biotin are water soluble. The potential for toxicity is generally dependent on the vitamin's solubility properties. Water soluble vitamins (thiamine, riboflavin, pyridoxine, pantothenic acid, niacin, biotin, folic acid, choline, inositol, and ascorbic acid) are rapidly depleted and these vitamins do not bioaccumulate in animal fatty tissue. Lipid-soluble vitamins A, D, E, and K bioaccumulate in fatty tissue (TR 847-876). Literature on bioaccumulation or persistence of vitamins in aquatic environments is limited. In general lipid soluble vitamins are more likely to bioaccumulate in fatty tissues (TR 830-836). Adverse effects due to persistence will be more severe in closed systems (TR 805-806).
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See 1, 5, and 7 above. Limited information is available regarding potential for environmental or human health toxicity at the small levels used (TR 1045-1050).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		It is unlikely that vitamins used in closed containers during aquatic plant production would enter a terrestrial agro-ecosystem. No studies have been found indicating toxic effects of vitamins in soil dwelling organisms (TR 1030-1033). Overloading aquatic ecosystems with nutrients could potentially reduce BOD , but with good regulations in place negative impacts are unlikely from use in closed systems as petitioned.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See 1, 7, and 9 above. No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms (TR 1033).

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 2. Is the Substance Essential for Organic Production?: Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			There are 3 vitamins petitioned. Production methods vary. All three can be produced by fermentation, but are typically commercially produced by chemical processes (TR 553-554). Fermentation can be considered synthetic or non-synthetic (TR 785-786).
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X	X		See 2 above. Extraction from natural sources is widely considered inefficient and low yielding (TR 574-773).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		There are no known natural alternatives (Petition page 7) Vitamin B1 can be produced from many plant sources. Vitamin B7 can be produced from both plant and animal sources, including fish meal and fish solubles. Vitamin B 12 can be produced from animal and fish by-products.
6. Is there an organic substitute? [§205.600(b)(1)]		X		None.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X	X		See 5 above .
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		Little information was provided to be able to answer this question

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 3. Is the substance compatible with organic production practices? Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Vitamins B1, C and E are presently on the National List at 205.601(j)(8) as plant or soil amendments. Vitamins are listed in the OFPA at 6517 (c) (1)(B)(i)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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	X	X		Thiamine and biotin are sulfur containing. (TR 537-539).
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion - Vitamins In aquatic plant production
February 21, 2014

A minority of the subcommittee suggested that the subcommittee adopt an annotation motion for plant vitamins use in aquaculture that set a 5-year expiration date on the listing, with a justification explaining that the specific time frame for an expiration date allows the Board to

monitor the use of the material, update its scientific and essentiality review, incentivize alternatives and continuous improvement, and vote on the continuation of use pending the receipt of a petition requesting that use be extended.

Support for the annotation is based on the following justification: Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time. Therefore, the NOSB needs to reconsider the approval in five years at the least. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to those in water receiving discharges or open water systems; alternatives derived from natural source; and compatibility with organic and sustainable agriculture. In particular, although the petitioner has stated that the vitamins would be used in closed systems and needed only for growth of starter cultures, there is nothing in the proposed listing from the subcommittee to restrict the use to starter cultures in closed systems. The review in 5 years provides an opportunity for the Board to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

In addition, the minority makes the following comments and additions to the majority checklist, which it believes does not provide a full assessment of environmental and health standards review required under the Organic Foods Production Act (OFPA): The petitioner has told the subcommittee that the vitamins will be used only in closed systems for starting cultures. The minority believes that this should be part of the annotation.

With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:

- Vitamin B1: Commercial production involves a six-step synthetic procedure beginning with ethyl 3-ethoxypropionate as the feedstock and reactants including ethyl formate, acetamidine hydrochloride, phosphorus(V) oxychloride, alcoholic ammonia, hydrobromic acid, and 4-methyl 5-hydroxyethyl thiazole. TR lines 594-600.
- A search of the patent literature revealed two methods for vitamin B1 (thiamine) production by fermentative methods that appear to use genetically engineered bacteria. TR lines 601-606.
- Vitamin B7 (H, biotin): The synthesis begins with fumaric acid as the starting material and involves 15 linear synthetic steps, including vicinal bromination of fumaric acid, benzylamine, oxalyl chloride, acetic anhydride, zinc, acetic anhydride, acetic acid, dihydrogen sulfide, potassium hydrosulfide, zinc/acetic acid, an appropriate Grignard reagent, hydrogen over palladium, hydrobromic acid, silver d-camphorsulfonate, sodium diethyl malonate, and hydrobromic acid. TR lines 660-672.
- Microbial fermentation methods have been developed to produce only the biologically active isomer of biotin. As an example, a microorganism of the genus Kurthia (bacteria) was developed with resistance through exposure to a mutagen, selecting lines capable of producing d-biotin under aerobic conditions (Hoshino, 2002). TR lines 673-679.
- MSDSs for several feedstock chemicals and other chemical reagents used in the synthesis of biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. TR lines 946-946.
- Vitamin B12. Microorganism fermentation is the exclusive commercial method of synthesizing vitamin B12. Some strains are genetically engineered. TR lines 770-773.
- All: The fermentative production of vitamins presents a slight risk of product contamination from genetic material in the fermentation broth and any chemicals used during processing. TR lines 918-920.
- If released to the water, most of the water-soluble vitamins are not expected to adsorb to suspended solids and sediment. TR lines 930-931.

- Many of the feedstock chemicals and reagents used in vitamin synthetic procedures are considered petrochemicals or may be obtained from genetically modified organisms (GMOs). Acetone, for example, is a commonly used chemical reagent derived from petroleum as well as from GMOs such as corn. TR lines 955-958
- Waste streams resulting from the fermentative production of vitamins may also pose risks to the environment. In general, the EPA assumes "no control features for the fermentor offgases, and no inactivation of the fermentation broth for the liquid and solid waste releases," suggesting that environmental exposure to these waste streams is likely. Some potential risks to the environment include the transfer of novel genes into crops, poisoned wildlife, and the creation of new and more potent viruses, in addition to a host of unknown risks. TR lines 959-966.
- Release of large amounts of vitamins into the environment may result in eco-toxic events, such as the promotion of algal blooms and red tides. TR lines 985-987.
- Unicellular photosynthetic algae require nutritional intake of vitamin B1 (thiamine), B7 (biotin), and B12 (cobalamin) (NAS, 1969). These vitamins, as well as other macro- and micronutrients, can be a limiting growth factor for environmentally beneficial and deleterious algae. TR lines 976-979
- Excessive vitamin loadings can lead to synergistic and/or antagonistic effects for the absorption and bioavailability of minerals and other trace nutrients. TR lines 1011-1012.
- Overloading aquatic ecosystems with nutrients, such as vitamins, could potentially lead to depletion of the dissolved oxygen content and eutrophication. This is commonly manifested through occurrences of algal blooms and red tides, fish kills, and overall loss of biodiversity from the aquatic system. TR lines 1075-1077.

With regard to checklist Category 2, Essentiality, the minority believes the following need to be considered:

- Vitamins B1, B7, and B12 may all be produced through fermentation. Vitamins B1 and B7 may also be produced through chemical reactions of synthetic chemicals. (See Category 1, question 2.)
- Natural forms are produced by plants, animals, and microorganisms.
- Natural sources of the three vitamins include:
    - **Vitamin B1:** Dried brewers yeast, wheat middlings, wheat mill run, rice bran, rice polishings, dried torula yeast, groundnut (peanut) meal, wheat bran, barley, dried fish solubles, cottonseed meal, soybean meal, linseed meal, dried distillers solubles, broad beans, lima beans, dried delactose whey, glandular meals (liver/kidney), green leafy crops, outer coat or germ of cereals.
    - **Vitamin B7:** Dried brewers yeast, dried torula yeast, dried distillers solubles, rapeseed meal, safflower seed meal, sunflower seed meal, whole hens eggs, rice polishings, dried brewers grains, liver and lung meal, rice bran, dried delactose whey, cottonseed meal, groundnut meal, soybean meal, dried skim milk, alfalfa meal, oats, sorghum, dried blood meal, dried fish solubles, fish meal, wheat bran, wheat mill run, legumes, green vegetables.
    - **Vitamin B12:** Animal by-products, liver, kidney, heart, muscle meats, fish meals, shellfish, meat and bone meal, condensed fish solubles, and poultry by-product meal. TR lines 1189-1192; 1207-1211; 1237-1238.

Under Category 3, Compatibility, the minority points out the following:

- Compatibility depends on how they are used—on routine basis, or occasionally, when needed.
- Synthetic vitamins are permitted for animals only when natural vitamins are not available in EEC, UK, Japan, and IFOAM standards. TR lines 495-525.
- It is not sustainable to depend on external synthetic inputs.

National Organic Standards Board
Compliance, Accreditation, and Certification Sub-Committee
Request for NOP Clarification and Guidance on Retail Compliance and Certification

***Reviewed February 25, 2014 - Minor revisions.**

1. Introduction

While the National Organic Standards and various National Organic Program (NOP) guidance resources are clear on the compliance expectations for growers, handlers, and livestock operators, the NOP's expectations are less clear for retail operators. Retail stores function not only as handlers of organic products, but also as purchasers, verifiers, and marketers of specific products and organic agriculture in general. In many cases, retail operations are exempt from the requirement for certification for handlers (7 CFR 205.101(a)(2)) and excluded from the certification requirement (§205.101(b)(2)). However, exclusion and exemption are not completely clear regarding the extent to which a retailer may handle and process products while still qualifying for the exemption and/or exclusion. Numerous retailers have become voluntarily certified as handlers, yet there are many areas where handling organic system plans (OSP) and operational expectations do not apply directly to retail operations, and the retail sector would benefit from clearer NOP guidance on its expectations for compliance for certified and non-certified retail operations. Finally, retailers who sell both organic and non-organic products, market their certification to consumers, often using the USDA seal. Retailers (along with other producers) need clear guidance on the use of the USDA Organic Seal and the "organic" claim in general, in the marketing of split operations.

The CAC Subcommittee (CACS) prepared a discussion document on this topic for the scheduled 2013 NOSB meeting in Louisville. While that meeting was not held, we received sufficient written comments from organic stakeholders to move forward with a proposal. The discussion document sought to engage all impacted stakeholders and ask for their input as to what specific issues need more clarity to help with understanding and compliance. We also sought detailed information about any existing inconsistencies that could use more clarity to enable a more consistent process of review and accreditation by the various accredited certifying agents (ACAs), NOP, and ultimately the retailers themselves.

Based on public comment received for the fall 2013 meeting, the subcommittee has prepared a proposal which asks the National Organic Program to provide enhanced education and outreach targeting the retail sector. The intent is to attempt to accomplish this through education and outreach, in a way that can provide better clarification to assist the retailers and certifiers with a more clear and concise understanding of what is required of an organic retailer by the regulation.

2. Background

In 2009, the NOSB approved a CACS Guidance Recommendation entitled "Clarification of Marketing for Voluntary Retail Certification." This recommendation presented general background on the exemptions allowed for retailers, and described a need for clearer guidance around the use of the USDA seal and the "organic" claim in the marketing of organic retail stores. The recommendation acknowledged that the phrase "Certified Organic Retailer" may be challenging to a consumer, and identified a need for clearer guidance around the use of this term.

The 2009 recommendation then identifies a number of specific certification areas where the NOP should provide clearer guidance in order to facilitate consistency and clarity among retail operators:

- Guidance on the use of the USDA seal in marketing certified retail operations.
- Clear and consistent guidelines for deli and bakery operations, identifying precisely under what conditions certification is required.
- Additional guidance on the ACAs' role in managing voluntary retail certification programs.
- Clarity on retailers' role in improving the marketing of voluntary retailer organic certification.

A number of the 2009 NOSB's recommendations remain unaddressed by the NOP. Given that the issues described in the earlier recommendation remain critical, we have updated that recommendation to include a number of additional concerns and requests.

The CAC subcommittee prepared a discussion document for the scheduled fall 2013 NOSB meeting, which was cancelled. However, the written public comment received for that discussion document was used in the development of the current proposal.

3. Relevant Areas of the Rule

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than 3.91(b)(1)(xxxvii) of this title per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.101 Exemptions and exclusions from certification.

(a) *Exemptions.*

(1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals $5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) *Exclusions.*

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.310.

(c) *Records to be maintained by exempt operations.* (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as “organic,” pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as “made with organic (specified ingredients or food group(s)),” pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: *Except,* that, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

§ 205.310 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.

Figure 1

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

(a) Comply with the Act and applicable organic production and handling regulations of this part;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;

(c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;

(e) Submit the applicable fees charged by the certifying agent; and

(f) Immediately notify the certifying agent concerning any:

(1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and

(2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

4. Recommendations

The CACS requests that the NOP provide clear general education and guidance on organic compliance to the retail sector, and clarify several specific sections of the Rule as it applies to retail operations.

Education and Outreach

Our discussions and comments received highlighted the need for increased education and training for retailers, especially non-certified retailers. While certified retailers receive oversight and certification from Accredited Certifying Agents, non-certified retailers (including farmers markets and online retailers) do not have the benefit of direct certifier outreach. We believe that the NOP can play a more active role in educating retailers about the regulatory requirements that govern their operations. Since the implementation of the Rule, a number of retailers have become voluntarily certified. As a number of commenters noted, such certification can benefit consumers through third-party verification of organic sourcing, handling and merchandising activities. NOP educational materials for retailers should highlight the opportunity and potential benefits of voluntary retail certification. Enhanced education and support services for retailers will ensure consistent compliance with the National Organic Standards, increasing consumer understanding of and trust in the USDA organic label.

Clarification of the Rule as it Applies to Retail Operations

Written comments described a number of sections of the regulations which are unclear as to how and when they apply to retail stores. We ask the National Organic Program to issue concise guidance, in conjunction with the education and training described above, which clarifies the application of the Rule's regulatory requirements to retail operations. We support the summary presented by the Organic Trade Association (OTA), based on its consultation with its retail members, in its written public comments:

- *Section 205.101(a) and (b) - The requirements for an "exempt" retail establishment vs. the requirements for an "excluded" retail establishment are not clear.*
    - *Are exempt retailers required to comply with the commingling and contamination prevention standard (§ 205.272) and/or the labeling provisions (§ 205.310) of the NOP regulations? The regulation under exemptions and exclusions (§ 205.101) only specifies that exempt retailers maintain records as detailed under § 205.101(c), while excluded operations are subject to § 205.272 and § 205.310.*

    - *Furthermore, are excluded operations required to comply with the record requirements of § 205.101(c)? The regulation specifies that records are to be maintained by "exempt" operations, but an "excluded" operation is not mentioned. In other words, the regulations appear to require the following:*
        - *Exempt retailers are required to maintain records as detailed under § 205.101(c).*
        - *Excluded retailers are required to comply with the commingling and contamination prevention standard and comply with the labeling provisions of § 205.310.*
    - *Can an exempt or an excluded retail establishment handle or process NOP certified products and then sell the products off-site? For example, can the products be handled or processed on-site of the retail establishment, but then sold as "organic" at a farmers' retail sales? The regulation is clear that excluded retail establishments must process "on the premises of the retail food establishment." The regulation is not clear about "where" the sale of the product must occur.*

- *Sections 205.308, 205.309 and 205.310 – Labeling requirements:*
    - *Can an exempt non-certified retail establishment "handle" a product and then display the USDA seal or represent the product as "certified" organic? In other words, can they handle a product (either transfer the product from a container to a display case, or, transfer from the product from the original container to a store container (i.e., bulk flour bin)) and then transfer the information from the original container/label to the store display label?*

As noted in the discussion document, the exemption in 7 CFR 205.101(a)(2) applies to a retailer that "handles but not process" organic agriculture products. However, the definition of "handle" in §205.2 includes the term "process," which is also defined in the regulation. While we believe that the intent of the regulation is to exclude retailers who handle organic products but do not otherwise transform them, we ask that the NOP clarify the precise contours of this exemption, especially as they apply to simple repackaging of organic foods.

We also ask that the NOP clarify the application of the exemption and exclusion to online businesses that ship organic products to customers, including the retail portions of certified farms and processing facilities that conduct online sales. As noted in the OTA's comments, the regulation clearly requires that processing activities occur on the retail premises, but does not specify where the sales of such products must occur. Does the online sales activity of a retail business constitute a "retail food establishment," and if the exemption does apply to online retailers, how should such products be labeled?

Finally, the written comments confirm an opportunity for clarification as to the conditions under which a retailer may label a product as "certified organic" or use the USDA seal when, for example, organic produce is removed from packaging and merchandised, or a bulk grain is placed into a bulk bin. The OTA notes:

There appears to be some contradiction between sections 205.308, 205.309 and 205.310 of the regulations, all of which together address how products at the point of retail can be labeled, and how products produced on exempt and excluded operations can be labeled.

As we have explained above, § 205.308 could be read to mean that a product produced in a certified facility can be displayed in a retail display using the USDA seal and identifying mark of the certifying agent. There is some confusion, however, about whether "prepared in a certified facility" would apply to the retailer that is handling or processing the product, in which case the retailer would need to be certified in order to display the USDA seal or make reference to certification. Furthermore, § 205.310 states that an agricultural product produced or handled in an excluded or exempt operation must not display the USDA seal or represent the product as certified organic.

The current and common practice at non-certified exempt retail establishments is to handle certified organic products and transfer from a box to a display case or from a bag into a bulk bin the same information as provided on the original container. For example, a bag of certified organic flour would be transferred to a bulk bin and the bulk bin label would display "certified organic flour. " It may also display the USDA seal. We believe this practice is compliant, as supported by section § 205.308 of the regulations. However, clarification is needed.

In conclusion, we ask that the NOP develop clear and actionable guidance for retailers on the points noted above and in the earlier discussion document. The development of such guidance should include the consultation of retailers and ACAs. We believe that focused education and outreach to the retail sector will help improve compliance with the regulation, foster consistency across certified and non-certified operations, and promote consumer confidence in the USDA Organic label. Retailers represent the final interface with consumers in the organic supply chain, and it is crucial that organic integrity in merchandising, handling and marketing be vigilantly maintained.

Recommended Motion:

Motion to accept the Request for NOP Clarification and Guidance on Retail Compliance and Certification proposal

Subcommittee Vote:

Motion by: Jean Richardson
Seconded by: John Foster
Discussion: none

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

Approved by Carmela Beck, Subcommittee Chair, to transmit to NOSB February 22, 2014.

National Organic Standards Board
Compliance, Accreditation, and Certification Subcommittee
Proposal
Toward Clarifying Accredited Certifying Agents' Application of §205.206(e)

August 20, 2013
Reviewed February 11, 2014. No revisions to content; submitted as a proposal instead of a discussion document.

Introduction:

Organic crop production has passed its first decade of existence under full implementation of the National Organic Program (NOP). While many positive features of this program stand out as contributing to a more sustainable, healthy environment as a function of the legislation and regulations we as an industry and community operate under, from time to time we identify areas for possible improvement. One of the legacy features found in the National Organic Standards (NOS) that is a derivative of many organic standards in existence prior to the NOP (e.g. CCOF, Oregon Tilth) was a codified preference for softer, less invasive, and less disruptive methods of pest control over their harder, more invasive, and more disruptive counterparts. The Compliance, Accreditation, and Certification Subcommittee (CACS) supports this preference without reservation while recognizing that pest control and management is one of the most challenging aspects of organic crop production, and that the very existence of a section on pest control in the NOS is a formal recognition of the essentiality of such activities to protect crops from the myriad of daunting and potentially devastating pests such as insects, mites and other invertebrates, weeds, plant pathogens, rodents, deer and other vertebrates.

Regulatory Citations Background:

§ 205.206 Crop pest, weed, and disease management practice standard, provides for the following:

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: Provided that, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: Provided, That, the conditions for using the substance are documented in the organic system plan.

Discussion:

The Crops, Accreditation, and Certification Subcommittee has determined that there is uncertainty and variability in the understanding and application of the mandates and nuances of § 205.206(e). Additionally there appears to be insufficient understanding in how substances reviewed and recommended by the NOSB, added to that National List by the Secretary of Agriculture, and allowed as listed on § 205.601 are utilized responsibly in the context of the cascading requirements found in § 205.206(e).

The underlying principle guiding this section of the regulation is that only when other, less disruptive, less harmful, less toxic methods, strategies, and tactics have been employed and found wanting may synthetic substances found on the National List be used as part of an Organic System Plan. It was never the intention of the regulation to allow the application of any synthetic crop input unless other, less toxic and persistent means had been tried without adequate success. This feature is unique in that it is the only federally-regulated mandate for Integrated Pest Management while also being a centerpiece of the crop production standards of which the organic community can be proud.

It is the Subcommittee's contention that a comprehensive and clear understanding of § 205.206(e) across all sectors of the organic community and industry is essential in the continued fair appraisal of substances on the National List and their alternatives, whether that appraisal occurs in the sunset process or in consideration of petitions. Only when the process is fair and equitable by which alternatives to pesticides—referenced in § 205.206(a)-(d)--are assessed as essential and viable can the essentiality and viability of pesticides--referenced in § 205.206(e)—be assessed fairly and equitably.

The Subcommittee also contends that the public is generally unaware of the rigors placed on organic operations and organic certifiers by § 205.206(e) and therefore undervalues the efforts of each in assuring compliance with the applicable regulation. This lack of awareness can allow for undeserved skepticism and second-guessing that impedes effective and efficient management of crop pests. Clarity about these rigors would serve the community well in allowing organic operations to focus on crop production and compliant activities instead of defending those actions.

Toward clarifying the collective understanding and unifying collective application of § 205.206(e), the Subcommittee is seeking comments on this subject and in particular would like to ask the following questions of the certification community.

1. What activities or practices do you require of applicants and certified operators in their Organic System Plans (OSP) with respect to their compliance with §205.206(e)?
2. What form of verification or records from the operator do you require in support of their compliance with § 205.206(e), either during review of the OSP, during the inspection, or upon the inspection review?
3. What information do you require when an operator needs to amend their OSP on short notice when pest pressure unpredictably or unexpectedly rises beyond their decision threshold?
4. Other than through records, how do you verify that approved substances are applied only when other, less toxic or aggressive means have been tried and found wanting?

Recommended Motion:

To approve and forward to the NOSB the discussion document "Toward Clarifying Accredited Certifying Agents' Application of § 205.206(e)".

Subcommittee Vote:

Motion: John Foster

Second: Joe Dickson

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Joe Dickson, Subcommittee Chair, to transmit to NOSB August 20, 2013.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ammonium Hydroxide

February 19, 2013
***Revised February 18, 2014 - request for further public comment**

Summary of Proposed Action:
Ammonium hydroxide is petitioned to be added to the National List at 205.605 as a boiler water additive. The Handling subcommittee proposes not to add Ammonium hydroxide to the National List.

Ammonium hydroxide is a powerful alkali petitioned for use as a boiler additive because it neutralizes carbonic acid in condensate to prevent corrosion, reducing pH to 8.5 or 9.0. The level of ammonium hydroxide required in steam would depend on the level of carbon dioxide in the steam. Ammonium hydroxide is produced by the addition of water to Ammonia. Ammonia is produced on a large scale worldwide and one of its largest uses by production volume is as an ingredient in conventional fertilizer (prohibited in organic agriculture).

Ammonium hydroxide is a severe irritant which must be handled properly because exposure by humans and other mammals during production or use presents a serious toxicological concern. It is toxic by all routes, inhalation, dermal and ingestion and the toxicity is well documented. It is an air and water pollutant and contributes as a greenhouse gas. It is toxic to fish and other aquatic species. Spillage could cause considerable environmental damage.

There are a number of alternative practices which can be used instead of boiler additives. These include replacement of steam lines with stainless steel piping, water treatment, physical or chemical deaeration, interruption of boiler water treatment prior to organic processing runs, bleed runs, dismantling and cleaning systems prior to organic food handling, steam to steam heat exchangers, a separate secondary boiler to generate steam for direct food contact applications.

The petition requests addition of ammonium hydroxide as a “boiler additive” to neutralize carbon dioxide in order to prevent acid attack in steam condensate lines. Where steam is used in or on food it is termed “culinary steam” and used in food processing for sanitation or sterilization of food contact surfaces, including packaging sterilization.

REQUEST FOR FURTHER PUBLIC COMMENT
The National List currently includes three volatile synthetic amines as boiler additives, namely Cyclohexylamine, Diethylaminoethanol , and Octadecyclamine, listed at 205.605(b) for use only as boiler additives in packaging sterilization. These three boiler additives will be discussed in fall, 2014, as part of Sunset Review (for 2016 materials). Because of Sunset Review for the three boiler additives listed above, the NOSB seeks further public comment on essentiality of ammonium hydroxide as a boiler additive, including scope of use as culinary steam.

Evaluation Criteria (Applicability noted for each category; Documentation attached)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☐ Yes	X No	N/A
2. Essential & Availability Criteria	☐ Yes	X No	N/A
3. Compatibility & Consistency	☐ Yes	X No	N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	No	X N/A

Substance Fails Criteria Category: [3] **Comments:**
Ammonium hydroxide has the potential to cause significant toxic damage to humans, mammals, aquatic systems and greenhouse gasses and is not essential or compatible with organic agriculture and handling.

Proposed Annotation (if any): None proposed

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation NA

Recommended Committee Action & Vote

Classification Motion:
Motion to classify ammonium hydroxide (CAS # 1336-21-6) as petitioned as synthetic
Motion by: Jean Richardson
Seconded by: Tracy Favre
Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Listing Motion:
Motion to list ammonium hydroxide (CAS # 1336-21-6) at § 205.605b
Motion by: Jean Richardson
Seconded by: Colehour Bondera
Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

Approved by John Foster, Subcommittee Chair, to transmit to NOSB February 19, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category1. Adverse impacts on humans or the environment? Ammonium hydroxide

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	X			Toxic to environment if spilled or volatized to atmosphere (TAP 2001 and petition pages 8, 9, and 10)
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			Worker injury through breathing, ingestion or dermal contact and terrestrial damage with spills during manufacture. (Petition pages 8, 9, 10, and TAP 2001).

3. Are there any adverse impacts on biodiversity? (§205.200)	X			Toxic damage will occur through spills in terrestrial or aquatic systems, and ammonia contributes to greenhouse gases (Petition pages 8-10) Fish are particularly at risk for toxic effects.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Yes if spilled, or released into air the gas contributes to Greenhouse gases.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	X			Yes toxic if inhaled, ingested or dermal contact
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Ammonium hydroxide

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Ammonium hydroxide is manufactured from natural gas which is used to convert atmospheric nitrogen to ammonia and then water is added to produce the hydroxide form (petition page 4 and TAP 2001).
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		

6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		Processors can utilize a number of alternative practices, such as stainless steel pipelines, physical and chemical deaeration, interrupt boiler water treatment prior to organic processing etc. These alternative practices cost time and money. (petition page 11) although economic considerations are not one of the criteria for suitability of materials used in organic production systems (TAP 2001, page 9)
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
9. Are there any alternative substances? [§6518(m)(6)]	X			There are 3 boiler additives on the NL
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			There are a number of alternative practices which can be used (Petition page11) These include pre-treating water, replacing steam pipelines with stainless steel etc.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		

Category 3. Is the substance compatible with organic handling practices? Ammonium hydroxide

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		As a general rule ammonia products are not considered compatible with organic production or handling (TAP 2001, page 7, page 9
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		See 1 above
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		See 1 above
4. Are the ancillary substances reviewed compatible with organic handling [?			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Ammonium hydroxide**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	
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?			X	
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?			X	
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?			X	
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Other issues which may present a challenge to a consistent supply?			X	

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Glycerin CAS # 56-81-5

August 20, 2013
Reviewed January 21, 2014 - No revisions

Summary of Proposed Action:

The petitioner has requested removal of Glycerin from 205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The petitioner believes that the process of microbial fermentation that is used to produce organic glycerin is a superior method for the production of organic glycerin because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). Further, they state "An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used "only when the product is not commercially available in organic form." Certified organic glycerin is currently available, but there is no "commercial availability" requirement to incentivize processors to use it or certifiers to require it. This is why glycerin should be removed from the National List in order to encourage organic agricultural production." (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924)

Because glycerin produced by hydrolysis of fats and oils is currently listed at 205.605(b), the NOSB seeks public comment regarding the potential impact to producers and industry should glycerin as is presently listed be removed from 205.605(b) of the National List. At present, the NOSB has not received a petition to add Glycerin produced by other methods to the National List.

Background

Glycerin is a viscous fluid that has a sweet taste. It is used in a wide variety of products including food, cosmetics, medical and industrial applications. As listed at 205.605(b), glycerin is formulated from hydrolysis of fats and oils. Per the Technical Review (line 122), there are a variety of methods for manufacture of glycerin from hydrolysis of fats and oils:

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantage claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent

	emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245^{o}C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.
Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495^{o}F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

Additionally, per the petitioner "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils." Hydrolysis of fats and oils does change the chemical properties of the source material, and therefore it is considered a synthetic.

Per the petition: Four general methods of commercial glycerin production are or have been used:

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11.
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation "produced by hydrolysis of fats and oils." It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock used at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils.

4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce non-synthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast Candida krusei1 is used commercially to produce certified organic glycerin as well as non-synthetic non-organic glycerin.

Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch (TR lines 130 – 131). There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674).

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	X Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	X No	☐ N/A
3. Compatibility & Consistency	☐ Yes	X No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	☐ Yes	X No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: N/A

Listing Motion: Motion to remove Glycerin produced by hydrolysis of fats and oils, CAS # 56-81-5 from 205.605(b) of the National List.

Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation (if any): N/A

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Approved by John Foster, Subcommittee Chair, to transmit to NOSB August 20, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		Wide variety of uses for food and industrial applications. Long-term history of safe use, TAP indicates no incidence of industrial poisoning. Glycerin should not come into contact with a strong oxidizing agent.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		For current listing: Manufactured from hydrolysis of fats and/or oils using steam splitting. Theoretically possible to have spill of oils, but unlikely. Fermentation methods: Unlikely
3. Are there any adverse impacts on biodiversity? (§205.200)			X	However, the petitioner claims that the residue from biodiesel production is used in the manufacture of glycerin, and one could argue that growing corn for biodiesel does have an impact on biodiversity.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Per Environmental Working Group (EWG), there seems to be no persistence in the environment. TR indicates it is readily biodegradable (line 568).
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		Glycerin is considered GRAS and has a long history of safe use in a wide variety of food, cosmetic and medical applications. It is metabolized as a carbohydrate in the body.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			See above comment.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X		Manufactured from hydrolysis of fats and oils using steam splitting and then concentrated using distillation. Fermentation methods include isolation of cornstarch from organic corn.

NOSB Evaluation Criteria for Substances Added To the National List Handling

Category 2. Is the Substance Essential for Organic Production? Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X	X		As currently listed it is not considered agricultural. However, the petitioner makes the argument that it should have originally been listed at 205.606 since it is manufactured using steam. If so, then it should be considered agricultural. The fermentation method could be considered agricultural since it is manufactured using isolated cornstarch from organic corn.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Per the petition: "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List." Hydrolysis of fats and oils does change the chemical properties of the source material. Fermentation methods: The process for producing organic glycerin by microbial fermentation from carbohydrate substrates begins with organic corn from which cornstarch is isolated. The cornstarch is treated with enzymes to hydrolyze the starch and liberate glucose. The glucose is then fermented with an appropriate microorganism to produce glycerin. The glycerin is purified by passing through ion-exchange columns to remove inorganic elements required for growth of the microorganism and through activated charcoal to remove color and impurities.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Hydrolysis is the opposite of condensation. A large molecule is split into smaller sections by breaking a bond, adding **-H** to one section and **-OH** to the other. The products are simpler substances. Since it involves the **addition of water**, this explains why it is called hydrolysis, meaning **splitting by water**. **A-B + H_2O --> A-H + B-OH** **(http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)** For fermentation method, see above.

4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		The process of hydrolysis is a naturally occurring process, but this material is manufacturing using high heat and pressure. Incidentally, all (food) digestion reactions are examples of hydrolysis, and the involvement of water is often not appreciated. Generally these reactions are controlled by enzymes such as carbohydrases, proteases, lipases, nucleases, more specific examples of which are fairly well known. **(http://www.biotopics.co.uk/as/ condensation_and_hydrolysis.html)** For fermentation, see above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	X			Petitioner claims to have a fully organic version manufacturing using a fermentation process. See petition, (http://www.ams.usda.gov/AMSv1.0/ getfile?dDocName=STELPRDC5101924) Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			Glycerin is used in a wide variety of products including food, cosmetics, industrial and medical. It is a strong humectant. In organic food products it is used to improve texture, increase volume and is a major carrier for flavorings and colorings.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		Alcohols could be used a carriers for flavorings. And there are myriad other materials that could have a similar functional use in other formulations (such as softening and mouth feel in ice creams, keeping baked items soft, etc.) but glycerin is unique in that it can serve in all these functions.
9. Are there any alternative substances? [§6518(m)(6)]	X			Glycerin manufactured from petroleum products, glycerin from saponification of fats and oils and fermentation methods.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X	X		Given the wide use of glycerin, it is likely that there are substitutes for particular uses, but it is unlikely that any one material would work in all the applications where glycerin is used.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

NOSB Evaluation Criteria for Substances Added To the National List
Handling

Category 3. Is the substance compatible with organic handling practices? Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			TR says consistent when used with specific food products
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		Current version on the National List is considered a synthetic, therefore it would not be preferred for organic handling. According to the petitioner, there is now sufficient capacity for organically produced glycerin to supply the organic market.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]			X	Petition is to remove this substance from National List
4. Are the ancillary substances reviewed compatible with organic handling?			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		One of the uses of glycerin is as a preservative but it has many more uses
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			Glycerin is used as a flavor and/or color carrier, and is used to improve textures.

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance: Glycerin**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	Petition is for removal of synthetic glycerin. Petitioner claims there is sufficient quantity of organic glycerin available. Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material			X	See above. Petitioner claims there is sufficient organic glycerin available and the synthetic non-organic version is no longer

/substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?				necessary.
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?	X			See petition at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924
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?	X			When synthetic glycerin was recommended for inclusion on the National List, there was an insufficient supply or organic glycerin. According to the petitioner, that is no longer the case. Per the TR: There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);	X			
b. Number of suppliers and amount produced;	X			There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;	X			
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or	X			
e. Other issues which may present a challenge to a consistent supply?	X			

National Organic Standards Board
Handling Subcommittee
Polyalkylene Glycol Monobutyl Ether (PGME)
Discussion Document

August 20, 2013
Reviewed January 21, 2014 - no revisions

I INTRODUCTION

The purpose of this document is to seek public comment on the proposal that the petition for PGME be removed from the NOSB workplan after the Fall 2013 meeting, and that the NOP should notify the petitioner that PGME is not eligible for petition to 205.605 (b) because it is not used in direct contact with organic products.

II BACKGROUND

On December 27, 2012, the NOP received a petition requesting the addition of PGME to section 205.605 of the National List as a boiler water additive. Based on information in the petition, the NOP determined that the substance was eligible for petition to the National List. This decision was made based on the description of PGME as a processing aid that functions as a lubricant and surfactant within the pelleting process.

On January 28, 2013, the petition was sent to the NOSB Handling Subcommittee for review. The HS requested the development of a third-party technical report, which is posted on the NOP website.

The technical report, dated June 7, 2013, indicates that, since PGME is non-volatile, it remains in the boiler and does not come into direct contact with processed organic products.

The Handling Subcommittee prepared the Petitioned Material Checklist which was ready for final discussion and vote on August 20, 2013, at which time the Subcommittee determined that when used as a boiler additive, PGME is not required to be on the National List because it has no contact with organic products.

III RELEVANT AREAS OF THE RULE

§ 205.607 Amending the National List.

> "(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act."

The petition requests addition of PGME to 205.605 – "Non agricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)."

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

> "(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."

IV DISCUSSION

In reviewing PGME and developing the Materials Checklist the Handling Subcommittee found the following:

Polyalkylene Glycol Monobutyl Ether (PGME) polymeric fluid is a boiler steam additive petitioned for use in feed pellet mills. The petition is specifically for PGME with a minimum molecular weight of 1500 in accordance with conditions required by 21CFR Section 173.310.

PGME functions to reduce foaming during production of pelleted livestock feeds and also functions as a lubricant. PGME has the unique property of inverse solubility such that it dissolves easily in cold water, but at temperatures over 104F (cloud point) it is completely insoluble. Thus PGME is not delivered with the steam, but remains in the boiler as a precipitate until the boiler cools below cloud point and thus PGME does not contact the feed.

PGME has very low toxicity, is not considered harmful to the environment or humans, and presently has a range of uses approved through the FDA. Canadian, CODEX and Japanese standards do not address this additive. EEC standards require that processed feeds shall not have been processed with the aid of chemically synthesized solvents. IFOAM requires all additives to be declared. This material is regulated by FDA as a secondary direct food additive, and is not considered a GRAS substance.

There are no natural sources of PGME and there are not many natural anti-foam chemicals. Natural oils, such as cotton seed, lard, sunflower, safflower, palm oil, carnuba and peat waxes can be used, but none of them is as effective and none also provide lubricant properties during production. Some of the natural oils are available in organic form, but very little data is available on use of these oils.

When used as a boiler additive, the Handling subcommittee finds that PGME is not required to be on the National List because it has no direct contact with organic products.

V REQUEST FOR PUBLIC COMMENT

Based on the new information provided in the technical report, there are now questions about whether the original eligibility decision made by the NOP is still accurate. The original eligibility decision for this substance, which was based on the information contained in the petition only, may no longer be applicable.

This Discussion Document provides the opportunity for the petitioner to comment on the accuracy of the technical description of PGME in the technical report and the opportunity for other members of the public to comment on the petition and technical report.

Subcommittee Vote:

Motion: To accept the Polyalkylene Glycol Monobutyl Ether (PGME) discussion document as amended August 20, 2013.
Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by John Foster, Subcommittee Chair, to transmit to NOSB August 20, 2013

Sunset 2015 Review List - Request for Public Comment
Handling Substances

*Reviewed and revised: February 26, 2014

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 which must be reviewed by the NOSB and renewed by the NOP before their sunset dates in 2015. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. 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 2014 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2014 public meeting. These comments should be provided through www.regulations.gov by April 8, 2014 as explained in the meeting notice published in the Federal Register on March 10, 2014.

The Handling Subcommittee has posed specific questions to solicit public comments regarding two of the substances, marsala and sherry (fortified cooking wines), due for sunset review by 2015. These questions are included in the listing below.

It is important for the public to engage in the Sunset Process early. We strongly encourage submission of comments on these substances in advance of or at the spring 2014 meeting. Providing your comments early is important to: 1) ensure that the NOSB has adequate time and information to develop any proposals to remove substances based on this information before its fall 2014 meeting; and, as such 2) provide stakeholders adequate opportunity to comment on any proposals to remove substances before NOSB votes and makes a recommendation at its fall 2014 meeting.

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.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on continuing the allowance of substances on this 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 new 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 organic 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. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

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.

Table 1. Guidance on submitting comments for alternatives to substances on the National List.

If the currently listed substance is used in…	And is a…	Then the recommended alternative should be a (an)…
Handling	Nonsynthetic (non-agricultural) substance	- Agricultural substance; or - Management practice.
Handling	Synthetic substance	- Another currently listed synthetic substance; - Nonsynthetic (non-agricultural) substance; or - Management practice.

Written public comments will be accepted through April 8, 2014 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

SUNSET 2015: HANDLING SUBSTANCES

Gellan gum — *Nonsynthetic*

Use – As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

Listing: Gellan gum (CAS # 71010-52-1) – high acyl form only.

Technical Report: 2006

Petition(s): Gellan gum (2004)

Past NOSB Actions: NOSB review and recommendation for addition to the National List – 04/22/08

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

Sunset Date: 12/14/2015

Reference: 7 CFR 205.605(a)

Tragacanth gum — *Nonorganic Agricultural*

Use – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Listing: Tragacanth gum (CAS #-9000-65-1).

Technical Report: none

Original Petition: Tragacanth Gum (PDF) (2007)

Past NOSB Actions: NOSB review and recommendation for addition to the National List 5/08

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

Sunset Date: 12/14/2015

Reference: 7 CFR 205.606(x)

Marsala — *Nonorganic Agricultural*

Use – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Listing: Fortified cooking wines. (1) Marsala

Technical Report: none

Petition(s): Marsala, (2007).

Past NOSB Actions: NOSB review and recommendation for addition to the National List 11/30/07.

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

Sunset Date: 12/14/2015

Specific Questions from Subcommittee:

As part of the Sunset review process, the Handling Subcommittee is considering putting forth a proposal to remove Marsala from 205.606 of the National List at the Fall 2014 public meeting. In anticipation of this, the Subcommittee seeks public input based on the following:

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

2. Has industry attempted to locate organic sources of marsala and with what degree of success?

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

Reference: 7 CFR 205.606(g)(1)

Sherry — *Nonorganic Agricultural*

Use – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Listing: Fortified cooking wines. (2) Sherry

Technical Report: none

Original Petition: Sherry (2007).

Past NOSB Actions: NOSB review and recommendation for addition to the National List, 05/08

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

Sunset Date: 12/14/2015

Specific Questions from Subcommittee:

As part of the Sunset review process, the Handling Subcommittee is considering putting forth a proposal to remove Sherry from 205.606 of the National List at the fall 2014 public meeting. In anticipation of this, the Subcommittee seeks public input based on the following:

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

2. Has industry attempted to locate organic sources of sherry and with what degree of success?

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

Reference: 7 CFR 205.606(g)(2)

National Organic Standards Board
Materials Subcommittee
Proposal: Update of the Petition and Technical Review Process
August 27, 2013
Reviewed December 10, 2013 - No revisions

Introduction

The National Organic Program (NOP) has asked the NOSB for input on revising the procedures for petitions and technical review. These procedures are encompassed by a 2007 Federal Register notice, 72 FR 2167, and sections of the NOSB Policy and Procedures Manual (PPM) appearing on pages 34, 35, 37 and 38 of the current version.

This effort is aimed at making it clearer for petitioners to submit complete petitions and to know what to expect in the petition process, for the NOSB to have clear policies for reviewing petitions in a consistent way, and for the public to have transparency in how petitions are received, evaluated and reviewed.

Subjects covered in this proposal include petitioning to add or remove substances to the National List, how such petitions proceed once they are received, and how the NOSB determines which substances are on the National List. Also covered is the subject of adding, removing or changing and annotation placed on a listed substance.

Used throughout this proposal is the ~~strikethrough~~ for old language to be removed, and an underline for new language to be added.

Part 1. Procedures for Submitting National List Petitions

Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List. When submitting petitions, an official petition contact should be designated for all correspondence and the petition should provide specific contact information including name, address, phone number, fax number and e-mail address.

To facilitate timely NOP review and NOSB consideration of petitions, petitioners must provide concise yet comprehensive responses to the required petition information items described under the guideline heading ‘‘Information to be included in a Petition.’’ Upon receipt, the NOP will review the petition for completeness of the required petition information. If the required petition information is incomplete, the petition will be returned to the petitioner with a request for additional information.

Petitions for substance evaluations to add a substance onto, remove a substance from, or amend a substance presently on the National List involves a public and open process. Confidential Business Information (CBI) is no longer accepted in petitions. ~~Petition information not categorized and accepted by USDA, pursuant to 7 CFR 1.27(d), as Confidential Business Information (CBI) will be considered available to the public for inspection. Published information usually cannot be claimed as confidential.~~ When a petition is considered complete and forwarded for NOSB evaluation, ~~except for CBI~~, the petition will be made available for public inspection. Substance petitions that are complete and under evaluation by the NOSB will be posted on the NOP Web site at: http://www.ams.usda.gov/nop. Public comments may be submitted to either

the NOSB or the NOP for any petitioned substance being evaluated by the NOSB. Comments also will be posted on the NOP Web site.

Information To Be Included in a Petition

The guidelines for required information to be included in a petition are as follows:

Item A—Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List. For petitions to change or add an annotation to an already listed substance, please indicate in which category of OFPA §6517 (c)(1)(B)(i) the substance is listed.

- Synthetic substances allowed for use in organic crop production, § 205.601.
- Non-synthetic substances prohibited for use in organic crop production, § 205.602.
- Synthetic substances allowed for use in organic livestock production, § 205.603.
- Non-synthetic substances prohibited for use in organic livestock production, § 205.604.
- Non-agricultural (non-organic) substances allowed in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients),'' § 205.605.
- Non-organic agricultural substances allowed in or on processed products labeled as ''organic,'' § 205.606.

Item B—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned (petitions to change annotations for an already listed substance need only complete #s 1, 2 (contact name), 3, 4, 12 (research backing up the change) & 13 (petition justification statement):

1. The substance's chemical and/or material common name.
2. The petitioners name address and telephone number, the manufacturer's or producer's name, address and telephone number (if different) and other contact information of the manufacturer/producer of the substance listed in the petition.
3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (*e.g.*, cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (*e.g.,* ingredient, flavoring agent, emulsifier, processing aid).
4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. ~~If used for handling (including processing), the substance's mode of action must be described.~~
5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. ~~Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.~~
6. For Handling substances provide information about the ancillary substances (such as, but not limited to, carriers, emulsifiers or stabilizers) that may be included with the petitioned substance, including function, type of substance, and source if known.
7. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.
8. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. The information provided must confirm that the intended use of the substance is permitted under EPA or FDA regulations, as applicable. If this information does not exist or is not applicable, the petitioner should state so in the petition.
9. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.
10. The substance's physical properties and chemical mode of action including

(a) Chemical interactions with other substances, especially substances used in organic production;
(b) toxicity and environmental persistence;
(c) environmental impacts from its use and/ or manufacture;
(d) effects on human health; and,
(e) effects on soil organisms, crops, or livestock.

11. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

12. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include substances onto the National List for organic handling, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. ~~Commercial availability does not depend upon geographic location or local market conditions.~~ If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

13. A ''Petition Justification Statement'' which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

. • Explain why the synthetic substance is necessary for the production or handling of an organic product.

. • Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods[1] that could be used in place of the petitioned synthetic substance.

. • Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

. • Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product, making sure to cover all uses of the listed substance.

. • Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance, and their availability and applicability to all situations where the substance is used.

C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604

. • Explain why the non-synthetic substance should not be permitted in the production of an organic product.

. • Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

. • Explain why the non-synthetic substance should be permitted in the production of an organic product.

[1] *Cultural methods.* Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

. • Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic or synthetic substances on the National List or alternative cultural methods.

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance Onto the National List, § 205.605(a)

. • Explain why the substance is necessary for use in organic handling.

. • Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

. • Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Non-Synthetic, Non-Agricultural Substance From the National List, § 205.605(a)

. • Explain why the substance is no longer necessary for use in organic handling.

. • Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance, making sure to cover all uses.

G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606

. • Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.

. • Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.

• Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria: (1) Regions of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and
(5) Other issues which may present a challenge to a consistent supply.

H. Removal of a Non-Organically Produced Agricultural Substance From the National List, § 205.606

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:
  (1) Region of production, including factors such as climate and number of regions;
  (2) Number of suppliers and amount produced;
  (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
  (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
  (5) Any other issues which may present a challenge to a consistent supply.

I. Adding, amending, or removing an annotation for a listed substance in all sections

- Provide evidence that the existing annotation is flawed, unnecessary, or outdated.
- Indicate why an annotation is needed or a change to existing one is needed.
- Explain what revision is needed to the annotation and why, with reference to the review criteria.

~~13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:~~
~~.(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim.~~
~~.(b) ''Trade secrets'' (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.~~
~~.(c) Each page containing CBI material must have ''CBI Copy'' marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and ''CBI.''~~
~~.(d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI). Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.~~
~~.(e) Each page with CBI-deletions should be marked ''CBI-deleted'' at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ''CBI-deleted.''~~
~~.(f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ''pages 7 through 10 have been CBI-deleted.'')~~
~~.(g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information cannot be claimed as confidential.~~
~~(h) Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). If a determination is made to deny CBI treatment, the petitioner will be afforded an opportunity to withdraw the submission.~~

Part 2. NOSB Policy and Procedures Manual proposed revisions

PPM, pp. 34-35:

MATERIALS REVIEW PROCESS
This section presents the procedures followed by the NOSB to evaluate petitions. First, the NOP material review process is presented. Second, a review of the NOSB process for selecting and reviewing the work of technical advisory panels is provided followed by a description needed in a formal petition. Third, the process for NOSB material review is provided. This section concludes by providing a graphical description of the sunset review process.

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List.

The petition process is open to all, including members of the NOSB. The priority system for determining in which order petitions are reviewed will be applied to all petitions (Section VIII). These procedures also apply to petitions to add, remove, or change an annotation to an already listed substance.

Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility
During this phase the NOP will:
• Notify the petitioner via letter and/or electronic mail of receipt of the petition. Determine whether the petition is complete
• Determine whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.
• Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA); the Food and Drug Administration (FDA); or other appropriate federal agency if applicable;
~~• Identify and secure any confidential business information (CBI) designated by the petitioner;~~
~~• Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI~~.
• Upon determination of completeness and eligibility, the following actions will be taken:
o Publish the petition on NOP website; and
o Notify the National Organic Standards Board (NOSB) ~~materials committee chairperson and the~~ chairperson of the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock, Handling or other pertinent committees). This notification will be sent via letter and/or electronic mail and inform the chairs that the petition is complete and provide OFPA review and EPA/FDA determination checklist. ~~and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report.~~

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Phase 2: Determine whether a Third Party Technical Review is Required
During this phase:
• The ~~NOSB materials committee, working with other~~ applicable NOSB committee has 60 days to submit any questions to the NOP. The questions requested by the committee should include items that need specific background information, recommended technical expertise, and be based on the OFPA criteria.
• Per the NOP materials review process, the NOSB should review the petition and using the NOP checklists for the material determine the following:

1) Whether the material is deemed appropriate for consideration on the National List (pending criteria). If the answer is no to this question, an explanation is required.
2) If the answer to question #1 is yes, the NOSB committee assigned for the review ~~(as identified by the Materials Committee Chair)~~ must decide whether
a) there is sufficient information in the petition,
b) the committee can reasonably research any pending technical information, or
c) there is the need to secure a technical review from a third party expert (see section titled Procedures for Handling Technical Reviews)

3) If the answer to question #1 is no, the appropriate sub ~~Materials~~ Committee Chair will inform the NOP that the petition is incomplete and will include an explanation. If the reviewing committee concludes there is a need for a third party technical review, the Materials Committee Chair will proceed to make the request to the Program.

• Notify the petitioner, via letter and/or electronic mail, that the petition is incomplete or ineligible; or *(proceed to Phase 3: Evaluation by a Third Party Expert)*

pp. 37-38

PROCEDURES FOR HANDLING TECHNICAL REVIEWS

The NOSB's role involves reviewing specific materials; however, a petition could involve a wide range of topics. Although members of the Board represent several areas of the organic community and hold advanced degrees in different scientific areas, they might lack the expertise, or time, required to address the data needs of a petition. In such cases the Board has the option of requesting the assistance of third party experts and expecting from these experts a written technical review or report.

Third party experts can consist of the following:
1. Employees of the USDA such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed.
2. Consultants or contractors.

A subcommittee should follow these steps in deciding the need for third party expert:
1. Define whether the subcommittee has the expertise needed to address the questions related to the petition, mainly:
a. Impact on the environment
b. Impact to human health
c. Sustainability and compatibility with organic principles.

2. If the subcommittee does not have the expertise or resources (e.g., time), the Subcommittee chair should make a request ~~to the Chair of the Materials Committee~~ for a third party expert specifying:
a. The third party expert's required background and level of expertise
b. Existence of potential sources of conflict that could result in biased reviews.

3. When requesting the assistance of a third party expert to evaluate a material, a subcommittee must identify the main technical issues needed to be addressed including, but not limited to:
a. All uses of the petitioned material beyond what the petitioner has requested
b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
d. All possible manufacturing methods for a petitioned material.
e. Potential effects on public health and biodiversity
f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability
g. Ancillary substances that may be used in conjunction with handling materials, such are carriers, stabilizers or emulsifiers.

4. ~~If required~~, The Subcommittee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert.

These are basic principles that should be considered when dealing with a third party expert:
1. A Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient ~~limited~~ valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.

2. The decision to request third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.

3. Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the subcommittee reviewing the material.

4. The decision to define the expertise needed in the third party expert is the responsibility of the subcommittee reviewing the material or issue.

5. To incorporate a diversity of opinions and to minimize the risk of bias, a subcommittee should aim to work with a range of technical experts (individuals, or institutions).

Once the Technical Reports are submitted to the requesting subcommittee, that committee determines if the issues have been addressed sufficiently. If there are remaining questions, the subcommittee can go back for further clarification and expansion of the technical report. Once the information is deemed sufficient, the report is acceptable for public posting.

Subcommittee Vote

Motion to accept the proposal on Updating the petition and TR process as described above and voted on August 27

Motion by: Zea Sonnabend
Seconded by: Tracy Favre
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 27, 2013

National Organic Standards Board
Materials Subcommittee
Proposal: Confidential Business Information in Petitions

July 23, 2013
Reviewed February 25, 2014 - No revisions

Introduction

In preparation for the Spring 2013 NOSB meeting, the Materials Subcommittee submitted for Board review and public input a discussion document "Confidential Business Information in Petitions". That document discussed the procedures currently being used to address Confidential Business Information (CBI) as it relates to petitions for materials for inclusion on the National List, and the challenges associated with evaluation of petitioned materials without full and complete information, some of which could be classified as CBI. The document put forth two possible recommendations for modification of the current CBI policy, along with the request for feedback from the public.

Possible Recommendation 1:

CBI is not allowed in petitions. Petitioners must provide complete information about manufacturing processes and ingredients so that the NOSB and the public can fully evaluate each petitioned material. A modified version of this choice would be to not allow CBI for manufacturing processes or ingredients but to allow back up research and references to be submitted as CBI to assist the TR development.

Possible Recommendation 2:

CBI be allowed in petitions with the following stakeholder responsibilities:

<u>For the National Organic Program</u>

A. The NOP will allow only information meeting the strict definition of CBI to be deleted from petitions considered by the board and posted for public viewing.

B. The NOP must make it clear to petitioners what happens to the CBI submitted and who does and does not have access to it, preferably by revising the Petition Guidelines. It should be very clear to petitioners that the NOSB does not see the confidential information.

C. The Technical Review contractor will have access to the CBI upon request. The contractor may then evaluate the CBI and conduct additional research to verify similar information.

D. The TR contractor will indicate that they looked at CBI in the course of their review.

<u>For Petitioners</u>

E. Petitioners are highly urged to provide complete information in their petitions, and keep CBI to the absolute minimum.

F. Petitions Guideline B.13 requires a statement of reasons for the CBI. This statement needs to be clearly stated, and is part of the public petition that will be seen by the NOSB.

G. Petitions will not be considered unless the rules in the Petitions Guidelines for CBI are followed completely.

H. Petitioners need to be aware that petitions containing CBI are rarely approved by the NOSB and the board reserves the right to reject such a petition that does not give complete manufacturing information. The NOSB may also send back a petition as incomplete if there is simply not enough information to make a decision.

For the National Organic Standards Board

I. The Policy and Procedures Manual will be updated to reflect any changes to CBI procedures based on this recommendation and the NOP revising the petition guidelines.

J. Petitions that come in with CBI will be looked at in the usual way by the subcommittees and any that have withheld too much information to allow the Board to make an informed decision may be returned to the petitioner. Others will move forward for a Technical Review.

K. If a petition is rejected because of CBI, the petitioner may re-petition and disclose the CBI. However, the NOSB will treat this at the lower level of priority with other re-petitioned substances.

Summary of Public Comments
Not surprisingly, there were differences of opinion regarding the need for allowances for CBI. Generally, public comments expressed the need for sufficient information for the NOSB to make determinations regarding the classification of materials – synthetic/non-synthetic and or agricultural/non-agricultural, and to determine the impact on human health and the environment. The majority of commenters expressed the opinion that a full list of ingredients should be disclosed. However, some commenters expressed the need for complete transparency regarding the full list of ingredients and manufacturing processes in the petitioned material. Others had concerns about protection of manufacturing processes and/or recipes of petitioned materials, and the potential for impact to participation in the National Organic Program, should CBI not be protected. The proposal for an affidavit process was generally either rejected outright or the opinion was expressed that the affidavit process would need more detail before it could be determined whether or not it would be effective.

Feedback pointed out the administrative difficulty in maintaining confidentiality of CBI provided to the NOSB and not the public and further stated that the transparency of the petition process and the relationship of the NOSB to the public could be adversely affected if such a procedure was implemented.

In order for the NOSB to discharge its responsibility for the proper evaluation of a petitioned material, the following information should be provided:

1. A complete list of ingredients included in the petitioned material. The exact recipes or formulations are not required; only sufficient information so that the NOSB can evaluate the impact on human health and the agro-ecosystem;
2. Sufficient information regarding the manufacturing process to allow for determining the classification of that material as either synthetic or non-synthetic and/or agricultural/non-agricultural and sufficient information regarding the manufacturing process to allow for an assessment of adverse health and environment effects that may be associated with

the product's production. Detailed, proprietary information regarding the manufacturing process is not required, except as it relates to the statement above.

Petitioners are encouraged to review the Classification of Materials Draft Guidance (NOP 5033), the Synthetic/Non-Synthetic Decision Tree (NOP 5033-1), and the Agricultural/Non-Agricultural Decision Tree (NOP 5033-2) for draft guidance on what minimum information is necessary for determination of Classification of Petitioned Materials.

Conclusion and Recommendation
The NOSB recognizes the investment and risk associated with development of proprietary materials and processes. The board's intention is not to place petitioners at economic risk through information provided as part of a petition process. However, the importance of transparency of the petition process, the right of the public to fully know the materials included in or on certified organic products, and the potential for an untenable administrative burden of management of CBI precludes the provision of CBI in materials petitions.

For this reason, the Materials Subcommittee is recommending a revision to the Material Petition process to eliminate the provision for Confidential Business Information.

Subcommittee Vote

The Materials Subcommittee moves to accept this recommendation and present it for full Board discussion at the fall 2013 NOSB meeting.

Motion by: Tracy Favre
Seconded by: Jay Feldman
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 27, 2013

National Organic Standards Board
Materials Subcommittee
Proposal: Research Priorities for 2013

August 27, 2013
Reviewed December 10, 2013 - No revisions

Introduction

A Recommendation for a Framework to set Research Priorities was approved at the National Organic Standards Board (NOSB) meeting in May 2012. Part of that recommendation was that the priorities from the previous year of NOSB deliberations would be presented at each fall meeting. Therefore, we have collected suggested research topics from the NOSB subcommittees and from suggestions within the public comments and present the top research priorities for approval this fall.

After a recommendation is finalized by the NOSB each fall the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

Background

The reasons for encouraging research into organic production systems are well discussed in the previous two Materials Committee papers from fall 2011 and spring 2012.

The recommendation that was passed recommends that potential topics be prioritized. The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but will be evaluated by the Materials Committee in selecting the top research needs.
Criteria for research topics are:

A. Persistent and chronic (i.e., perennial topics of debate and need)
B. Challenging
C. Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
D. Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear), for example, improved methods of weed control.
E. Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
F. Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Call for Researchers

We hope that this information will be useful for researchers in many fields to defend and solicit funds for research that benefits organic production and handling. Therefore, we invite the public to comment on these topics, to circulate this widely, and to recommend that funders also prioritize these topics. Please submit comments on funders who might want to remain informed of research opportunities in organics.

NOSB Research Priorities 2013:

For 2013 the Subcommittee has re-emphasized four topics that were on the list last year, and has added several more pertinent topics. The top priorities are in this section without any ranking, with a description of some research questions and why each topic is important. The

following section titled "Topics for future review" contains other subjects that the NOSB subcommittees put forward but are secondary to the top priorities here. Research into these and interrelated issues is urgently needed.

Whole Farm Systems

How can working with the natural world by including diversity of habitat, cropping systems, and biological life benefit an organic farm? Selected subjects within this heading include: Can crop species and varieties be specifically adapted to their site through plant breeding or cultural practices? How does biodiversity contribute to pest and disease resistance? What is the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests? How can the need for a diverse ecological system be balanced with food safety concerns for a sustainable organic farming system?

Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight

With oxytetracycline and streptomycin due to expire from the National List in October of 2014, the organic apple and pear growers must find suitable alternatives to control the deadly fire blight disease. Since apples and pears are grown throughout the United States in many regions, these alternatives must work in a variety of climates and a variety of management systems. The following research issues are important to investigate: location, planting density, choice of varieties of cultivar and rootstock, soil improvement practices, pruning practices and general sanitation, groundcovers or intercrops, pollinator management, dormant copper sprays, bloom thinning/lime sulfur, early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment, surveys for fire blight activity, and other cultural and preventative techniques.

Evaluation of Genetically Modified Vaccines (GMO)

Prevention and avoidance of unintended GMO contamination are foundational to organic production and brand. It is of such importance that NOSB has a GMO Ad-Hoc Subcommittee. A need exists for research and/or outreach on easier ways to determine the types of vaccines. A better way of identifying the types of vaccines is critically important to our stakeholders, especially livestock producers. The testing of products that could be alternatives to GMO vaccines in livestock production is a top priority.

Methionine Alternative

Methionine is an essential amino acid for poultry. Prior to the 1950’s poultry and pigs were fed a plant and meat based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), “We have seemingly made vegetarians out of poultry and pigs”. As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heighten need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and help find approaches for making them more commercially available.

The key research areas are on alternatives such as herbal methionine, corn gluten meal, potato meal, management practices, pastures management, fish meals, animal by-products, and other non-plant materials. Additional research on the more promising alternatives related to bringing them into commercial production is also encouraged.

Organic Aquaculture

Organically-labeled aquaculture products are increasing rapidly in markets around the world.

In the U.S., debate continues on appropriate use(s) of the organic label for aquaculture systems, and whether such use should be approved for open-water systems as well as closed systems such as ponds or tanks. Therefore, research efforts pertaining to both open and closed systems are needed.
Research needed includes:
- evaluating the environmental impacts of fish wastes from aquaculture systems on the environment;
- appropriateness of feed and other supplements such as trace minerals that may have synthetic sources;
- organic practices for fish health and management of diseases and parasites;
- and impacts and control of fish escapes in open water situations.

The subcommittee notes that application of organic agriculture principles (as described in OFPA) to aquaculture poses some definitional problems. OFPA refers to organic management principles and practices that were developed in the context of terrestrial plant and animal systems. Research approaches are needed which explore the extension of these principles to aquatic systems. (For example, see following discussion of “aquatic biodiversity”)

Aquatic Biodiversity

Organic farmers promote biodiversity in cultivated and uncultivated areas through crop rotations and other practices. They are expected to maintain areas like hedgerows, woodlands, wetlands, and wildlife corridors to promote non-crop biodiversity on the farm. The conservation of biodiversity must be included in organic systems plans for aquaculture as well. NOSB materials recommendations need to be made with a goal of preserving and enhancing biodiversity. With the impending implementation of rules on organic aquaculture, it is important that decisions be made with a firm understanding of aquatic ecology and possible impacts of the Board’s decisions. Decisions concerning terrestrial inputs derived from aquatic environments also need to be based on an understanding of the impacts from such activities.

In particular, the NOSB needs to understand: nutrient and mineral cycling in various aquatic systems, the structure of aquatic food webs, the movement of pollutants in various aquatic systems, bioaccumulation and bioconcentration in aquatic organisms, and the status and impacts of overharvesting and other stresses on aquatic/marine plants and animals. Board members, certifiers, and aquaculture operators all need to know how biodiversity conservation measures should be implemented in aquaculture systems and materials decisions.

Herd Health

The assessment of preventive organic practices to improve organic livestock health is critical and of high importance. These include general animal health as it relates to diseases prevention, uterine infections in peri-parturient animals, growth, and identification of vaccine types, nutrition, and production systems. Research that could lead practitioners to better prevention strategies, use of non-synthetic substances such as feed supplements that would improve health and management practices that minimize health issues are all important topics.

Pastured Poultry and Salmonella

Raising poultry on pasture where the birds get a varied diet, are outdoors and have space to roam makes sense from an organic standpoint. But does pasturing of poultry lead to higher

rates of Salmonella infection? Some critics have claimed this but there is scant evidence to support or refute this opinion. Exploring where Salmonella infections can originate, whether the pasture system has some inherent buffering capacity against pathogens getting a foothold, and whether there truly is more risk involved in raising organic poultry on pasture are key research topics.

Commercial Availability Assessments

The NOSB must make assessments of commercial availability or organic sources every time there is a petition or a sunset review for substances on §205.606 in particular (agricultural substances that may be used from non-organic sources). What are some resources for commercial availability information? Is it out there? If there is no information available, how could such information be developed?

Consumer Demand

The NOSB get told often by commenters who are or claim to represent consumers that consumers have expectations about what organic means and what inputs and ingredients should be in organic food. Sometimes there is a wide difference between what consumer activist groups claim and sales of specific categories of organic products in the marketplace. How can the NOSB determine whether the consumers and groups who speak up are truly representing all consumers of organic, and if not, is there a better measure of consumer preference and expectations than sales figures for organic products? This has come up in the past year with particular regard to fortification by synthetic nutrients in infant formula and other processed food, as well as in the apple and pear marketplace with the discussion of oxytetracycline. Research into the relationship of consumer buying habits and their beliefs about them would be helpful.

Fate of Genetically Engineered Plant Material in Compost?

What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (*bacillus thuringienses*) after composting?

Reduction of Genetically Modified Content of Breeding Lines

In grappling with the issue of a Seed Purity Standard, it came up in comment that breeding lines of corn and other crops had become polluted by GMO pollen entering their germplasm. This research question is posed to determine what techniques can be applied to reduce or eliminate contamination by unintended GMO presence in seed breeding materials. Can lines be "purified" so that there are non-detectable levels of GMOs after several selection cycles and how many generations would it take?

Topics for Future Review

This group of topics was submitted by the Crops and Livestock Subcommittees of the NOSB but did not make it into the Priorities for Research in 2013. They will remain in consideration for future year priorities.

- **Chlorine Alternatives**

Chlorine compounds are the most common equipment and food contact sanitizers used in the food processing and handling. They are also common disinfecting agents for farm equipment and tools. In its reactive forms –chlorine gas, hypochlorite, etc. – chlorine may react with organic matter to form organochlorines, which are generally persistent, toxic, carcinogenic, and often endocrine disruptors. Sometimes the reactions are purposeful, to create pesticides, solvents, pharmaceuticals, and other synthetic chemical products. Other times unintentional byproducts, such as chloroform or carbon tetrachloride, result from processes such as disinfection.

The fact that use of chlorine –as opposed to chloride– is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based chemicals. Since chlorine compounds have so many adverse impacts in the production-to-disposal life of the materials, we recommend that the NOSB support research to determine how organic production can move beyond reliance on chlorine-based materials.

- **Sulfuric Acid Alternatives**

Sulfuric acid is commonly used to lower the pH in the manufacture or processing of some agricultural inputs. The NOSB has received petitions for sulfuric acid itself and also for materials that have sulfuric acid as a processing aid in the manufacture. Recent examples include vinasse, magnesium oxide, and laminarin.

In 2006, the Crops Subcommittee voted unanimously to reject a petition to allow use of sulfuric acid in anaerobically digested livestock manure because “Sulfuric acid, when used in livestock manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient. Additionally, it is an important air pollutant, e.g. acid rain. Other wholly natural materials can be used.” In 2012, the Crops Subcommittee took a similar position on a similar petition.

Unfortunately, the NOSB is not always able to identify alternatives, despite concerns about sulfate as a synthetic plant nutrient and environmental impacts. Research into natural acids or other substitutes that could be used in place of sulfuric acid to lower pH in the production of inputs for organic agriculture, as well as whether the pH lowering step is always required to purify, extract or stabilize raw inputs is important to the NOSB deliberations on materials.

- **Parasitism**

The control of internal and external parasites is important to animal welfare, growth, reproduction, and production. In organic production, the control of parasites is critical. The use of antibiotics is prohibited. A limited number of substances are available to control parasites. Antibiotics are not allowed in organic livestock production for growth, reproduction, and production. Antibiotics can be used on sick animals. However, these animals cannot be sold as organic. A critical need exists to explore ways to find materials for the control of internal and external parasites in organic livestock operations.

- **Mastitis**

Mastitis is a disease of the mammary gland. It is an inflammation in the mammary gland. It is generally associated with dairy cattle. It can be caused by bacteria, physical injury, etc. Mastitis is one of the most common and expensive diseases of dairy cattle. It can result in reduced milk production, discarded milk, treatment, and veterinary expenses. An urgent need exists for looking at ways to reduce mastitis in dairy herds. The research needs include the areas of herbal treatment of mastitis and management practices.

- **Pneumonia**

Pneumonia denotes a swelling of the lungs. Pneumonia is rare when animal populations and densities are low. In the winter, animals are housed or gather more closely together, increasing

the concentration of pathogens in their environment. Confinement and higher animal densities result in increased air temperatures, humidity, and condensation, which are beneficial conditions for pathogen survival and transmission. Pneumonia in a herd or flock means animals are not performing up to their maximum potential, production costs are higher, labor is increased, and food product quality is compromised. Responsible animal caretakers know it is their duty and responsibility to address animal welfare concerns and ensure a safe and healthy environment for their animals.

Subcommittee Vote

Motion to adopt the proposed recommendation on NOSB Research Priorities for 2013.

Motion by: Zea Sonnabend
Seconded by: Tracy Favre
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB September 3, 2013

National Organic Standards Board
Materials/GMO ad hoc Subcommittee
Report
Seed Purity from GMOs
+February 25, 2014

Introduction

The GMO ad hoc Subcommittee has issued a discussion document on Seed Purity from GMOs over a period of two NOSB meetings that were six months apart. This report summarizes the public comment received from this effort and provides the subcommittee analysis of the situation. The subcommittee has chosen not to submit a proposal at this time.

Organic stakeholders are concerned about keeping genetically modified organisms (GMOs) (i.e., the products of transgenic plant or animal breeding) out of organic livestock feed, crops, and food. The production and handling of organic goods prohibits the use of "excluded methods" including transgenic modification. This prohibition applies to seeds used on organic farms. The organic community continues to be proactive in developing positions, procedures, and practices to prevent GMO contamination. An important part of such prevention is ensuring genetic purity of seed used on organic farms. Pure seed is a cornerstone of true sustainability in an organic farming system.

Policy Memo 11-13 from the National Organic Program (NOP) affirms that organic certification is process based. Part of that process is implementing measures to prevent and exclude GMOs. In order to determine that these preventative practices are adequate to avoid contamination with prohibited substances or excluded methods, there may be a role for seed purity testing, similar to the role for residue testing.

In the Discussion Document the suggested standard would be based on presence or absence of GE content in a specified seed sample size (e.g. 3000 seeds). The use of terms like "non-detect" or "none found in the sample" is less confusing than the statistical expression summarizing what "none found" in a sample means relative to the level of certainty that the whole lot is not contaminated.

The public comments to National Organic Standards Board (NOSB) and NOP continue to indicate a strong concern by both producers and consumers of organic foods for stronger steps to limit the potential and/or unintended presence of GMOs. Seed may be the most impactful and efficient point in the supply chain at which GMO contamination of organic feed, crops, and food could be limited and controlled.

The conclusion of the GMO ad hoc Subcommittee is that a seed purity standard can be consistent with a process-based standard when analytical limits[1] are used to verify that adequate measures are in place to prevent contamination with excluded methods. This would also be consistent with the residue testing program under NOP.

The challenges of doing this and the valid issues raised by the public are examined here.

[1] Using analytical limits means that the sample size is specified in which no contamination is found, as opposed to stating a percentage of contaminated seed. The "analytical limit" approach is appropriate for two reasons: (1) No contamination is acceptable to the organic community, and (2) the only way to specify a zero contamination level is statistically, through specifying the sample size in which no contamination is found.

Background

• The NOP Organic Rule refers to Genetic Engineering (GE) as an "excluded method". “Organic” is a label that indicates that a process has been followed to exclude GMOs.

• Producing organic feed, crops, and food uncontaminated by GMOs requires starting with seed that is not contaminated by GMOs.

• Public and marketplace expectations for the absence of GMOs in organic goods call for implementing best practices on conventional and organic farms to minimize the potential for such contamination.

• We suggest that the process for ensuring genetic purity of commercial seeds in organic production must be stricter than conventional crop production. Clean seed must be planted for the farmer to harvest uncontaminated food or feed. Planting and harvesting contaminated seed can increase the likelihood of “creeping contamination” from year to year, since any additional GE contamination in seed handling or pollen drift into a field planted with partially contaminated seed would produce food, crops, or feed with a higher level of contamination than in the original seed.

• This strict process must protect organic seed growers in order to protect seed purity.

• In spite of conventional agriculture's discomfort with the reference to "contamination" from genetically altered DNA in organics (such as on page 4 of the public comment from the American Seed Trade Association from Sept. 2012[2]), the entire organic community considers GMO movement outside of the areas that they are grown in to be pollution. Therefore the encroachment into organic seed and crops is considered to be contamination of organic crops, and that is the vernacular used in this report.

• For the past two years since Genetic Engineering has been addressed in discussion by the NOSB, we have received many[3] public comments from consumers and farmers alike that organic means no GMOs, and maximum effort must be taken to keep them out of organic food.

• The public comment process on the Discussion Document raised several fundamental concerns about adopting a Seed Purity Standard. These are discussed below. The subcommittee analysis and discussion around these concerns is addressed in separate sections.

Relevant areas in the Rule

[2] Andrew LaVigne, commenting on behalf of the American Seed Trade Association (ASTA) to Docket AMS-NOP-12-0040, Sept. 2012.

[3] Ninety-three comments pertaining to the April 2011 NOSB meeting on the Regulations.gov website mentioned GE, despite the fact that nothing on the agenda addressed genetically modified organisms. In addition, eight people used at least part of their precious three minutes of comment time to address GE. The comments came from a variety of viewpoints and reflected a wide range of concerns.
Fourteen comments were received on seed purity discussion paper in October 2012.
Sixteen commenters submitted comments on the seed purity discussion paper in April 2013. Ten of these were commenters who did not submit comments in October 2012. In addition to comments specifically addressing agenda issues, 85 comments expressed general concern about GE contamination of organic crops and products. 216 comments were received in the Fall of 2013, when no agenda item addressed GE.
The largest outpouring of public comments was close to 300,000 comments opposed to GMOs (along with irradiation and sewage sludge) in organic production in the original proposed rule in 1998.

NOP standards[4] adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibited the use of GMOs in the production and handling of organic products certified to national organic standards.

The terminology used for GMOs in the NOP Regulation is “excluded methods” and is specified under section 205.2 (Terms Defined) as:

> **Excluded methods**. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.
>
> **Detection and Testing Requirements:** Under the residue testing requirements of NOP, 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 “organic.”
(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 finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMO. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO presence alone does not necessarily constitute a violation of the regulation.

Commercial Availability of Organic Seed: The NOP regulations at 7 CFR § 205.204 require that organic producers use organic seeds, annual seedlings, and planting stock. The regulations allow producers to utilize non-organic seeds and annual or perennial planting stock when organic varieties are not commercially available.

The term “commercial availability” is defined under section 205.2 (Terms Defined) as:
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.

[4] Title 7 CFR Part 205 - National Organic Program

Discussion of Public Comments & Subcommittee Evaluation

This section summarizes the comments from the public and then reports on the GMO subcommittee's thinking for each point raised. Quotes were taken from selected comments that illustrate each point, but not every commenter is quoted separately.

The large majority of public commenters wants to keep GMOs out of the organic system and is in favor of a proposal to address seed purity. Among the commenters from affected parties (farmers, seed companies, trade associations, certifiers), the majority were in favor and felt they could meet such a standard with enough time. The primary areas of concern among organic industry stakeholders about the example seed purity standard that was described in the Discussion Document are the following:

- Inconsistent with the "process" standard
- Not enough data about testing protocols and thresholds for rejection
- Not ready to implement because source material is unavailable
- Expensive for organic farmers, especially organic small-scale farmers
- Seed availability decreased, especially organic seed
- Policy must distinguish between organic and conventional seed
- Genetic diversity decreased because of contamination of breeding lines
- Should be the responsibility of the greater USDA to regulate, not just NOP

We will address each point with reference to public comment in particular.

<u>Inconsistent with the "process" standard</u>

Public Comment
"...setting a purity standard can be consistent with a process-based standard when analytical limits are used to verify that adequate measures are in place to prevent contamination with excluded methods. This can be analogous to the detection of prohibited pesticides. Organic standards prohibit the use of toxic and synthetic pesticides. Analytical testing and rejection levels are used to verify this process- based standard." (Organic Trade Association [OTA] public comment, spring 2013)

Subcommittee Evaluation
The Subcommittee agrees with this position and would like to move toward a recommendation, although there are some hurdles to overcome as discussed below. Any seed purity testing would be an analytical enforcement tool that would be used to supplement an overall seed purity protocol required as part of the organic systems plan that would include documenting seed sources, selection of appropriate field locations, maintaining appropriate buffer zones, and documenting equipment cleaning for both planting and harvest.

<u>Not enough data about testing protocols and thresholds for rejection</u>

Public Comment
The request for company data that was included in the discussion document did not result in enough information to help the subcommittee know what is currently occurring in the marketplace. "USDA should conduct a comprehensive analysis of existing contamination at the seed level." (Organic Seed Association [OSA] public comment, fall 2012) This recommendation coincides with one made in 2012 by the USDA Advisory Committee on Biotechnology and 21st

Century Agriculture ("AC21"). [5] USDA is currently developing implementation plans for the AC21 2012 recommendations.

Subcommittee Evaluation
The subcommittee supports any efforts made by the USDA in collecting relevant information. If good data is not provided through the NOSB public comment process, the NOSB does not have the ability to mandate data collection, only to suggest it to other parts of USDA. Any recommendation would have a significant amount of time for phase-in so that data can be collected and analyzed. We hope that such data will help inform us as to the scope of the problem.

Not ready to implement because source material is unavailable

Public Comment
Several commenters in the seed trade commented on the difficulty of finding breeding lines that are not already contaminated. Often they cannot test their incoming materials due to licensing rules.

Subcommittee Evaluation
We agree that source materials are limited and will become less and less available and contamination worse and worse in the future. Therefore, any proposal that eventually is recommended will certainly require a long lead time for starting a testing scheme and even longer for breeders and researchers to evaluate source materials that can comply. Our goal is to create a thriving organic seed industry for all crops, and we believe that to do this we need better tools to keep GMOs from encroaching into our seed supply and crops.

Expensive for organic farmers, especially organic small-scale farmers

Public Comment
Many stakeholders pointed out that organic farmers already assume the burden of taking many preventive measures to keep GMOs out of their products. Maintaining buffer zones in fields, delayed planting to avoid GMO pollen, cleaning procedures for harvest and seed cleaning equipment and final product testing are a few of such measures.

"The issue of both cost effectiveness and costs of testing escalating to the point of being prohibitive could actually reduce organic acreage or cause certified operators to leave the organic industry altogether." (OFARM public comment, fall 2012) This was a common sentiment expressed by seed companies and farmers and their representatives.

Subcommittee Evaluation
After reading all the public comment and inviting several key stakeholders to the subcommittee calls, the subcommittee discussed how any threshold for GMO contamination of seed would place a significant burden on organic farmers and small seed companies, and such cost burden should be coupled with liability for the GMO patent holders..

The subcommittee is unanimous in believing that the costs of preventing contamination should be borne by the GE seed patent holders. We don't believe that farmers who grow GMO crops

[5] The AC21 recommendation was part of the report, "Enhancing Coexistence." The specific recommendation at page 22 reads, "Conduct research…including…gathering and aggregating, on an ongoing basis, data from seed companies on unintended GE presence in commercial non-GE seed supplies intended for IP uses."

should be held responsible for losses. The patent holders need to be held accountable for the pollution caused by the escape of their genes into organic fields through seeds.

Most of the public comment from direct stakeholders was concerned with cost, timeline for implementation, and logistics of obtaining and maintaining pure source material, but not as much with the reasoning behind needing an analytical tool, or the specifics of a seed sampling size.

Achieving true accountability for the pollution of organic crops from those who cause it is a challenging concept to implement. The Subcommittee acknowledges that this issue goes beyond the scope of the NOSB and the NOP and therefore the usual type of NOSB recommendation cannot be used to reach this goal. We recognize that without larger changes outside the scope of NOP and USDA itself, imposing a seed purity standard on organic producers might be damaging to the overall growth of organic production and use of organic seed.

Nonetheless, three concepts for compensation by outside entities were discussed by the subcommittee, with the acknowledgement that neither the NOSB nor the NOP has the ability to implement any of them alone. Each of these concepts would appear to require Congressional action. These suggestions would only apply to compensation for seed purity testing and compensation when GE contamination is found.

A. CERCLA model - The objective of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) is to clean up uncontrolled releases of hazardous substances. The name "Superfund" comes from the fact that clean-up activities are financed by a fund originally created by taxes on oil and chemical industries.[6] We discussed applying the Superfund model to compensation for testing for seed purity and contamination.

B. Crop Insurance for polluters - Rather than make organic farmers pay for crop insurance, we would like the patent holders of GMO seed be required to get crop insurance in order to sell the seed. This could be built into the cost of the GMO seed. A portion of this crop insurance fund would be available to pay for the organic farmers and organic seed companies to test seed lots.

C. Government administered compensation - This concept is for the government to use taxpayer money or perhaps money assessed through the patent process and regulatory review of new GMO crops and products. This would make sure that conventional farmers would not bear the burden directly but the patent holders would. We realize that this approach would require Congressional action. However, this would place responsibility on the parties who are responsible for the pollution.

The topic of "GMO contamination insurance" for organic producers was also discussed, along the lines of what was suggested by the AC21 recommendations. Discussion points included whether insurance should be voluntary or mandatory and whether this was a solution for enough people to make pursuing it worthwhile. The majority of the past and present members of the subcommittee felt this approach was untenable because it places the entire burden on

[6] Three dedicated taxes on oil and chemical industries -- on petroleum, chemical feedstock, and corporate income[6]— historically provided the majority of the trust fund's income. Those taxes expired at the end of 1995, however, and the amount of unobligated money in the fund gradually dwindled. Since President Obama has been in office, he has regularly proposed reinstatement of the Superfund taxes. General funds have been used for site cleanup meanwhile.

organic producers and involves no acknowledgement or accountability on the part of the patent holders, or any incentive for them to contain their pollution.

Seed availability decreased, especially organic seed

Public Comment
Commenters expressed that seed availability would certainly decrease if the proposal went into effect soon. Several suggested that a long time frame for the entire organic community to start working towards this as a goal could make this achievable in the future.

Subcommittee Evaluation
Increasing the variety and quantity of organic seed is very important and the NOSB has issued several past recommendations in support of organic seed. Yet, just as trueness-to-type, good viability, and high performance are important traits in seeds for organic systems, so is keeping GMOs out of the seed supply.

We recognize that there are significant challenges to overcome and among them are the needs for data on what seed is already available that can meet the standard, as well as a need for basic research on whether GMO content in breeding lines can be bred out over time to re-gain a wider assortment of germplasm to produce clean organic seed.

An important step would be to create a timeline by which to measure forward progress. We want all stakeholders notified of our intentions to keep working on this topic, and would like continued support from stakeholders on this effort if we are ever able to move forward with a recommendation.

Policy must distinguish between organic and conventional seed

Public Comment
Several commenters called for a distinction in policy between testing of organic seed and testing conventional seed used in organic production. "The organic community needs to aggressively support and increase the use of organic seed, or we risk losing access to many genetic traits and varieties..."(Blue River Hybrids public comment, Fall, 2012)

Subcommittee Evaluation
The NOSB as a whole has issued recommendations to favor the use of organic seeds. Yet we are concerned that preferring contaminated organic seeds over identity-preserved non-GMO conventional seed may not be desirable. We welcome more public comment on how a seed purity standard should address this dilemma, including incentives to favor the use of organic seed. Possibilities to favor organic seed in any future proposal could include a longer timeline for implementation, a less stringent sample size, less frequency of testing based on other preventative practices taken, or other ideas for spurring on the use of organic seed.

Genetic diversity decreased because of contamination of breeding lines

Public Comment
Not only has the seed supply available to organic farmers been contaminated, but the breeding lines and foundation stock used to produce seed have often been contaminated. From the survey of seed companies done by the Organic Seed Alliance came the following information: "....some companies relayed that it’s not uncommon for germplasm licensing agreements to prohibit testing for GE content. This puts companies who want to protect their reputation as a supplier of “clean” seed in a vulnerable position of risking litigation if they decide to test illegally.

Public plant breeders have also relayed similar experiences regarding limited access to germplasm that does not come with restrictions or fears of unintended patent infringement" (OSA public comment, fall 2012). If we do not act soon, the choice of available breeding material that meets any seed purity standard may end up being of poorer genetic quality as a result (OSA public comment, fall 2012).

Subcommittee Evaluation
The subcommittee strongly agrees with this concern and believes it is a vital part of an organic system to encourage genetic diversity. Addressing this issue will take even longer than it may take to bring a standard into existence. Therefore we would suggest a longer period of time for breeding lines and foundation seed, such as the 5 additional years suggested in the Discussion Document, with a variance or waiver to provide yet additional time if found to be necessary. We intend to re-visit this over the time we spend doing further work on this issue, while at the same time putting forward a strong call for research into procuring and maintaining clean breeding materials. We additionally recommend the development of more strategies that the GMO farmer may use to reduce or eliminate contamination from GMO agriculture farm systems.

<u>Should be the responsibility of the greater USDA to regulate, not just NOP</u>

Public Comment
In light of recent events concerning the detection of GMO wheat escaping into a farm field, the lack of regulation and oversight of genetically modified crops has become more and more apparent. Many of our public commenters expressed this quite eloquently.

> "USDA should play an assertive role in safeguarding the private property rights of American organic farmers when it comes to preventing unwanted trespass and genetic drift by GE patent-holders onto organic farms. Organic farmers have a right to farm in the way they choose on their farm without threat of intimidation and transgenic trespass." (Organic Seed Grower and Trade Association [OSGATA] public comment, spring 2013)
>
> "A meaningful regulatory framework for GE seed and crops would mandate proven containment measures in the field, from field trials to commercialized production, and strict post-market monitoring and evaluation of their effects on the environment and other production systems and markets, especially organic. The framework would also include routine monitoring of gene flow, and a comprehensive evaluation of the genetic purity of our nation's foundation seed." (OSA public comment, fall 2012)
>
> "Demand that Congress create laws and authorize funds for the USDA to map planting of GE crops and non GE crop contamination, and hold contaminators accountable for cleanup cost and organic farmer losses." (Dietrick Inst. for Applied Insect Ecology public comment, spring 2013)

Subcommittee Evaluation
We echo the points raised by our stakeholders above. Organic producers are already going more than half way to bear the costs of maintaining organic integrity. It is not the conventional farmers who should be penalized for this; it is the patent holders who cannot keep their genes contained and the regulators who have not done enough to enable all farmers to produce crops in the way that they choose. We also recognize that the regulators are hampered by underlying limitations in their authority to act on the concerns of the stakeholders on GMO issues. However change can only happen by speaking out at every opportunity and this report is the ad hoc GMO subcommittee's opportunity to do so.

Conclusions

The GMO ad hoc Subcommittee has concluded that a genetic purity standard is desirable for seed used in organic production systems where there are conventional genetically engineered varieties of that crop. The main reasons why it is desirable are:

- •• It can be a useful tool to verify compliance with the excluded methods process standard, much as residue testing is a tool to verify compliance with other sections of the rule.
- •• The marketplace is increasingly demanding it. As awareness of GMOs grow among consumers because of labeling efforts, the consumers need assurance that organic represents a label from which GMOs are truly excluded, thereby leading to organic food that is less likely to be contaminated with GMOs. .
- •• There is no way to prove irreparable harm when a contamination event occurs if there is no benchmark for rejection from the organic supply chain.
- •• Developers of future GMO traits and varieties are claiming that there is no impact of their agricultural trespass on organic producers because there are no grounds for rejecting contaminated seeds.
- •• Genetic engineering is not compatible with organic food or farming and the organic community needs all the tools it can possibly use to keep GMOs out.

We believe that this is an urgent issue but as we have noted above, there are several fundamental problems with designing and implementing such a standard (lack of clean breeding lines, disincentives to be organically certified, lack of data on where the problem actually exists, excessive costs, etc.). Because of these unknowns and obstacles, it is not possible to put forward a workable standard at this time.

Based on the comments received and our own discussion, we believe that an eventual seed purity standard should have the following features:

- The standard we have discussed would be based on presence or absence of GE content in a specified seed sample size (e.g. 3000 seeds). The use of terms like “non-detect” or” none found in the sample” is consistent with this goal, and less confusing than the statistical expression summarizing what “none found” in a sample means relative to the level of certainty that the whole lot is not contaminated. We see this as an analytical tool to verify compliance with the process-based standard for excluded methods.
- Organic seed growers should be protected from and compensated for contamination of their seed crops.
- The cost should not be borne by organic seed producers. The cost of seed testing and costs resulting from detected contamination of the seed supply should be borne by the patent holders of the contaminating genes.
- The standard should apply equally to organic seed and untreated conventional seed used for planting organic fields, however provisions to favor organic seeds should be explored.
- More details on how often to test, what method of testing, and what to do with seed that does not pass should be worked out between now and the time this moves forward, acknowledging that these issues and detection limits can change as technology advances.
- Initially, additional time will be needed to achieve purity for breeding lines and foundation seed, and this time period should be extended with variances or waivers based on experience and need.

As noted in this report, the third bullet point above is outside the authority of the NOSB and the National Organic Program. The subcommittee welcomes constructive suggestions from the public on funding mechanisms and the other points raised in this discussion that are within the scope of the NOP and NOSB to work on going forward.

We understand that the role of the NOP is limited in this matter, and in fact some points raised extend beyond the USDA and into the Coordinated Framework[7]. Therefore, solution-oriented comments to this report must be addressed to areas within our ability to work on.

The subcommittee also urges increased research into testing protocols, contamination avoidance methods and technologies, methods to minimize or eliminate contamination from breeding lines and foundation seed, rejection levels, and amount of contamination currently being found in the field be prioritized by the USDA and organic funders. These needs should be included in the NOSB's research recommendations to USDA.

Subcommittee Vote

Motion to accept the Seed Purity report presented February 25 as outlined above.

Motion by: Zea Sonnabend
Seconded by: C. Reuben Walker
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 25, 2014

[7] The U.S. "Coordinated Framework for Regulation of Biotechnology" document was issued by the Office of Science and Technology Policy in 1986. See *Fed Regist.* 51 (123): 23302–50.