



Comments to the National Organic Standards Board

April 29-May 2, 2014 Meeting
San Antonio, Texas

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The Cornucopia Institute's

Comments to the

National Organic Standards Board

Spring 2014 Meeting
April 29 – May 2
San Antonio, Texas

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INTRODUCTION

The Cornucopia Institute is a 501(c)(3) public interest farm and food policy research organization. Cornucopia engages in educational activities supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture.

Through research and investigations on agricultural and food issues, The Cornucopia Institute provides educational information to farmers, consumers, other stakeholders involved in the good food movement, and the media.

We are proud to represent over 10,000 supporting members, and an impressive percentage of the nation's certified organic farmers.

We do not sell materials seeking approval or sunset reauthorization, and we do not sell organic products that utilize any substances that might be petitioned.

We have no financial interest in the approval of any of the materials proposed for use in organic foods.

Cornucopia adamantly believes that a thorough and appropriate review process needs to take place for all petitioned materials, and that all materials should conform with the Organic Foods Production Act of 1990 (OFPA) and the federal organic standards. We hope that the Board will benefit from Cornucopia's independent perspective in these comments.

Readers will also find the comments that were prepared by Cornucopia for the Fall 2013 meeting that pertain to the now-disbanded Policy Development Subcommittee. These comments are provided for NOSB members as, according to the minutes of the Executive Subcommittee, the Policy and Procedures Manual remains the guiding document for the NOSB.

CROPS SUBCOMMITTEE

Streptomycin

SUMMARY

Reject the petition to remove the existing expiration date of October 21, 2014 for streptomycin on §205.601 and replace it with an expiration date of October 21, 2017, for both apples and pears.

The antibiotic streptomycin, marketed as streptomycin sulfate, is currently allowed as a plant disease control in organic crop production, for fire blight in apples and pears. In 2011, the NOSB voted to specify a sunset date of October 21, 2014.

In order to be approved for use in organic production, synthetic materials such as antibiotics must meet three criteria: They must be **essential** for organic production, **compatible** with organic production practices, and cause **no harm** to humans or the environment. We believe that streptomycin fails to meet all these criteria set forth in OFPA.

The Crops Subcommittee prepared a well-researched 17-page proposal outlining both the majority and minority opinions. The majority (5 members) voted to remove the existing expiration date; the minority (3 members) voted to retain it.

Rationale:

- **Streptomycin is not essential for control of fire blight.**
  - Cultural controls are available to manage fire blight.
  - Biological controls are available to manage fire blight.
  - Several materials other than antibiotics are available to control fire blight.
  - Many orchardists, both in the U.S. and in Europe, grow apples without using streptomycin or other antibiotics.

- **Streptomycin is not compatible with organic production practices.**
  - Antibiotics represent an input-substitution mentality.

- **Streptomycin is harmful to humans and the environment.**
  - Streptomycin can decrease biodiversity and harm the soil ecosystem.
  - Streptomycin use in orchards may contribute to development of antibiotic resistance in animals and humans.

- **New NOP sunset policy may prevent future reviews by the full Board.**

Much research has been conducted on apples to demonstrate that the cultural practices and materials available to organic growers are sufficient to manage fire blight without streptomycin. Its use in apple orchards may prove harmful to humans, as it contributes to antibiotic resistance. The expiration date for streptomycin on apples should be maintained at October 21, 2014.

Research on pears, however, is more limited. Pears are naturally more susceptible to fire blight, and there are fewer research studies available to demonstrate effective controls. Despite concerns about human health and environmental impacts, it may be necessary to consider extending the expiration date until October 21, 2017 for pears only.

DISCUSSION

Streptomycin is a broad spectrum antibiotic that is used in both human and veterinary medicine to treat a variety of bacterial diseases. The National List §205.601(i)(12) lists streptomycin as an allowed material for plant disease control.

The petitioned use of streptomycin is to control fire blight on apples and pears, caused by the bacterium *Erwinia amylovora*, which infects blossoms of apple and pear trees. If the disease is not controlled, flowers die, resulting in crop loss, and the woody branches can become infected, resulting in loss of limbs or an entire tree.

Antibiotics in organic agriculture

Antibiotics are prohibited for production of organic livestock, for both milk and meat. Antibiotics may not be used on any organic crops, other than apples and pears. Only tetracycline and streptomycin are allowed for control of fire blight, a disease of apple and pear trees. They are listed on the National List §205.601:

> *(i) As plant disease control.*
> *(11) Streptomycin, for fire blight control in apples and pears only until October 21, 2014.*
> *(12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.*

Streptomycin for plant disease control is prohibited by international standards. It is not allowed for organic production in Canada, Europe or Japan. It is not allowed by the CODEX Alimentarius Commission or by the International Federation of Organic Agriculture Movements (IFOAM).[1]

[1] ICF International. 2011. Tetracycline (Oxytetracycline) Technical Evaluation Report, April 1, 2011

The international organizations listed above also prohibit the use of tetracycline for plant disease control. The NOSB, at the April 2013 meeting, considered a proposal to remove the existing expiration of October 21, 2014 for oxytetracycline. After careful deliberation, the Board voted to reject that proposal, meaning that tetracycline use will be prohibited in organic crop production after October 21, 2014.

Regarding streptomycin, Cornucopia encourages Board members to once again vote to uphold the existing expiration date.

Evaluation for approval of synthetics to be added to the National List

In organic agriculture, synthetic materials such as antibiotics are prohibited unless:

1. The substance is **essential** for organic production.
2. The substance is **compatible** with organic production practices.
3. There are **no** adverse impacts on humans or the environment.

In the following section we discuss reasons why the use of streptomycin in organic agriculture is not essential, is not compatible with organic principles, and is harmful to humans.

Cultural and biological controls are available

The NOP regulations, §205.206 Crop pest, weed, and disease management practice standard, specifically states*, "The producer must use management practices to prevent crop pests, weeds, and diseases."* Producers must also use "*[a]pplication of nonsynthetic biological, botanical, or mineral inputs."*

Effective management of fire blight should rely on prevention of the initial infections of the blossoms, rather than control after the bacterial populations are high. This is a fundamental organic principle applicable to any disease. Fortunately, scientists have studied fire blight for decades, and many university extension publications explain traditional preventative measures. Much is known about prevention, and several materials can provide effective control. The threat of fire blight can be minimized by using cultural practices, biological controls, and natural materials.

Cultural and management practices to prevent fire blight:

- resistant varieties
- resistant rootstocks, specifically non-dwarfing rootstocks
- blossom thinning
- canopy management
- avoiding high-density plantings to allow greater air flow in the orchard

Biological controls to manage fire blight:

- Bloomtime Biological (*Pantoea agglomerans* bacteria)
- BlightBan C9-1 (*Pantoea vagans*, also called *Pantoea agglomerans,* bacteria)

- BlightBan A506 (*Pseudomonas fluorescens* bacteria)
- Blossom Protect (*Aureobasidium pullulans* fungi)

Materials to control fire blight:

- Serenade Max (antimicrobial pesticide)
- lime sulfur
- fish oil
- copper sulfate

In general, inputs should only be used after other practices have failed to control the disease. If inputs are required, farmers should use natural materials and biological controls before using synthetic materials such as antibiotics. With all these cultural practices and materials available, antibiotics have been proven unnecessary for control of fire blight.

In addition to knowing what material to use, it is important to know when to use it for maximum effectiveness. Scientists have developed models to predict when the pathogenic bacteria will be likely to infect blossoms. These fire blight prediction models help growers decide when to apply a biological control agent.

Resistant varieties and rootstocks are available

From an organic perspective, the systems approach should be the first line of defense against fire blight, because a properly designed system will have less disease.

Selection of a resistant cultivar is the most effective method of controlling fire blight.[2] The relative resistance and susceptibility of different apple cultivars is well known; university extension specialists in many parts of the country publish this information.

Selection of a rootstock that is tolerant to fire blight is also an essential component of a well-designed system. To manage fire blight, it's important to avoid planting apples on susceptible rootstocks. The dwarfing rootstocks, in particular, such as Malling 9 and 26, are highly susceptible to fire blight.[3]

Growers taking a proactive, systems approach to fire blight management would plant resistant varieties on resistant rootstocks. <u>This has not always been the case, even though apple and pear growers have known that antibiotics would likely be prohibited for organic production at some time in the future</u>. Instead, cultivars with greater susceptibility to the disease, such as Braeburn, Fuji, Gala, and Pink Lady, have been

[2] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*
[3] Ibid.

planted.[4] For example, in 2009 in Washington State, 45% of the organic apple acreage was planted to Gala and Fuji, both of which are susceptible to fire blight.[5]

To make matters worse, the cultivars have been planted on dwarfing rootstocks, in high-density plantings. The current practice of high-density plantings increases the speed at which fire blight can spread.

At one point, fire blight primarily was a concern to pear growers only, not apple growers, but the situation has changed:

> *"Now that there are extensive acreages of highly susceptible apple varieties on super-susceptible rootstocks in warmer parts of the state, the possibility of serious fire blight damage in Washington apples has evolved into a reality."*[6]

Biological controls and other inputs are available

There are numerous materials available to control fire blight: biological controls (Bloomtime Biological, BlightBan C9-1, BlightBan A506 and Blossom Protect), the antimicrobial pesticide Serenade Max, plus several brands of lime sulfur, fish oil and copper sulfate.

Several research trials described in the Technical Evaluation Report showed some success in fire blight control using biological materials. In addition, Smith reported success using biological controls in eastern Washington:

> *"Over four years and in seven separate apple and pear fire blight control material trials, a dried yeast product, Auriobassidium pulullans [sic], called 'Blossom Protect' in Europe, controlled fire blight as well or better than the standard and test antibiotics."*[7]

Ken Johnson, in a webinar in March 2012[8], presented his research on materials that provided **"a fantastic level of control" of fire blight**. He stressed that management is vitally important—growers must begin to manage fire blight early in the season, when pathogen populations first start to build up. He suggested that growers begin with copper products, to delay the onset of disease. When trees begin to bloom, several

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[4] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*

[5] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University

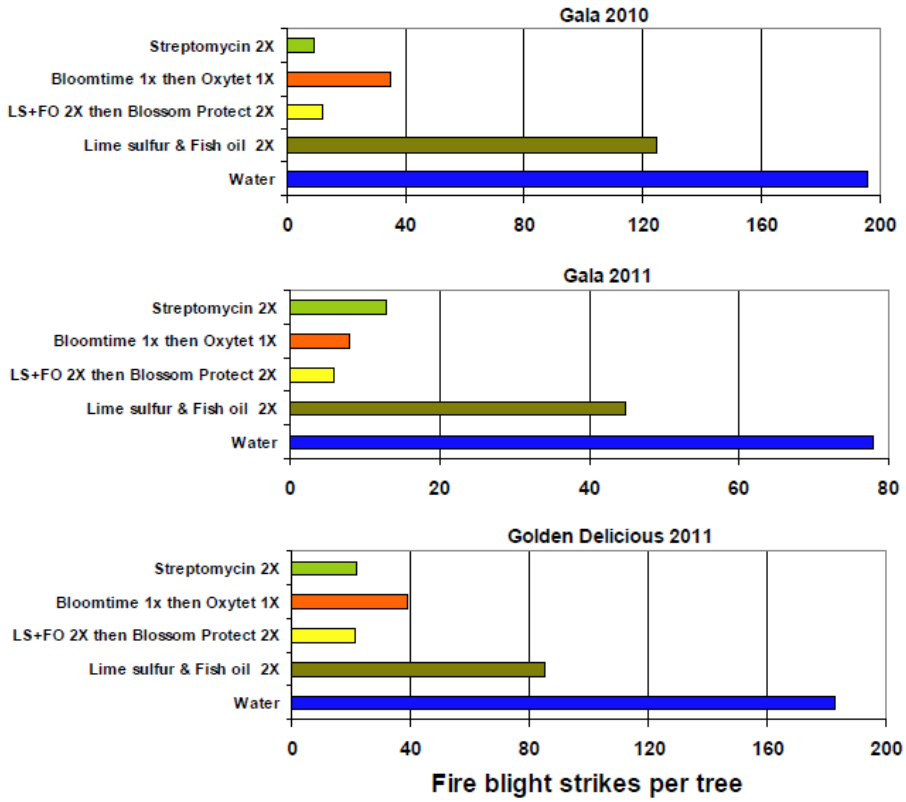
[6] Smith, T. 2012. Fireblight Management in the Pacific Northwest USA. Downloaded Nov 2012 from http://county.wsu.edu/chelan-douglas/agriculture/treefruit/Pages/Fire_Blight.aspx

[7] Smith, T. 2011. Improving the Management of Two Critical Pome Fruit Diseases. Final Project Report, WA Tree Fruit Research Commission Project Number CP-09-904.

[8] Johnson, K. 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. Webinar date March 13, 2012. www.extension.org/organic_production

different materials must be used at the appropriate times, first to reduce the number of infection sites, then to protect the remaining blossoms with biological controls.

Blossom thinning to remove flowers is essential because the bacteria that cause fire blight will initially infect the stigmas of the flowers. When flowers are removed, there are fewer places where bacteria can cause fire blight infections. Blossom thinning also reduces the crop load, reduces stress on the tree, and results in larger and more marketable apples. In Johnson's research study, he used lime sulfur (LS) and fish oil (FO) for blossom thinning. The remaining flowers were sprayed with Blossom Protect, a microbe that colonizes the flowers. Results in the graph below indicate that those treatments were as effective as antibiotics, even on Gala apples, a susceptible variety. The experiment was repeated in 2012, with the same results, showing the effectiveness of lime sulfur plus fish oil followed by Blossom Protect.[9]



Johnson tested the use of Bloomtime Biological early in the season, followed by Serenade Max, which resulted in "very good to excellent control." In a recent webinar, Johnson[10] presented results of additional research, and verified that effective non-

[9] Granatstein, D. 2012. Fire Blight Update. Organic Tree Fruit Industry Work Group. Presented at the NOSB Meeting, Providence, Rhode Island, 10/16/2012

[10] Johnson, K. 2013. Research Update on Non-antibiotic Control of Fire Blight. Webinar date March 19, 2013. www.extension.org/organic_production

antibiotic control of fire blight can be achieved on apples through an integrated control program. Johnson was also able to achieve fire blight control on pears, although reliable control is expected to be more difficult than on apples.

Although these biological products control infections as well as antibiotics, they must be sprayed more frequently—four sprays instead of two. **As long as antibiotics remain allowed in organic agriculture, growers are more likely to use them rather than biological controls, as a cost-saving measure.**

If antibiotics are prohibited, cost of apple production may increase slightly. However, cost is not a factor, by law, in deciding which materials to allow. We believe that organic consumers, who already expect to pay a price premium for organics in order to avoid harmful inputs, including antibiotics, will be willing to pay the extra price, if any, to avoid the harmful effects of antibiotics on humans and the environment.

Many orchardists grow apples without using antibiotics

Europe does not allow antibiotics in organic production of apples or pears, yet there were approximately 57,582 acres planted to organic apples in Europe in 2008.[11]

In addition to the fruit acreage planted in Europe, many apple growers in Washington State grow organic fruit to be exported to Europe. In order to export apples to the EU, orchardists must verify that they have not used antibiotics for the previous three years.

As of March 2011, approximately one-third of the organic apple producers in Washington were certified to sell apples to Europe.[12] In Washington State in 2012, crops in the European program included Braeburn, Fuji, Gala, Granny Smith, Honeycrisp, and Pink Lady apples, and Bartlett, Bosc, and D'Anjou pears, plus many other varieties. Clearly, orchardists are able to grow popular apple varieties without antibiotics, if the market demands it.

Apple growers throughout the U.S. are able to grow fruit without antibiotics. The Cornucopia Institute, in early 2013, conducted a nationwide survey of apple and pear growers to obtain information on antibiotic use. The questions were sent to all the organic apple and pear growers in the U.S., over 700 orchardists, and received a response rate of 11%.

The majority of apple growers who responded, 56%, stated that they never use antibiotics to control fire blight. Some of those orchardists have been growing organic apples for 20 years or more. Almost half, 44%, of apple growers stated that prohibiting antibiotics will not affect them at all. An additional 19% will simply use more biological and cultural controls. The full survey is attached in Appendix 1.

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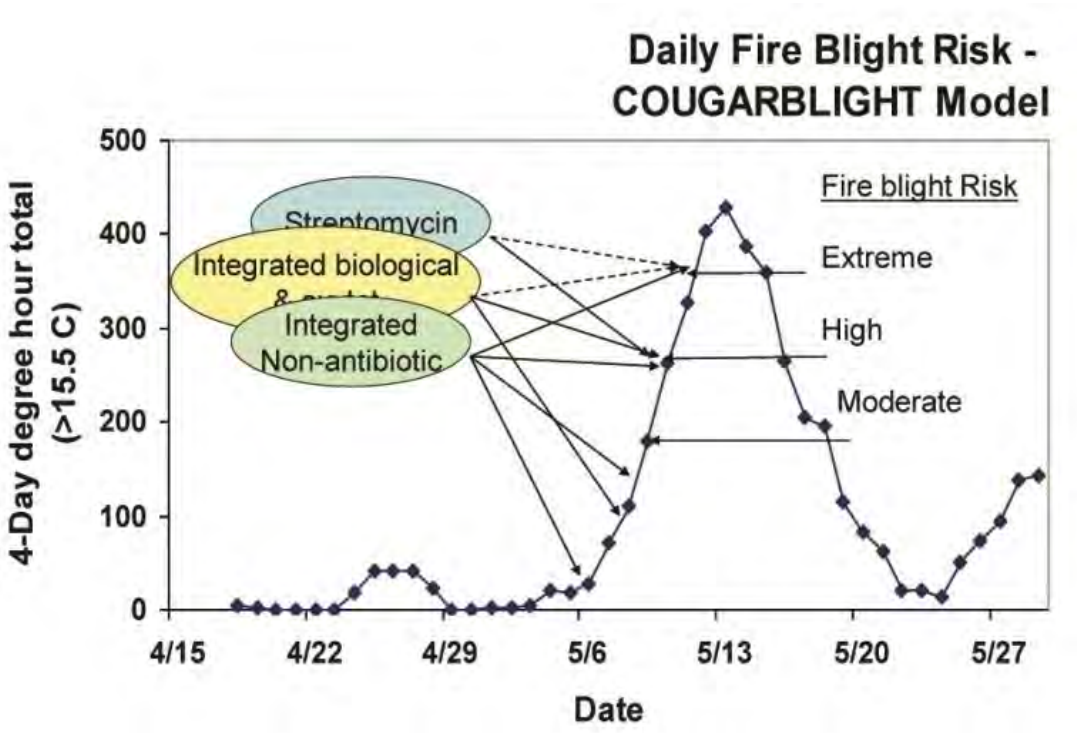
[11] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University

[12] Washington State Department of Agriculture. 2011. *International Organic Program—EU Compliant Operations, March 10, 2011*. http://agr.wa.gov/FP/Pubs/docs/wsda_eu_compliant.pdf

Antibiotics represent an input-substitution mentality

As discussed above, fire blight is a serious disease that has been aggravated by the planting of vast acres of susceptible apple varieties on susceptible rootstock at high densities. Growers who have ignored preventative practices are relying on inputs for disease control.

The following graph, extracted from Johnson's 2012 eOrganic webinar, shows how the risk of fire blight increases in the spring.[13] As the weather gets warmer (seen on the y-axis degree hours), the bacterial populations increased, reaching their maximum on May 13. As bacterial populations increase, the risk of fire blight disease increases.



In order to manage the disease without antibiotics, growers must use integrated control measures early in the spring, when the pathogen population is starting to build. In this case, integrated controls and biological controls must be started shortly after May 6. However, if antibiotics are available, this investment in a proactive approach is less important. Streptomycin applications can be delayed until the risk of infection is high, in this case approximately May 10.

As Dr. Johnson said in his webinar,

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[13] Johnson, K. 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. Webinar date March 13, 2012. *www.extension.org/organic_production*

> *"When streptomycin was effective, for us on the west coast, we could ignore the whole pathogen build-up phase…. We could come in with streptomycin at fairly high levels of risk and … we could get good control."*

This philosophy relies on treating the disease after it becomes serious. An organic philosophy should rely on prevention—management before the disease becomes serious.

Streptomycin causes harm to humans and the environment

Streptomycin is a broad-spectrum antibiotic; therefore, the environmental effects of streptomycin are significant. Application of streptomycin involves airblast sprayers that spray the entire tree. Although the streptomycin is needed only on the flower surfaces, the spray lands on the tree leaves, tree trunk, cover crops in the orchard and soil, as well as the flowers. Rain washes some streptomycin off the plant surfaces, into the soil.

Antibiotic residues have been detected in or on the apple fruit. When apple trees at blossom stage were sprayed with streptomycin, residues of streptomycin were found on the apple fruit sampled 86 days later.[14]

Streptomycin has decreased bacterial diversity in soils to which it was applied. When streptomycin was added to three different types of soils, it significantly affected the numbers and species of bacteria present.[15] Numbers of bacteria present were reduced by between 50% and 80%. Streptomycin also caused some beneficial bacterial species to be eliminated from the soils. This study was conducted in a laboratory setting, which ensures that the results seen are due to the antibiotics, not to other factors.

Streptomycin use in orchards may contribute to development of antibiotic resistance

The World Health Organization includes tetracycline and streptomycin antibiotics on its list of critically important antimicrobials. They state:

> *"It is critically important to prevent resistance to these antibiotics due to non-human antimicrobial use."*[16]

At the April 2013 NOSB meeting, members of an invited panel discussed the use of antibiotics for fire blight control. One member of the panel, Dr. J. Glenn Morris, director of the Emerging Pathogens Institute, was clear in his opposition to the use of antibiotics in agriculture. He stated: "***Even very, very low doses of an antibiotic are able to cause***

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[14] Mayerhofer, G, I Schwaiger-Nemivora, T Kuhn, L Girsch, F Allerberger. 2009. Detecting Streptomycin in apples from orchards treated for fire blight. J. Antimicrob. Chemother. 63(5):1076-1077

[15] Popowska, M., Miernik, A., Rzeczycka, M., Lopaaciuk, A. 2010. The impact of environmental contamination with antibiotics on levels of resistance in soil bacteria. J. Environ. Qual. 39: 1679-1687

[16] World Health Organization (WHO). 2009. Critically Important Antimicrobials for Human Medicine, 2nd Revision

gradual shifts in population levels of resistance across time." There is a very real threat that human pathogens will develop resistance to streptomycin and tetracycline, rendering these ineffective as human medicines.

The increase in apple acreage, and the increase in high-density plantings of susceptible varieties, only increases the likelihood of resistance to streptomycin. An article published in *ASM News*, by the American Society for Microbiology, states:

> "*Although antibiotic use on plants is minor relative to total use, application of antibiotics in the agroecosystem presents unique circumstances that might influence the buildup and persistence of resistance genes in the environment. Antibiotics are applied over physically large expanses. In regions of dense apple and pear production, antibiotics are applied to hundreds of acres of nearly contiguous orchards. Moreover, the past decade has seen a dramatic increase in the planting of apple varieties and rootstocks that are susceptible to the devastating bacterial disease fire blight.*"[17]

Laboratory experiments were conducted to examine the development and persistence of antibiotic-resistant bacteria. The authors found that antibiotic resistance develops even when the antibiotics are present at very low concentrations. Even with low levels of antibiotics present, mutants were found with high levels of antibiotic resistance. The authors concluded that this resistance is likely to persist in the bacterial populations over time.[18]

A recent article, published in 2013, is the first study to show the effect of agricultural use of streptomycin on animals grazing in contaminated fields. Scherer, et al., compared the development of antibiotic-resistant *Escherichia coli* and *Staphylococcus* spp. from sheep allowed to graze in fields sprayed with streptomycin vs. unsprayed fields. The authors confirmed that low concentrations of streptomycin increased the percentage of antibiotic-resistant *E. coli* and *Staphylococcus* that were isolated from nasal passages and manure of the grazing sheep. This increase occurred even at the concentrations that would normally be used in orchards for control of fire blight. Many of the bacteria were resistant to multiple antibiotics, not just streptomycin.[19]

The threat of streptomycin-resistant bacteria is a serious one, and we need to use the precautionary principle. Scientists must assume antibiotic resistance will occur in the future, because we know that it has happened in the past. The tree fruit industry has already experienced a problem with antibiotic resistance—the bacterium *Erwinia amylovora* (causative agent of fire blight) has developed resistance to streptomycin.

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[17] McManus, P. 2000. Antibiotic Use and Microbial Resistance in Plant Agriculture. ASM News

[18] Gullberg E, Cao S, Berg OG, Ilback C, Sandegren L, et al. 2011. Selection of Resistant Bacteria at Very Low Antibiotic Concentrations. PLoS Pathog 7(7): e1002158. doi:10.1371/journal.ppat.1002158

[19] Scherer, A., Vogt, H., Vilei, E., Frey,J. and Perreten, V. 2013. Enhanced antibiotic multi-resistance in nasal and faecal bacteria after agricultural use of streptomycin, Environmental Microbiology 15(1), 297–304.

Bacteria that develop antibiotic resistance typically remain resistant for a long period of time.[20]

Additional research continues to show that use of antibiotics in agriculture contributes to the development of antibiotic-resistant human pathogens. The Centers for Disease Control and Prevention (CDC) issued a report on September 16, 2013, addressing the threats of antibiotic resistance. The report notes that concern over antibiotic-resistant infections is growing.[21],[22]

NOP sunset policy reduces opportunity for future evaluation

The Crops Subcommittee unanimously passed a resolution:

> *"The NOSB is committed to the phase out of this material [streptomycin]."*

Even so, five members of the Crops Subcommittee voted to allow the continued use of streptomycin until 2017 (three opposed this motion). Under the sunset procedures that have been used since OFPA was implemented, this would provide a further opportunity for the full Board to evaluate streptomycin.

Unfortunately, due to the new sunset rules posted by the NOP, the public can no longer be assured that streptomycin will be carefully reviewed by the full Board in 2017. Extending the use of streptomycin at this time may mean that the full Board never again has an opportunity to evaluate new research, hear consumer comments, and discuss the best course of action. The Crops Subcommittee could simply vote to relist streptomycin and negate the ability of the full Board to review the matter.

We urge NOSB members to reject this petition. If streptomycin is approved at this meeting, it may be retained on the National List in perpetuity, with no further opportunities to obtain an updated TR and have a review by the full Board. With this new sunset policy in place, any Board member who believes that streptomycin should be phased out in the future must take this opportunity to vote "no" on this petition now.

CONCLUSION

We encourage the NOSB to uphold the current expiration date of 2014 for streptomycin, as they did for tetracycline.

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[20] Levy, SB, and B Marshall, 2004. Antibacterial resistance worldwide: causes, challenges and responses. Nature Medicine Supplement, Published online 30 November 2004; doi:10.1038/nm1145

[21] Zuraw, L. 2013. CDC Acknowledges Role of Farms in Antibiotic Resistance. Food Safety News. Downloaded on September 17, 3013, from http://www.foodsafetynews.com/2013/09/drug-resistant-infections/#.UjhvGGzn_IV

[22] Centers for Disease Control and Prevention. 2013. Threat Report 2013. Downloaded on September 17, 3013, from http://www.cdc.gov/drugresistance/threat-report-2013/.

The antibiotic streptomycin is not essential for control of fire blight. Research indicates that fire blight can be managed in apples without the use of antibiotics. There are cultural, biological, and natural controls available; reliance on streptomycin represents an input-substitution mentality. Streptomycin is harmful to humans and the environment, as it contributes to antibiotic resistance and a decrease in soil flora.

We do recognize that pears are highly susceptible to fire blight, and there has been relatively little research done on alternatives to antibiotics on pears. Due to these differences, the NOSB may want to consider different regulations for apples and pears. This would allow removal of antibiotics from apple production without impacting pear growers, while further research can be conducted. All uses of antibiotics on organic crops should be prohibited as soon as possible.

Prohibition of antibiotics on organic apples is essential to maintain consumer confidence. Parents feed large numbers of apples to their children in the form of applesauce, apple butter, fruit leathers, juice and, of course, apples. Given the prohibition against antibiotics in all other areas of organic food production, consumers expect that fruit is also grown without antibiotics, especially antibiotics that are important in human medicine.

Magnesium Oxide (MgO)

SUMMARY

Reject the petition to add magnesium oxide (MgO) to the National List under §205.601 Synthetic substances allowed for use in organic crop production.

We urge NOSB members to table all petitions for new materials to the National List, because of the NOP's recent revisions in the sunset policy.

Rationale:

- ✓ Magnesium oxide has not been independently researched since 2007.
- ✓ Due to the new sunset process, this may be the **only** opportunity for a vote by the entire Board.

DISCUSSION

Magnesium oxide (MgO) is intended to be used as an "other ingredient" in sprays on crops. It is added to clay, which is then used as a suspension agent in a spray tank. Currently it is used for finely ground humates, but may be used for any wettable powders. The purpose of magnesium oxide is to control the viscosity of the clay suspensions when farmers spray substances that are insoluble in water. This allows farmers to get uniform coverage when they spray finely powdered materials on their crops. In this sense, it may be considered a spray adjuvant. A pesticide adjuvant is broadly defined as any substance added to the spray tank, separate from the pesticide formulation, which will improve the performance of the pesticide.

We agree with the Crops Subcommittee proposal that "magnesium oxide appears to be a fairly benign compound." Magnesium oxide is available as a dietary supplement for humans, although allergic reactions can occur in rare cases.[23] Magnesium supplements have been prescribed for people with osteoporosis,[24] and have been used to treat constipation.[25]

Magnesium sulfate is currently allowed for organic crop production; and magnesium hydroxide is allowed with restrictions for livestock production.

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[23] Medline Plus, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601074.html

[24] Castiglioni, S., Cazzaniga, A., Albisetti, W., and Maier, J. 2013. Magnesium and Osteoporosis: Current State of Knowledge and Future Research Directions, *Nutrients*. 5(8): 3022–3033.

[25] Tatsuki, M., Miyazawa, R., Tomomasa, T., Ishige, T., Nakazawa, T. and Arakawa, H. 2011. Serum magnesium concentration in children with functional constipation treated with magnesium oxide. World J Gastroenterol. 17(6): 779-783. doi: 10.3748/wjg.v17.i6.779. Downloaded Jan 12, 2014, from http://www.wjgnet.com/1007-9327/full/v17/i6/779.htm)

Technical evaluation needed

Although the petitioned use of magnesium oxide appears to be consistent with organic agriculture, we urge the Board to request a new Technical Evaluation Report (TR) before voting on magnesium oxide. In this case, the most recent TR was conducted in 2007; thus it is seven years out of date. When adding materials to the National List, it is important to follow a standard, rigorous process of material review to be sure of obtaining recent scientific research. The standard practice must include a current TR to obtain the most current research, both when adding new materials and when re-evaluating materials during the sunset process.

Furthermore, the TAP (Technical Advisory Panel) review used for evaluation of magnesium oxide was actually for magnesium hydroxide, $Mg(OH)_2$, not magnesium oxide (MgO). The two substances have different chemical formulas, different molecular weights, and different CAS numbers. This alone is sufficient reason to request a new TR for magnesium oxide. In addition, the 2007 TAP review was for use in livestock production, to be directly administered to animals. The petitioned use is for crop production, to be used in aerial spray application. The 2007 TAP review does not begin to address questions of the essentiality for crop production.

The format of the 2007 TAP review is fundamentally different from the current format for TRs. A current TR is needed to answer the questions on NOSB Evaluation Criteria that are included in recent TRs.

Specifically, further research is needed to assess the question of whether magnesium oxide is essential for this application. The Crops Subcommittee proposal states that there are no alternative substances (category 2, question 8), but this assertion is based solely on the words of the petitioner. Alternative substances, such as soil additives, could be used in place of foliar humic acid. Further research is also needed on the manufacturing process and its possible environmental impacts.

NOP sunset policy reduces opportunity for future evaluation

If magnesium oxide is approved at this meeting, it may be retained on the National List in perpetuity, with no further opportunities to obtain an updated TR, review questions of essentiality and environmental harm, and have a review by the full Board.

We are in agreement with the annotation proposed by the minority:

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].

Every material on the National List should be reviewed by the entire Board every five years. A complete review requires an updated TR conducted by a knowledgeable organization. This annotation is needed to ensure that the review process is followed.

CONCLUSION

Although magnesium oxide appears to be consistent with organic production, we request that the NOSB follow the accepted practice of having all materials reviewed by an independent scientific study before voting to add them to the National List. This is especially important because the new sunset policy may allow this material to remain on the National List indefinitely without additional reviews.

Please reject this proposal or table this material until a TR is completed and the NOP sunset policy is revised.

Vinasse

SUMMARY

Reject the motion to classify vinasse as non-synthetic.

Reject the Crops Subcommittee proposal to amend the Guidance on Materials for Organic Crops Production (NOP 5034-1) as follows:

> *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.*

We urge the Board to request that the Crops Subcommittee draft a motion that defines the distinctions between the synthetic and non-synthetic forms of vinasse. This motion should be independent of NOP's draft guidance.

A minority opinion, to list vinasse on the National List at both §205.601 and §205.602, represents a compromise position.

Rationale:

- Use of vinasse must be regulated through the National List process, not through amending NOP 5033 and 5034, the draft guidance from NOP.
- The NOSB is responsible for clearly determining whether a material is synthetic or non-synthetic.
- Some types of vinasse are synthetic.
- Synthetic forms of vinasse must be reviewed by the full NOSB for possible addition to the National List.

DISCUSSION

Vinasse is a byproduct of molasses fermentation, which itself is a byproduct of sugar production. It is petitioned for use as a plant nutrient, due to high levels of potassium, calcium, magnesium, sulfur, and nitrogen. Some of these nutrients may be due to the addition during processing of synthetic materials that contain sulfur and nitrogen. Vinasse is a liquid that is diluted and sprayed on crops or soil.

The Crops Subcommittee considered a petition to add vinasse to the National List §205.601 as a synthetic substance allowed for use in organic crop production. Before this can be done, the Board needs to decide if vinasse is synthetic or non-synthetic. The subcommittee voted that vinasse is non-synthetic, 4 (yes) to 3 (no). If the full Board

determines that vinasse is not synthetic, then it can be used in organic crop production without further review of the manufacturing process.

We urge the Board to ensure that vinasse is fully reviewed, because there is abundant evidence that some vinasse is indeed synthetic. For that reason, vinasse should not be allowed in organic production until it is more carefully reviewed.

NOSB should not amend the text of the draft guidance.

The Crops Subcommittee is attempting to restrict the use of synthetic vinasse by amending NOP's draft guidance (NOP 5033 and 5034), rather than through the National List process. The Board should not amend the draft guidance on the classification of materials for two key reasons. First, this is draft guidance—it has not been implemented. Second, being a guidance, it was written by the NOP and is subject to change by the NOP without future input from the NOSB or the public. Guidance documents are not legally binding.

NOSB determines status: synthetic or nonsynthetic

When a material is petitioned for addition to §205.601 of the National List, the procedure is to first determine whether the material is synthetic or non-synthetic. In this case, the determination is challenging, because vinasse is not a direct product of a specific chemical process. Rather, it is a byproduct of a series of industrial processes in the production of sugar. It appears that some vinasse is produced through natural processes, but other vinasse results from industrial processes that would classify it as synthetic and therefore prohibited. The Crops Subcommittee recognizes this.

The proposal states "*vinasse with synthetic materials added to it after fermentation should not be permitted in organic cropping systems*." Cornucopia agrees with this statement, and believes that the best way to effect this prohibition is to classify the appropriate forms of vinasse as synthetic.

Some vinasse is clearly synthetic

Vinasse is the material that is left over after sugar and other materials are extracted from an agricultural product, either sugar cane or sugar beets:

1. Harvest sugarcane or sugar beets.
2. Extract juice. The byproduct is molasses. (Sulfur dioxide, chlorine, ammonium bisulfite, or other biocides may be added, plus poly acrylamide.)
3. Ferment molasses to obtain ethanol, organic acids, or other useful compounds. (Antibiotics such as penicillin and tetracycline, chlorine dioxide, ammonium bifluoride, or quaternary ammonium compounds may also be added. Residues may remain in the vinasse.[26])
4. Remove the yeast. (The petition states that there will be some yeast residues.)
5. The final byproduct is vinasse.

[26] Pesticide Research Institute. 2013. TER Vinasse. Lines 369- 377.

The petitioner, BioBizz Worldwide, does not manufacture vinasse, they purchase it as a complete ingredient. They do not have the details regarding the manufacturing process or whether the sugar beets or yeast are genetically modified, although that is highly likely. Any approvals for vinasse in organic agriculture should include a restriction on vinasse made from genetically modified sugar beets.

Synthetic forms of vinasse contain many materials that are prohibited for organic crop production. It is a byproduct of two or more industrial processes. The TR explains, "*As such, it contains every substance added to the fermenter, plus yeast metabolites and yeast cell contents.*"[27]

The minority opinion addresses valid concerns

The minority opinion suggests listing vinasse on the National List in two places:

> *§205.601 Synthetic substances allowed for use in organic crop production*
> *§205.602 Non-synthetic substances prohibited for use in organic crop production*
> *Both listing would include annotations that describe the concerns about synthetic additives.*

Although this addresses some concerns about vinasse, we suggest it is more clear and straightforward to send this petition to the Crops Subcommittee, so it can bring forth to the NOSB a motion that clearly distinguishes synthetic and non-synthetic vinasse.

Synthetic forms of vinasse must be vetted by the NOSB through the petition process

We recommend that the Crops Subcommittee should review this classification question. If they distinguish the synthetic vinasse, then it could be petitioned for listing on the National List at §205.601. At that time the Board can consider all the OFPA criteria with the help of a complete checklist.

If the petition process is followed, then the concerns of the minority and majority can be addressed. It may be necessary to follow the minority opinion and create the listing on both §205.601 and §205.602, in order to address the concerns that the manufacturing process results in numerous synthetic additives.

CONCLUSION

Cornucopia urges the Board **not** to amend NOP's draft guidance.

We urge the NOSB to recognize that some forms of vinasse are synthetic, despite the fact that vinasse can also be obtained in a way that would allow it to be classified as non-

[27] Pesticide Research Institute. 2013. TER Vinasse. Lines 32-33.

synthetic. This uses the precautionary principle, to prevent harmful chemicals from being used in organic food production.

The synthetic forms of vinasse can then be reviewed by the NOSB and the organic community for use in organic crop production.

Laminarin

SUMMARY

Reject the motion to classify laminarin as non-synthetic.

Laminarin is extracted with both sulfuric acid and sodium hydroxide, leaving residues of those synthetics in the final product. Although the source of laminarin, seaweed, is non-synthetic, the extraction process results in a material that should be classified as synthetic. This determination is necessary so that the petitioned material, laminarin, can be reviewed by the full Board.

Rationale:

- Synthetic substances are used in the manufacture of laminarin.
- NOSB guidelines indicate that laminarin is synthetic.
- NOP guidelines indicate that laminarin is synthetic.
- The NOSB is responsible for clearly determining whether a material is synthetic or non-synthetic.

DISCUSSION

Laminarin is an extract of a brown seaweed, *Laminaria digitata*. This extract is used to stimulate a plant's defense reaction, thereby helping the plant to resist disease. Laminarin is sold under the trade name, Vacciplant, which is registered with the EPA as a biopesticide to be used on conventional crops. The Vacciplant label indicates that laminarin, the active ingredient, makes up 3.51% of the product, and "other ingredients" make up the remaining 96.49%.

The manufacturer of Vacciplant, petitioned to have laminarin added to §205.601, Synthetic substances allowed for use in organic crop production. Before the NOSB reviewed laminarin, the NOP reviewed it, to determine if it was natural or synthetic. The classification is extremely important—a material classified as non-synthetic is allowed for use without further review, but a material classified as synthetic requires review and approval from the NOSB.

Classification of synthetic or non-synthetic can be challenging, and it is made more difficult in this case by the availability of two different review criteria. **OFPA established the NOSB to make determinations regarding the synthetic materials on the National List**. Since the classification of materials is an essential first step in this process, the NOSB should use the review criteria they have established.

In this case, the NOP reviewed laminarin before the NOSB and judged it to be non-synthetic using their draft guidance. Since OFPA mandates that the NOSB make this determination, we believe it was inappropriate for the NOP to exert undue influence by evaluating this material before the NOSB reviews it. The majority of the Crops Subcommittee accepted the determination, voting to classify laminarin as non-synthetic: 5 (yes) to 2 (no).

The minority opinion presents sound reasoning for classification of laminarin as synthetic. We agree with the minority, that laminarin should be classified as synthetic, and should be subject to further review before being allowed in organic crop production.

Synthetic substances are used in the manufacture of laminarin

The substance being petitioned is not a natural substance, seaweed, but rather an extract of that natural substance. To obtain this extract, sulfuric acid is used to lower the pH to 2. Sulfuric acid is a synthetic substance. There are natural alternatives that could be used to lower pH, such as vinegar or citric acid. After laminarin is extracted, sodium hydroxide, another synthetic substance, is added to neutralize the acid.

The final product that will be sold to farmers, Vacciplant, also contains synthetic materials—**in fact 96% of the formulated product is other ingredients**. Although we realize that these other ingredients will be reviewed, we remind the Board that EPA List 4 inerts are currently allowed in organic crop production. These are synthetic substances that have not been evaluated for suitability for organic agriculture. The EPA eliminated these categories in 2006, recognizing that the materials are not in actuality inert.

NOSB guidelines indicate that laminarin is synthetic

According to specification guidelines adopted by the NOSB, a substance is synthetic if there are significant residues of synthetic materials added during extraction. In this case, significant amounts of synthetics are required to produce laminarin.

Specifically, sulfuric acid is used to reduce the pH to 2 during extraction. The pH of tap water is neutral—pH 7. Since pH is measured on a logarithmic scale, a pH 2 is 100,000 times as acidic as tap water.

After this acidification step, significant amounts of another synthetic material, sodium hydroxide, must be added to bring the pH back to neutral (pH 7). Although the acid and base combined to make water and neutralize the pH of the solution, they also leave residues of sulfur and sodium.

NOP guidelines indicate that laminarin is synthetic

The NOP, in its review of the classification of laminarin, used their draft guidance, NOP 5033, section 4.6 Extraction of Nonorganic Materials.

According to those guidelines:

> *For purposes of classification … a material may be classified as nonsynthetic (natural) if: 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.*

In this case, the synthetic materials added have not been removed. For example, if the sulfuric acid was removed there would be no need for the sodium hydroxide. Instead both materials remain in the final product. This classification terminology presents difficulty because it requires the NOSB to determine whether the sulfur and sodium have a technical or functional effect.

Sulfur in particular may have a functional effect. Although likely the concentration is too low for sulfur to act as a fertilizer, the sulfur may be acting as a pesticide, similar that to the use of lime sulfur. Lime sulfur is being used as a plant disease control, in the same way that laminarin will be used. Without a technical review it is difficult to be certain that there is no technical or functional effect.

Using these NOP guidelines it can be argued that laminarin should be classified as synthetic.

The NOSB is responsible for determining classification status

Since the primary responsibility of the Board is to oversee the National List, the determination of the classification method is also under the domain of the Board. For this reason we believe that the NOSB classification system should be used. The fact that the NOP guidelines were inconclusive results when applied to this material, indicates that there is a need for the NOP guidelines to be revised.

Another reason to use the NOSB classification system is that the criteria are consistent with expectations of the organic community. **The NOSB guidelines state that a substance is synthetic if "*there are significant residues of a synthetic added during extraction*."** Using this definition results in a determination that is consistent with previous decisions. In the past, materials that were processed using strong synthetic acids were classified as synthetic (examples include fish products and livestock manure).

CONCLUSION

The precautionary principle should be applied to classification of materials as synthetic or non-synthetic. If there is any suggestion that the material is synthetic it should be classified as synthetic until a more thorough review demonstrates that it is natural. In the case of laminarin, a wise precaution would be to determine that it is synthetic. We believe in this case that both the NOP and the NOSB classification systems indicate that laminarin is synthetic.

Cornucopia encourages the board to vote **no** on this classification motion.

Sunset Materials

In the Request for Public Comments, the USDA NOP requests that commenters only provide **new** information since the last NOSB review. We encourage the NOSB to review **all** relevant information, in order to comply with OFPA and fulfill their responsibilities as board members.

Given this mandate, we urge the Board to request that a new Technical Evaluation Report be performed for every material that is up for sunset review. Discussion of any material to be added to the National List must be based on recent, unbiased, comprehensive review of the scientific literature.

First, new TRs are needed because we apparently cannot always rely on the work of past TRs/TAP reviews. While some TRs have been objective, others have appeared biased, failing to identify serious human health and environmental impacts of the petitioned material.

Second, new TRs will provide the most recent scientific data for discussions by the Board. Older TAP reports are often incomplete, as compared to the newer TRs, in part because they do not explicitly list the evaluation questions and the answers to those questions. New TRs can include new information on health effects, as well as advances in the development of alternative materials.

The NOP is asking the public to provide new information on these materials, given a public comment period of less than one month. In order to gather the most informative and useful public comments to the discussions, we suggest that TRs must be available to the public before sunset materials are open for public comment at NOSB meetings.

Sulfurous Acid - Sunset

SUMMARY

Do not renew the listing of sulfurous acid on National List under §205.601 Synthetic substances allowed for use in organic crop production.

Rationale:

- The entire Board should vote on the relisting of sulfurous acid.
- Initial approval was based on insufficient review.
- Alternatives are available.
- Specific uses must be delineated.
- International standards do not allow sulfurous acid in crop production.
- High-quality contractors should be chosen to prepare TRs.

DISCUSSION

Sulfurous acid, an aqueous solution of sulfur dioxide, is a weak acid with the chemical formula H_2SO_3. It is added to soil and irrigation water to lower the pH of alkaline soils.

Sulfurous acid is currently on the National List:

205.601 (j)(9), as a plant or soil amendment, for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2).
Elemental sulfur is currently on the National List:
205.601 (j)(2), as a plant or soil amendment.

The entire Board should vote on the relisting of sulfurous acid

When sulfurous acid was initially approved, a robust sunset policy was in place. The Board members who approved sulfurous acid in 2009 were assured that it would be thoroughly reviewed and voted on by the entire NOSB in five years. Those Board members believed that sulfurous acid would automatically be removed from the National List, unless a majority of NOSB voted in favor of renewing the listing.

Under the new sunset process directed by the NOP, most of the Board members (and in turn the organic stakeholders) have been disenfranchised. The Crops Subcommittee may choose to renew sulfurous acid in their subcommittee meeting, thereby preventing their fellow Board members from having a voice in the matter. We urge the Crops Subcommittee not to renew sulfurous acid. Instead, we urge them to develop a proposal to remove it as part of their preliminary review. This is the only way to ensure that the

full Board reviews this material, as required by OFPA, and as practiced successfully for more than a decade of NOSB meetings.

Cornucopia strongly urges the Crops Subcommittee to recommend against relisting of sulfurous acid, by preparing a formal motion for the next Board meeting.

Due to the new NOP sunset rules, the only way the Crops Subcommittee can ensure that the Board conducts a full review of sulfurous acid is to vote in favor of a proposal for removal.

There are several reasons why sulfurous acid requires a full review, and may need to be removed from the National List.

Initial approval was based on insufficient review

Sulfurous acid was petitioned in July 2008 by Harmon Systems International, manufacturer of a generator that burns sulfur to produce sulfurous acid on the farm. In May 2009, the NOSB approved sulfurous acid for addition to the National List.

The NOSB review from the 2009 meeting does not reference any technical report, and we question if a TR was available. A TR for sulfurous acid is dated March 23, 2010, after the NOSB vote. The TR, written by the Technical Services Branch of the USDA, is of poor quality. It appears that sulfurous acid was approved without adequate Board review.

The Crops Subcommittee wisely requested a new TR in 2013.

Alternatives are available

The initial review states that there are no natural substitutes or other practices. Although there are no natural sources of H_2SO_3, there are alternatives that serve the same purpose, to reduce the pH of the soil. Acidification of soil can be effected by addition of peat moss, wood chips, elemental sulfur, or humic acids. Irrigation water can be acidified with citric acid or acetic acid (vinegar).

Specific uses must be delineated

The Crops Subcommittee has requested information on whether sulfurous acid is used to remedy conditions resulting from unsustainable agricultural practices. We suggest that one remedy for this situation is to specifically delineate the conditions under which sulfurous acid can be used.

Clearly sulfurous acid is used to lower soil pH. Under what conditions, though, is that practice considered necessary and sustainable? A thorough Technical Review should describe those conditions under which the use of sulfurous acid is necessary to produce a specific set of crops.

It is common practice to lower soil pH in the arid West to a pH of 4 in order to grow acid-loving crops. Is it sustainable to lower pH using sulfurous acid, a synthetic, rather than using natural soil amendments or growing crops where the soil pH is naturally low? This use should be clearly described in the proposal, if it is allowed.

Sulfurous acid is also being used to remove salinity from soils. Since the salinity buildup often occurs from excessive or inappropriate irrigation, it could be argued that using sulfurous acid is a band-aid approach to a management issue. We suggest that the best independent information on issues such as this can be gained through a supplemental TR rather than requesting the general public to supply it.

If these two uses are clearly delineated and noted in the listing motion, it will be easier for the Board to evaluate the essentiality of sulfurous acid.

International standards do not allow sulfurous acid in crop production

Sulfurous acid is not allowed as a soil amendment for crop production by international organic standards in Canada, Japan, or the European Economic Community. It is not listed by CODEX, but it is listed by IFOAM as a remedy for salinization of soil.

High-quality contractors should be chosen to prepare TRs

The decision to add a synthetic material to the National List is not one to be taken lightly. NOSB members have a responsibility to carefully investigate materials. To fulfill this responsibility they rely heavily on impartial investigations in the technical report. The quality of the report depends on the quality of the contractor. Therefore, the utmost care must be taken in choosing high-quality contractors.

The National Organic Standards Board Policy and Procedures Manual, 2011, describes the qualifications expected of a contractor hired to conduct technical reviews:

> *4. Minimum Skills and Experience Requirements*
> *Contractor(s) shall utilize qualified individuals or organizations who have specialized knowledge of the petitioned substances. Contractor(s) must have demonstrable expertise in organic production and handling or scientific disciplines such as veterinary medicine, chemistry, food technology, microbiology or toxicology. Contractor(s) must be familiar with the requirement for technical advisory panels described in the Organic Foods Production Act of 1990.*

In 2012, the NOP issued a request for applications from potential contractors to prepare TRs. After reviewing qualifications of applicants, the NOP chose three contractors that they deemed qualified. The organization hired to prepare the TR for sulfurous acid was not one of the three prequalified contractors. Since the quality of the TR is of vital importance to the work of the Board, we encourage the NOP to choose only the most qualified contractors. We understand that using a branch of the USDA may cost less initially, but ultimately this approach is not cost effective.

The current Technical Review for sulfurous acid was prepared by the USDA Agricultural Marketing Service (AMS) Agricultural Analytics Division. Based on our review of the TR, and the above description of the contractor requirements, it appears that the contractor did not have sufficient expertise. The AMS describes the Agricultural Analytics Division (AAD) thusly:

> *"Bringing together the best in market and statistical analyses, AAD is comprised of AMS statisticians and the Chief Economists for the former Livestock and Seed and Poultry Programs. AAD will provide statistical and mathematical support; conduct market analyses needed for day-to-day AMS business and commodity surplus removal; and related activities."*[28]

The TR was requested by the Crops Subcommittee in April 2013, and the final copy was dated January 30, 2014, almost a year later. The initial TR was deemed insufficient by the Crops Subcommittee and had to be returned to the contractor for additional research. Due to the questionable quality of their work, the fact that they were not vetted through the open bidding process, the apparent lack of technical qualifications, and the inordinate amount of time required to complete the TR, we request that the NOP not use this contractor again.

CONCLUSION

Sulfurous acid needs to be fully evaluated. When OFPA was passed by Congress, sunset reviews were mandated to ensure that synthetic substances only remain on the National List if they are fully reviewed every five years and determined to be consistent with organic principles. The new sunset procedures allow approval by the Crops Subcommittee to take the place of a full Board review. We urge the subcommittee to prepare a proposal to delist sulfurous acid. This will ensure that the entire Board has an opportunity to exercise the responsibility of care and evaluate whether sulfurous acid is consistent with organic principles.

[28] 2012 Merger of AMS Livestock and Seed Program with AMS Poultry Programs, October 2012 Status, downloaded from http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5100920

Sodium Carbonate Peroxyhydrate - Sunset

SUMMARY

Do not renew the listing of sodium carbonate peroxyhydrate on the National List under §205.601 Synthetic substances allowed for use in organic crop production.

Rationale:

- The entire Board should vote on the relisting of sodium carbonate peroxyhydrate (SCP).
- Use of SCP for aquatic plants must be evaluated.
- SCP is harmful to the environment.
- Alternatives are available for control of algae.
- SCP does not fit any OFPA categories.
- International standards do not allow SCP in crop production.
- High-quality contractors should be chosen to prepare TRs.

DISCUSSION

Sodium carbonate peroxyhydrate (SCP) is made from hydrogen peroxide and sodium carbonate. It was petitioned in 2006 by BioSafe Systems, to be used as an **algaecide** in irrigations systems and natural waterbodies.

SCP is currently on the National List:

> *§205.601 (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.*
> *(8) Sodium carbonate peroxyhydrate—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.*

OMRI lists the following products:

- GreenClean Granular (50% SCP and 50% other ingredients)
- GreenClean Pro (85% SCP, 15% other ingredients)

The 2012 label for GreenClean Pro granularstates that it is a "**bacteriocide, fungicide, algaecide**." DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin.[29] [emphasis added]

[29] 2012 Label for Greenclean Pro. Downloaded from http://www.biosafesystems.com/documents/GreenCleanPRO%20Specimen%20Label.pdf.

The Crops Subcommittee, in 2007, voted against adding SCP to the List, 0 (yes) to 5 (no), because SCP did not satisfy evaluation criteria 1, 2, or 3. At the November 2007 meeting, the full Board approved adding SCP to the List. **The checklist verified that SCP was harmful to the environment, not essential because alternatives are available, and not consistent with organic production and handling**.

Despite all of those concerns, at the November 2007 NOSB meeting, SCP was approved for addition to §205.601 for use as an algaecide. One of the reasons given for approving this substance was the possibility that SCP could replace the use of copper sulfate in rice. Given the fact that the first subcommittee affirmed that SCP violates all evaluation criteria, we believe it essential at this time for the Crops Subcommittee to once again bring SCP to the full Board for review and vote.

The following discussion outlines reasons why SCP should be removed from the National List. Some of these reasons are not **new**; they are the same reasons that led to the initial rejection of this petition. We believe they are still valid. The meeting proposals drafted by the NOP indicate that they ask only for **new** information. We encourage the Board members to consider all relevant information. Board members represent the organic community, not the NOP.

OFPA cannot be superseded by NOP memorandum changing the sunset process. It remains the right and responsibility of NOSB members to carry out the law by fully reviewing all materials on the National List every five years.

The entire Board should vote on the relisting of sodium carbonate peroxyhydrate

When sodium carbonate peroxyhydrate (SCP) was initially approved, a robust sunset policy was in place. The Board members who approved SCP were assured that it would be thoroughly reviewed and voted on by the entire NOSB in five years. Those Board members believed that it would automatically be removed from the National List, unless a majority of the NOSB voted in favor of renewing the listing.

Under the new sunset process directed by the NOP, most of the Board members have been disenfranchised. The Crops Subcommittee may choose to renew SCP in their subcommittee meeting, thereby preventing their fellow Board members from having a voice in the matter. We urge the Crops Subcommittee **not** to renew SCP. Instead, we urge them to develop a proposal to remove it as part of their preliminary review. This is the only way to ensure that the full Board reviews this material, as required by OFPA, and as practiced successfully for more than a decade of NOSB meetings.

Cornucopia strongly urges the Crops Subcommittee to recommend against relisting of sodium carbonate peroxyhydrate, by preparing a formal motion for the next Board meeting.

Due to the new NOP sunset rules, the only way the Crops Subcommittee can ensure that the Board conducts a full review of SCP is to prepare a proposal for removal, to be voted

on at an NOSB meeting. There are several reasons why this material requires a full review, and may need to be removed from the National List.

Use of SCP for aquatic plants must be evaluated

Recently, the NOP clarified that aquatic plant production is allowed under USDA organic regulations. A Policy Memorandum issued on September 12, 2012 stated:

This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List … 205.601 – 205.602, as the basis for production and certification of cultured and wild crop harvested aquatic plants.

When the NOP chose to allow aquatic plant production, and to allow the use of synthetic materials on §205.601 that had been approved only for terrestrial crop production, the NOP allowed the use of SCP in a way that was not approved by the NOSB.

A review by the entire Board is needed to clarify **all** uses of SCP.

SCP is harmful to the environment

The product label states that SCP is a **bacteriocide, fungicide, and algaecide**. When applied in an aquatic environment, such as a pond or rice field, its action is not limited to the intended use—to kill algae. It also acts as a **general biocide**, to kill bacteria and fungi. This is not consistent with the pest control practices of successful organic farmers, who use pest control products that have the least damage to non-target species. If released into natural waterbodies, SCP could cause undue ecological damage because of its broad-spectrum abilities.

Alternatives are available for control of algae

The TR mentions several ways to reduce algae in ponds and rice paddies:[30]

- Rice straw
- Barley straw
- Allelopathic plants
- Herbivorous fish

Sodium carbonate peroxyhydrate does not fit any OFPA categories

All materials added to the National List must contain an active synthetic ingredient in one of the OFPA categories. SCP fails this essential requirement; therefore, it should never have been approved. **This is not new information; it was noted by the Crops Subcommittee in the original checklist**. It is, however, a valid reason to remove SCP from the National List.

[30] AMS Agricultural Analytics Division. 2014. TER Sodium Carbonate Peroxyhydrate (Crops) Lines

International standards do not allow SCP in crop production

The raw materials to manufacture SCP, hydrogen peroxide and sodium carbonate, are allowed by some international standards for disinfection of processing equipment and buildings.

The use of SCP for cleaning irrigation lines, for use in rice production, or for addition to natural waterbodies are fundamentally different uses than disinfection of processing equipment. SCP is not listed for crop production by Canada, Japan, or the European Economic Community. It is not listed by CODEX or IFOAM.

High-quality contractors should be chosen to prepare TRs

Note: Please review the full discussion of this issue in the Sulfurous Acid section, above.

The current Technical Review for SCP was prepared by the USDA Agricultural Marketing Service (AMS) Agricultural Analytics Division. The TR was requested by the Crops Subcommittee in February 2013, and the final copy was dated January 15, 2014, almost a year later. The initial TR was deemed insufficient by the Crops Subcommittee and had to be returned to the contractor for additional research. Due to the fact that they were not vetted through the open bidding process, the apparent lack of technical qualifications, and the inordinate amount of time required to complete the TR, we request that the NOP not use this contractor again.

CONCLUSION

Sodium carbonate peroxyhydrate needs to be evaluated by the full Board. When OFPA was passed by Congress, sunset reviews were mandated to ensure that synthetics substances only remain on the National List if they are fully reviewed every five years and determined to be consistent with organic principles. The new sunset procedures allow approval by the Crops Subcommittee to take the place of a full Board review. We urge the subcommittee to prepare a proposal to delist sodium carbonate peroxyhydrate. This will ensure that the entire Board has an opportunity to exercise the responsibility of care and evaluate whether sodium carbonate peroxyhydrate is consistent with organic principles.

Aqueous Potassium Silicate - Sunset

SUMMARY

Do not renew the listing of aqueous potassium silicate on the National List under §205.601 Synthetic substances allowed for use in organic crop production.

Rationale:

- The entire Board should vote on the relisting of aqueous potassium silicate.
- Initial approval was based on insufficient review.
- Specific use—fertilizer, disease control, insecticide—should be clarified.
- Alternatives are available.
- Information is needed on accumulation of silica in plants.
- International standards do not allow aqueous potassium silicate in crop production.
- High-quality contractors should be chosen to prepare TRs.

DISCUSSION

Aqueous potassium silicate is currently on the National List §205.601 (e)(2) and (i)(1):

(e) As insecticides (including acaricides or mite control).
(i) As plant disease control.
Both listings state: Aqueous potassium silicate—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand

APS was petitioned by PQ Corporation, manufacturers of the formulated product Sil-Matrix. The label attached to the petition states that the product is 29% potassium silicate, 71% other ingredients. The potassium silicate used in agriculture contains potassium carbonate and silicon dioxide in a ratio of 2.5 to 1.[31]

The entire Board should vote on the relisting of aqueous potassium silicate

When aqueous potassium silicate (APS) was initially approved, a robust sunset policy was in place. The Board members who approved APS in 2007 assumed that it would be thoroughly reviewed by the entire Board every five years. They believed that the entire NOSB would have the opportunity to vote on removal of any material from the National List, if it proved to be incompatible with organic production principles.

Under the new sunset process directed by the NOP, most of the Board members have been disenfranchised. The Crops Subcommittee may choose to renew APS in their

[31] AMS AAD. 2014. TER Aqueous Potassium Silicate (Crops). Lines 87-88.

subcommittee meeting, thereby preventing their fellow Board members from having a voice. There is only one way to ensure that the full Board reviews this material, as required by OFPA, and as practiced successfully for more than a decade of NOSB meetings. "*The NOSB subcommittees can develop proposals to remove substances as part of their preliminary review*."[32] If the subcommittee chooses not to develop a proposal to delist, the other Board members will have no opportunity to voice their opinions and vote.

Cornucopia strongly urges the Crops Subcommittee to develop a proposal that recommends against relisting of aqueous potassium silicate, by preparing a formal motion for the next Board meeting.

Due to the new NOP sunset rules, the only way that the Crops Subcommittee can ensure that the Board conducts a full review of APS is to vote in favor of a proposal for removal.

There are several reasons why this material requires a review by the full Board to determine whether it is compatible with organic production.

Initial approval was based on insufficient review

The PQ Corporation submitted a petition for aqueous potassium silicate in 2002 and substantially revised the petition in June 2006. The 2006 petitioned uses were:

- Plant disease control
- Insecticide/miticide
- Soil/plant amendment, for hydroponic use only

A TAP review was compiled by UC SAREP (the University of California Sustainable Agriculture Research and Education Program) in 2003. **This review addressed petitioned use for disease control and as a soil amendment. It did not address insecticide use.**

In the TAP review from 2003, two reviewers felt APS should be prohibited. One of these reviewers cited the nature of potassium silicate as a **highly soluble synthetic fertilizer**, and questioned its effectiveness as a fungicide. The other dissenting reviewer raised similar concerns, questioning the need for silica amendments in organic systems and the legitimacy of supporting evidence. The third reviewer was in favor of adding the substance to the List, with annotations. Clearly, **two of the three experts had serious reservations about this material**. That, in itself, should signal that a complete review is needed at this time.

Regarding the fungicidal activity, a TAP reviewer commented:[33]

[32] Notification of sunset process, document number AMS –NOPP – 13 – 0057; NOP – 13 – 03.
[33] UC SAREP. 2003. TAP Review Potassium Silicate.

"Unfortunately, there is not convincing evidence that potassium silicate will be even as effective as the alternatives, and its mode of action is not understood. These are important considerations. Sulfur and copper are allowed synthetics because, although they have some non-target toxicity and environmental troubles, they have a well-understood mode of action and breakdown products, have been used by organic farmers for a long time, and are proven effective. Potassium silicate does not have significant non-target toxicities, environmental risks or breakdown products, but does have a poorly understood mode of action, a short history of use, and has not been proven widely effective."

In 2007, the Crops Subcommittee considered three uses of APS and voted as follows:

- insecticide - Yes: 1, No: 3, Absent: 2
- plant disease control - Yes: 1, No: 3, Absent: 2
- plant or soil amendments (for hydroponic use) Yes: 0, No: 4, Absent: 2

They determined that APS fails categories 2 (essentiality) and 3 (compatibility).

At the November 2007 meeting, the NOSB approved the addition of APS to the National List. The rationale to approve was based on testimony from the petitioner and interested stakeholders at the meeting. APS was added to the List in 2010.

Specific uses should be clarified

The label for aqueous potassium silicate states that it can be used to control fungal diseases and certain insects. However, it does not kill fungi; instead, it functions by strengthening the cell walls of plants so that the fungi cannot penetrate the plant epidermis. The silicon remaining on the plant surface kills certain insects.

APS also functions as a fertilizer, in which case it should be listed under §205.601 (j) *As plant or soil amendments*. Clearly the product provides silica, but it also provides synthetic potassium, as noted above. The petition specifically requested use as a hydroponic fertilizer, for K_2O (potassium) supplementation. Recently, the NOP clarified that hydroponic production is allowed under USDA organic regulations; therefore, we assume that APS is currently allowed as a synthetic source of potassium in hydroponic production. At the time that APS was reviewed by the NOSB, in 2007, hydroponic production was not allowed by organic standards. In 2008, the NOSB reviewed hydroponic production, and recommended that it should be prohibited in organic production. When the NOP chose to allow hydroponic production, disregarding the recommendation of their advisory board, the NOP allowed the use of APS in a way that was not intended.

A review by the entire Board is needed to clarify all uses of APS.

Alternatives are available

Organic production is based on the fundamental principle of feeding the soil with natural minerals to maintain plant health and resistance to insect infestations. If natural minerals are not sufficient, there are numerous synthetic plant and soil amendments on the National List. There are also many substances used as plant disease and insect control that have been used for a long time and are well understood.

Organic farmers also use management practices that maintain plant health, such as avoiding high nitrogen fertilizers which encourage fast but weak plant growth.

Natural sources of silica soil amendments are commercially available to U.S. farmers (based on a recent Internet search), including granite dust, bentonite, greensand, azomite, and diatomaceous earth. Standards written by Canada, Japan, EEC, CODEX, and IFOAM mention natural sources of silica. They do not mention the use of aqueous potassium silicate.

Information is needed on accumulation of silica in plants

Use of APS for disease and insect control may entail multiple applications of a potassium silicate over the course of the growing season, and over the course of many growing seasons. This increases potential for soil accumulation of silica, but the effects are not well understood. There may be need for an annotation stating that silica should be used in a manner that does not cause accumulation in the soil, similar to the restriction on the use of copper for disease control.

High-quality contractors should be chosen to prepare TRs

Note: Please review the full discussion of this issue in the Sulfurous Acid section, above.

The 2014 Technical Review for aqueous potassium silicate was prepared by the USDA Agricultural Marketing Service (AMS) Agricultural Analytics Division. The TR was requested in April 2013, and the final copy was dated January 6, 2014, nine months later. The initial TR was deemed insufficient by the Crops Subcommittee and had to be returned to the contractor for further work. Due to the poor quality of their work and the inordinate amount of time required to complete the TR, we request that the NOP not use this contractor again.

CONCLUSION

When aqueous potassium silicate was first petitioned, the Crops Subcommittee determined that it was not essential and it was not compatible with organic agriculture. Nonetheless, it was approved, with the assumption that it would be removed from the National List after five years, unless a majority of the members voted to relist it.

At this time aqueous potassium silicate needs to be fully evaluated. Cornucopia urges the subcommittee to prepare a proposal to delist aqueous potassium silicate. This will

ensure that the entire Board has an opportunity to exercise the responsibility of care and evaluate whether aqueous potassium silicate is consistent with organic principles.

LIVESTOCK SUBCOMMITTEE

Methionine – Poultry

SUMMARY

Support the NOSB Livestock Subcommittee proposal submitted 8/20/13 to amend §205.603(d) 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.*

Although we support the sunsetting of synthetic methionine in 2017, we believe amending the language as listed above will support organic poultry producers to adjust their poultry diets according to the state of life of the bird. Younger birds need more methionine than older birds. By changing the language to read "over the life of the flock," this would allow producers to make minor methionine inclusion adjustments over the life of their birds.

That said, The Cornucopia Institute questions whether synthetic methionine is necessary given that it appears certain practices and natural alternatives are increasingly available.

Therefore The Cornucopia Institute believes that the NOSB should encourage aggressive research on natural sources of methionine, alternative poultry management systems, and breeding for poultry that perform well on less methionine. All of these methods have been shown to be effective in preliminary studies but require more robust research to be commercially viable. If the proposal above passes, we recommend that the Board also pass the following:

Resolution: The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production by the 2019 sunset date.

Rationale:

This substance has been scheduled to sunset many times (2005, 2008, 2010) and is always extended because viable alternatives are purportedly not available. However, feed mills and poultry scientists say there are alternatives and that flock management

plays a large role as well. In order to encourage the adoption of alternatives to synthetic methionine supplementation, this substance should be allowed to sunset once and for all in 2019.

DISCUSSION

Methionine is an essential amino acid; therefore, it must be present in poultry diets to maintain optimal bird health. This proposal allows farmers to supplement their poultry feed with minimal amounts of synthetic methionine if their flock requires supplementation.

This proposal suggests that poultry require synthetic methionine, but that is only partially true. When poultry are raised on a restricted diet of corn and soybeans without access to meat scraps, insects, or foraging outdoors, methionine supplementation is indeed necessary.

According to the current Technical Report, Methionine is considered to be the first limiting amino acid in corn-soy poultry diets. However, poultry do not need to be raised on such a restricted diet. A balanced, diverse diet for omnivorous poultry includes fresh green plants, insects, worms, and other animal protein. This is what poultry have evolved to eat and what they would eat in the wild to obtain all of their essential nutrients and amino acids. Both the proposal and the Technical Report failed to fully consider the benefits of a healthy, diverse natural diet for poultry—a management approach that would be consistent with the overall philosophy of organics.

Poultry have been domesticated for thousands of years. During that time, farmers and homesteaders have maintained healthy poultry without synthetic methionine. Surely, modern organic growers can do the same. Commercial-scale, conventional poultry are raised with the addition of synthetic nutrients because their diets are uniform and restricted, and the birds are confined at very high stocking densities without outdoor access. In organic production, diversified diets and management practices should be the primary approach of ensuring adequate nutrition for livestock since the principles of organic state that it is a system based on ecology, not input substitution.

Natural alternatives to synthetic methionine

There are many natural sources of methionine. Indeed, feed mills already blend in varying quantities of these natural sources of methionine (MET) to meet the requirements of the birds, in addition to the small amounts of synthetic methionine that they add. The amount of total sulfur amino acids (MET + CYS) in feedstuffs should be considered instead of only focusing on MET. If Cystein (CYS) is inadequate, some of the MET will be used to satisfy that requirement (Fanatico 2010). Some high MET/CYS amino acid feedstuffs include: fishmeal, crabmeal, milk powder, meat and bone meal, potato meal, black soldier fly larvae, algae, sesame meal, corn gluten meal, sunflower

meal, soybean meal, and brewer's yeast. However, with every feed ingredient, there are nutrients and anti-nutrients or other tradeoffs to consider. It is never a simple formula.

Some of the challenges with these alternative feeds include:

- Limited organic supply or not available in organic form (such as corn gluten meal or potato meal)
- Based on unsustainable supply (often the case with fishmeals such as Menhaden)
- Utilize GMO ingredients (farmed fish or some algae processes)
- Use non-organic preservatives (ethoxyquin in crabmeal)
- Chemical solvents in extraction (such as hexane in oilseed crops)
- Can impart bad flavors in eggs or meat (such as with fishmeal, crabmeal, or flax)
- Low digestibility (i.e., sesame seed meal,- even though high in MET, is not in a digestible form)
- Not yet approved by FDA for poultry rations (such as black soldier fly meal)

A few organic feed mills interviewed by The Cornucopia Institute stated that they utilize some of these alternative sources of methionine in their feed blends, but that supplies of alternatives to synthetic methionine are constrained and costly.

One stated that if synthetic methionine is eventually eliminated, the largest vertically integrated egg and poultry producers would likely snatch up these limited natural methionine sources for their own, vertically integrated feed mills and little would be left for the independent feed mills and smaller producers.

Price would also go up as demand for limited supplies goes up. Conversely, it would likely stimulate demand for increasing the production of these alternatives. This has already happened in a similar vein with the increasing demand for alternatives to soy protein in poultry feed. Crops like sesame and camelina are in more demand and production has increased to meet that demand over the last few years.

Vegetarian vs. omnivore

Simply replacing synthetic methionine with alternative plant-based feeds overlooks the natural feeding habits of poultry. Just because consumers have come to expect organic poultry to be "vegetarian-fed" does not mean that poultry should be forced to be vegetarians. Vegetarian-fed is more of a marketing-oriented approach than something that consumers demand, especially if they are informed about the true nature of poultry. Indeed, the Livestock Subcommittee issued a discussion document on 8/21/2013 about allowing omnivorous species like poultry and swine to be allowed omnivorous diets through the addition of <u>organically certified</u> meat-scraps or animal byproducts in their feed.

Currently seafood and insects are the only approved animal products allowed in poultry feed, but they have their limitations as described above. If organic poultry producers could utilize certified organic blood meal, bone meal, fresh and dried meat meal, they could likely satisfy all of their methionine needs, as well as a percentage of their protein

and fat needs. This would also help develop a market for those animal byproducts that may not be fully utilized or are diverted into the pet food industry. It could help organic slaughterhouses and meat marketers operate more profitably if they had markets for all of the animal parts.

If these animal-derived products were properly cooked and/or dried, they would be free of pathogens and safe for feeding to poultry (or swine). Some feed mills interviewed reported that they would not want to handle mammalian animal products in their mills due to perceived contamination issues and the need to maintain some of their buyers "vegetarian-fed" marketing claims. Other feed mills are already using fishmeal and crab meal, thus adding other animal-based ingredients would not be problematic.

It should be noted that the "consumer expectations" that are being referenced have nothing to do with organic production per se but rather the ability to market eggs as produced with "vegetarian feed," an unnatural diet for omnivorous poultry. However, we understand that under current NOP rules, the feeding of mammalian proteins to poultry is prohibited and thus the genesis of the statement "vegetarian-fed" was a way for producers to explain that.

Aquatic animals such as fish and crabs have always been allowed as a poultry feed, but research has shown that their inclusion above 5% of the diet leads to off-flavors. Many poultry producers have chosen to not use fish or crab meal at all and stick to completely plant-based nutrients, with the exception of synthetically derived methionine.

Foraging for methionine?

In nature, poultry species forage outdoors, looking for insects, grubs, and soil-dwelling invertebrates to obtain their needed levels of methionine, as well as fresh green plants and seeds. They also eat small animals such as rodents, amphibians, and reptiles when they have the opportunity. In order to allow poultry to better obtain adequate levels of nutrients and amino acids such as methionine from their natural diet, it would be necessary to allow them to forage outdoors on pasture. This management approach would provide a natural alternative to synthetic methionine.

The Livestock Subcommittee proposal goes on to state:

> *"Pasture may provide some supplementation during the right conditions, but is certainly not a dependable solution."*

For thousands of years, pasture has been a dependable solution. Access to the outdoors, including access to soil and vegetation, allows chickens to include in their diets all nutrients they need if their stocking densities are kept at reasonable levels. We understand that severe weather may prevent pasture access at some times of the year, but we do not believe that pasture access should be dismissed as in the above quote.

Allowing birds to have adequate access to pasture can allow them to meet much of their

methionine needs. An experiment conducted by poultry scientist Dr. Joe Moritz of West Virginia University verified this; he concluded that growth impairments and compensatory feed intake associated with marginal methionine deficiency (in birds not supplemented with synthetic methionine) were largely overcome by foraging. However, fall pastures had lower levels of methionine and therefore pasturing is not suitable for year-round methionine needs. [34] His study did not look at winter or spring pastures, only summer and fall. It can reasonably be concluded that winter pastures would be low in methionine, too, since fall ones were. Spring pastures, however, may have sufficient new plant growth that would allow them to have adequate levels of methionine in the plants. Further research would benefit the industry's understanding of this option.

While it might not be possible for densely packed poultry barns with 10,000 to 100,000 birds to be able to provide enough pasture for the birds to meet their methionine requirements, organic operations with lower stocking densities and rotated pasture may be able to do it.

There is a blurry line between what is essential for poultry health and well-being and is, essentially, being used as a "growth and production aid" when it comes to synthetic methionine.

Many other countries, including those in the European Union, limit poultry stocking densities both indoors and outdoors. EU organic standards require 43 square feet of space per bird outdoors, which is equivalent to just around 1,000 birds per acre. This is much lower than the stocking densities of some US organic poultry producers, who may have only a very small fenced in yard which 25,000 birds are supposed to share (obviously not all birds can go outside at the same time, and the overall densities are high).

This makes the value of the outdoor area virtually useless because there is little to no vegetation, bugs, or worms due to the high stocking density. In fact, the outdoor area is probably so covered with manure that it is not only useless for the birds' diet, it is actually detrimental to their health due to the level of manure caking the ground.

That is not an excuse to not have outdoor access; rather, it is a call to have meaningful access to pasture with the **right stocking density of birds**, and appropriate management, so that the pasture remains healthy. That is where the birds do best and are able to meet some of their methionine needs through foraging behavior.

EU organic poultry standards now include a nitrogen loading rule to better determine appropriate stocking densities assuring outdoor areas do not have unhealthy levels of manure loading and to minimize any possibility for nutrient pollution.

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[34] Moritz, J. S., et al. "Synthetic methionine and feed restriction effects on performance and meat quality of organically reared broiler chickens." *The Journal of Applied Poultry Research* 14.3 (2005): 521-535.

Allowing poultry to forage on pasture also provides an opportunity for them to hunt and eat insects and other invertebrates, and provides the birds with animal protein containing methionine.[35,36] This also meets the regulatory requirement for promoting livestock's natural instinctive behaviors.

This thesis is not strictly based on academic research only; some poultry producers have been able to raise chickens without synthetic methionine. The practices include adequate access to pasture, natural supplements of organic whole wheat, organic whole oats, alfalfa meal, sunflower meal, and fishmeal.[37]

An Organic Approach

A production system that minimizes the need for synthetic methionine may include:

- Access to healthy, growing pasture, not just a porch
- Stocking densities that allow pastures to maintain vegetative cover and natural biodiversity (insects, worms, etc.) to thrive.
- Sufficient "popholes" in the chicken house to encourage outdoor foraging
- Locating some feed and water outside to encourage foraging
- Slow-growing or heritage chicken breeds that are capable of superior foraging
- Management practices that include opening doors as much as possible
- A varied diet of diverse, nutritious foods, not just corn/soy
- Natural supplements that could include herbal methionine or non-GMO fermented methionine (two new products that may take a few years to be approved in the U.S.).

CONCLUSION

The Cornucopia Institute encourages support the proposal to allow limited synthetic methionine in poultry flocks at the current levels but adjustable over the lifetime of the flock. However, our stance is that if this adjusted methionine proposal is approved it should be expected to sunset in five years if research shows alternative management practices and/or natural supplements or organic feed sources can supply adequate levels of methionine for poultry health.

Support aggressive research into the alternatives to synthetic methionine.

Support a resolution by the NOSB to sunset this material in 2019.

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[35] Fanatico, A. 2010. Organic Poultry Production: Providing Adequate Methionine. NCAT. 20 pp.
[36] Spencer, T. 2013. Pastured Poultry Nutrition and Forages. NCAT. 20 pp.
[37] Hungerford, C. 2007. There's a synthetic in my organic chicken. The New Farm. Retrieved July 7, 2011 from 1050 http://newfarm.rodaleinstitute.org/columns/org_news/2005/0405/methionine_print.shtml

Sodium Chlorite (acidified)

SUMMARY

Reject the petition to list acidified sodium chlorite to §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.

Rationale:

- The Livestock Subcommittee unanimously rejected this petition.
- Acidified sodium chlorite is not essential for this use. Many alternatives are available.

DISCUSSION

Acidified sodium chlorite (ASC) contains various chlorine compounds, which act as a disinfectant, in a solution at very low pH, approximately 2.3 – 3.2. When acidified with citric acid, ASC is allowed in organic handling as an antimicrobial food treatment for organic foods.

The current petition is to add acidified sodium chlorite (ASC) as an allowed synthetic in organic livestock production for use as a disinfectant and topical treatment (i.e., teat dip) for dairy animals.

This material does not appear to have wide support in the organic industry. The TR states, "International regulations regarding the use of acidified sodium chlorite (ASC) solutions in organic agricultural production, processing, and handling are lacking."[38] Presumably that means that ASC is not approved for organic livestock under international organic regulations.

The Livestock Subcommittee deemed it unnecessary, after speaking to organic farmers.

Harmful to human health

According to the TR, sodium chlorite is extremely destructive to the tissues of the mucous membranes and upper respiratory tract, and will burn the skin upon dermal exposure. Likewise, gaseous chlorine dioxide is highly irritating to skin and mucous membranes of the respiratory tract.[39]

[38] Pesticide Research Institute. 2013. Acidified Sodium Chlorite (Livestock) Technical Evaluation Report.
[39] Ibid.

According to the MSDS from a manufacturer of ASC, skin eruptions may occur after direct contact, and fumes from ASC can cause respiratory problems.[40] Other citations in the TR verify the irritation to skin and respiratory systems that can be caused by ASC.[41] Since this substance is designed to be repeatedly applied to the skin (of cows), there seems a likelihood of irritation.

Alternatives are available

Although controlling mastitis in dairy animals is essential, use of ASC to control mastitis is not essential, because many alternative practices have been developed.

Management practices to prevent mastitis include keeping animals in a clean dry environment and ensuring a healthy balanced diet. Alternative materials listed in the TR include vinegar (acetic acid), hydrogen peroxide, iodine, the alcohols ethanol and isopropanol, glycerine, tea tree oil, and chlorhexidine.[42]

The Livestock Subcommittee confirmed that alternative substances are already in use by organic farmers. Therefore, an additional material is not essential.

CONCLUSION

Acidified sodium chlorite is a chlorine compound with potential to irritate skin and respiratory systems. ASC is not needed for its intended use as a topical antimicrobial. Please reject this petition.

[40] MSDS Acidified Sodium chlorite. GO2 International. Downloaded on Sept. 12, 2013 from http://www.go2intl.com/pdfs/SAF004en.pdf

[41] Pesticide Research Institute. 2013. Acidified Sodium Chlorite Technical Evaluation Report. Lines 472-483.

[42] Ibid. Lines 515-539.

AQUACULTURE – General Comments

The Cornucopia Institute is dismayed to see the current NOP focus on the approval of petitioned materials for aquaculture. We have serious concerns about the overall process of the development of aquaculture regulations. Therefore, Cornucopia believes that all petitions for aquaculture materials should be tabled until the organic regulations pertaining to aquaculture have been finalized by the NOP. The revised sunset process compromises the Board's ability to conduct future reviews of synthetic materials that may be added to the National List at this meeting. In addition, we believe that every synthetic material approved for aquaculture use should have a firm expiration date.

Concerns about the organic approach to aquaculture:

- Fundamental differences between aquatic and terrestrial ecosystems must be recognized.
- Open-net pens are not consistent with organic principles.
- Organic diets for carnivorous fish have not been resolved.

Concerns about the process of petitioned materials:

- The NOP should not request review of aquaculture material when they have not published the Aquaculture Standards.
- Synthetic materials for aquaculture should have a firm expiration date.
- The Technical Evaluations must be relevant to aquatic systems.
- Petitioners should not be invited to participate in NOSB Subcommittee meetings.

In this section, we address the areas that apply to the aquaculture regulations and the process that has been followed. We discuss concerns that apply to individual petitioned materials in the later sections of this document.

ORGANIC PRINCIPLES APPLIED TO AQUACULTURE

In 1995, the NOSB defined *organic agriculture* thusly:

> "Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain, and enhance ecological harmony."

In 2002, the NOP defined the term *organic* in CFR §205.2:

> "Organic production [is] a **production system** that…respond[s] to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biological diversity."

Fundamental differences between aquatic and terrestrial ecosystems must be recognized

§205.200 of the Organic Production and Handling Requirements states that organic production practices "must maintain or improve the natural resources of the operation, including soil and water quality."

The current NOP regulations were written only for land-based production systems. Regulations for aquatic systems must take into account the significant differences between aquatic and terrestrial ecosystems, particularly with regard to the quantity of nutrients released into the environment, and the subsequent effects on native fauna.

Livestock farms increase the nutrient levels in the nearby ecosystem in the form of animal wastes. Judicious use of nutrients in manure can be beneficial in terrestrial systems, because the animal manures fertilize crops grown on land. The aerobic environment allows rapid nutrient cycling.

In contrast, added nutrients are harmful in aquatic ecosystems. Added nutrients in lakes can increase growth of algae, which then die and decompose, leading to anaerobic conditions and death of fish. Similar effects are seen in oceans, where the added "nutrients" (feces) from fish farms sink to the ocean floor and create dead zones.

Open-net pens are not consistent with organic principles

Organic production is required to "promote ecological balance" but organic aquaculture in open oceans is likely to destroy ecological balance.

Food and Water Watch, in a report on the open ocean fish farming industry[43], concluded: "*evidence indicates that offshore fish farms … will threaten the marine environment in a variety of ways*." One of the most important results will be the production of large amounts of nitrogenous waste (feces) that is released into the ocean.

Sera, et al. [44] studied the nitrogen and phosphorous added to the Mediterranean Sea due to aquaculture. They concluded:

> *"This paper demonstrates for the first time ever that off-shore aquaculture may affect the marine ecosystem well beyond the local scale and provides an additional element of concern to be kept into consideration when allocating oceans' space for new fish farming activities."*

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[43] Food and Water Watch, 2011. *Fishy Farms, The Government's Push for Factory Farming in our Oceans*. 24 pp. Downloaded on Aug. 27, 2013 from http://www.foodandwaterwatch.org/reports/fishy-farms/

[44] Sarà, G, Lo Martire., M, Sanfilippo., M, Pulicanò, G., Cortese, G., Mazzola, A., Manganaro, A., Pusceddu, A. Impacts of marine aquaculture at large spatial scales: evidences from n and p catchment loading and phytoplankton biomass, Marine Environmental Research (2011), doi: 10.1016/j.marenvres.2011.02.007

Escape of farmed fish into oceans will also harm the environment. A chart prepared by the Center for Food Safety [45] indicates that, in the years from 2006 to 2011, hundreds of thousands of fish escaped from fish farms into the ocean each year. Escaped fish will compete with native fish for food and will alter the population genetics by breeding with native fish.

NOSB members have expressed their concern about the harm that can be done by fish farming in the oceans. Notes from the March 5 meeting of the Livestock Subcommittee stated:

> *"A member noted that based on a comment sent in by Food and Water Watch, the science had changed a bit since the NOSB recommendation was written, and this needed to be revisited."*

Without publication of the Aquaculture Standards, the NOSB and the public do not know if open-net pens will be allowed by the organic standards. Because the NOP defined the term *organic* in CFR §205.2 as *"a* ***production system that…respond[s] to site-specific conditions***," [emphasis added] it is essential to understand the site, i.e., open water or closed system, before approving materials.

In contrast to the harm that can be done in open water systems, there are excellent models of fish farming that are consistent with organic principles. For example, the Land-Based Recirculating Aquaculture Systems can provide a model of how organic fish farming can truly "*maintain or improve the natural resources of the operation, including soil and water quality*."

Organic diets for carnivorous fish have not been resolved

When raising carnivorous fish, there are two options: feed an unnatural diet of corn and soybean meal, or feed other fish. The feeding of wild-caught fish, fish meal, and fish oil has been discussed at several NOSB meetings, in 2007 and 2008, but the issue has not been resolved, since the Aquaculture Standards have not been published.

Feeding of wild-caught fish is not consistent with organic principles, because it would require capture of large quantities of fish, which would lead to depletion of fisheries.

Attempting to raise carnivorous fish on a vegetarian diet should be prohibited, as it requires the addition of large numbers of feed additives. This is evident from perusing the petitions to the Livestock Subcommittee.

THE PROCESS OF APPROVAL OF PETITIONED MATERIALS

[45] Center for Food Safety, *Reported Escapes from Fish Farms*, Downloaded on August 26, 2013 from http://www.centerforfoodsafety.org/files/fish-escapes-chart_14767.pdf

Organic regulations for aquaculture have not yet been established

No regulations have been established for aquatic animal or plant production. The first order of business, before petitions are approved, must be the establishment of organic regulations. This, alone, is reason enough to vote against any materials petitioned for use in aquaculture.

The NOP should not request review of aquaculture materials when they have not published the Aquaculture Standards.

A memo from NOP to the NOSB dated May 16, 2012 specifically requested that the NOSB review aquaculture materials. Cornucopia suggests that the NOSB has the authority to delay review of the aquaculture materials until the NOP completes their proposed rule for the production and certification of organic aquaculture products. As the NOP stated in their memo, they expected the rulemaking process to take place "over the next two years," which would be by May 2014. Certainly it is feasible to postpone review of these materials, especially since the NOP has now waited five years, and counting, to review the NOSB Aquaculture Standards Recommendation.

Placing these aquaculture materials onto the already full NOSB work plan is not only premature, it is disrespectful of the many volunteer hours that were invested in developing the Aquaculture Standards by NOSB members and many industry stakeholders. The NOSB recommendations were published in 2007, and they were discussed at NOSB meetings in 2007 and 2008. Today, six years later, with an expanded staff of professionals, the NOP still has not published a draft rule for Aquaculture Standards. Yet, the NOP requested that the volunteers on the NOSB should devote time to review of materials.

In addition to the volunteers on the NOSB, numerous stakeholders in the organic community devoted their time to review research, prepare comments and attend meetings to speak about the Aquaculture Standards. The organic community deserves to see the results of their efforts, in the form of a published set of Aquaculture Standards, before we are asked to comment on individual materials.

Several proposals state that they are based on NOSB recommendations of standards voted in 2007, 2008 and 2009. The fact that NOSB recommendations have not yet been approved, five years after they were developed, suggests that there will be significant differences between the NOSB recommendations and the final NOP regulations. When considering whether to approve petitioned materials for aquaculture, the Board needs to consider that their original recommendations may be ignored or even directly contradicted.

In the past the NOP has directly contradicted Board recommendations. For example, in 2010 the Board passed a recommendation that hydroponic systems are prohibited for organic production. However, the current statement recently put on the NOP website

specifically states that hydroponic production is allowed—a direct contradiction to NOSB recommendations.

Synthetic materials for aquaculture should have a firm expiration date

In addition to these current issues, Board members must consider what may happen in the future. The revised sunset process compromises the Board's ability to conduct future reviews of synthetic materials that may be added to the National List at this meeting. Given that aquatic systems are less well understood than terrestrial, and that the organic standards have not been established by the NOP, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

Several proposals offer a way to ensure a full evaluation, namely an annotation to set a five-year expiration date on the listing. Although this suggestion is placed at the end of the several proposals, and it is titled a minority opinion, we believe that the suggestion would represent a majority opinion in the organic community. Aquaculture, particularly production of organic fish, is a completely new production system for organic certification. A full review after the system has been in place for a few years will allow more informed decision-making.

The expiration date is needed to address changes in the sunset process. This ensures that the Board will conduct a thorough review of each of the aquaculture materials after five years, and that the entire Board, all 15 members, will participate in a vote on retaining them. The original sunset process ensured that the entire Board, all 15 members, would be required to vote, and at least 10 members would need to approve re-listing of the material. This respected system is no longer in place; hence a five-year expiration date should be included in every motion for aquaculture materials.

Based on our reading of the subcommittee notes it appears that the Board members are more closely following the NOP's wishes, rather than the sentiments of the organic community.

Notes from the Livestock Subcommittee meeting of 2/18/14 stated:

> *"A member proposed another annotation regarding the materials' 5-year review …. **The NOP does not support this annotation** as it is in direct conflict with the new sunset policy, and several members agreed that it would not be accepted by the NOP so it was not useful to include it." (emphasisadded)*

As NOSB members consider the wisdom of adding an expiration date to these proposed listings, we encourage you to consider the sentiments of your constituents, the organic community, not the wishes of the NOP. We also encourage you to consider OFPA, which clearly states that every material added to the National List must be fully reviewed after five years.

The Technical Evaluation Reports must be relevant to aquatic systems

Technical Evaluation Reports (TRs) must be based on the particular use of the substance. Specifically, the NOSB must be supplied with a TR for the use of each petitioned material in aquatic systems. TRs prepared for terrestrial crop or livestock production are not adequate to evaluate a material to be used in aquatic systems, because they do not consider factors important in aquatic systems.

For example, chlorine has been petitioned for both aquatic plant and aquatic animal production. Yet, the most recent TR evaluates use of chlorine only for terrestrial crops. The following question needs to be completely revised to apply to aquatic environments:

- Evaluation Question #8: Are there detrimental physiological effects on soil organisms, crops, or livestock by using the petitioned substance?

Answers to other questions are based on the effects of chlorine in agriculture in terrestrial systems. These questions must be addressed in aquatic systems:

- Evaluation Question #5: Is the petitioned substance harmful to the environment?
- Evaluation Question #7: Are there adverse biological or chemical interactions in the agro-ecosystem by using the petitioned substance?
- Evaluation Question #10: Is there undesirable persistence or concentration of the petitioned substance or its breakdown products in the environment?

In short, TRs, because they are intended to be the primary source of unbiased information available to the NOSB, must address the environmental effects of the petitioned material in aquatic environments.

This concern has also been voiced by NOSB members. The minutes of the July 16, 2013 Crops Subcommittee state: "One member noted his concern about using information about micronutrients in a terrestrial system and applying them to an aquatic system." A similar comment was also made in the June 18 Livestock Subcommittee meeting, when a member indicated that he was not comfortable moving forward with some of the materials using soil-based systems as the basis for making judgments about aquatic systems.

Cornucopia is also concerned about comments made in the July 16 Crops Subcommittee meeting indicating that the NOSB wants to rely on obtaining information from public comments, instead of requesting a new TR. Although we certainly encourage public comments, they should not substitute for the unbiased literature review that is expected to be part of a TR. A relevant, comprehensive TR applicable to each material is essential for both the NOSB and the public who wish to comment on a material.

Petitioners should not be invited to participate in NOSB Subcommittee meetings

The aquaculture petitions were submitted by George Lockwood. Despite the fact that he is the petitioner, he attended the February 19 and the March 5 meetings of the Livestock Subcommittee.

The 2006 report of the Aquaculture Work Group lists George Lockwood as a "consultant" indicating that he has a financial incentive in getting those petitions approved by the NOSB.

At the March 5, 2013 meeting of the Livestock Subcommittee, the following comments were noted:

> *"A member noted that based on a comment sent in by Food and Water Watch, the science had changed a bit since the NOSB recommendation was written, and this needed to be revisited. George Lockwood added that the NOSB had already made its recommendation on practice standards, and the issues under consideration now are the petitions for various synthetic substances to be used in organic aquaculture."*

In this instance, an NOSB member voices a valid concern relating to his responsibility to fairly evaluate materials under review. The petitioner, because he has access to the NOSB meeting, was in a position to attempt to override the NOSB member's opinion. This is a dangerous precedent. Petitioners should not be allowed access to NOSB subcommittee meetings.

We applaud the efforts of the NOSB to learn more about aquaculture. We were encouraged by noting that representatives from Food and Water Watch and the PEW Charitable Trust attended some of the meetings. These representatives have no financial interest in the approval of the petitioned materials and therefore can be trusted to provide unbiased information.

Chlorine – animals

SUMMARY

Reject the petition to add chlorine materials to the National List at §205.611 Synthetic substances allowed for use in organic aquatic animal production. The listing motion is:

> *Motion to add chlorine materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) to §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.*

Rationale:

- Organic regulations for aquatic animals have not yet been developed.
- Two different uses have been petitioned.
- Relevant TR for aquatic systems is needed.
- Chlorine as a medical treatment is not essential.
- Chlorine is harmful to humans.
- Chlorine materials are harmful to the environment.
- Synthetic materials for aquaculture should have a firm expiration date.

DISCUSSION

Chlorine materials are used as disinfectants, to kill bacteria and fungi on hard surfaces and in drinking water. Calcium hypochlorite and sodium hypochlorite are sold as household bleach. Currently, chlorine is allowed for crops, livestock, and handling, as a disinfectant for hard surfaces.

Organic regulations for aquatic animals have not yet been established

Organic agriculture is a production system that responds to site-specific conditions and promotes ecological balance. The raising of livestock, primarily fish but also aquatic invertebrates, is fundamentally different from the raising of terrestrial livestock. From an organic standpoint, it is essential to take these differences into account when considering both the regulations and any possible additions of synthetic materials to the National List. The fact that organic regulations have not yet been developed and approved by both the NOSB and the NOP indicates that these differences have not been fully resolved. The first order of business must be the discussion of organic regulations.

Two different uses for chlorine materials have been petitioned

One of the uses requested in the petition is the use of chlorine as a disinfectant, for both hard surfaces and culture water. Current organic regulations for livestock specify that chlorine materials may be used for "disinfecting and sanitizing facilities and equipment."

A second use requested in the petition is the use of chlorine to be added to culture water "as a medical treatment." Current organic livestock regulations do not indicate that chlorine materials may be added to livestock drinking water, and they do not state that chlorine materials may be used as medical treatments.

For aquatic livestock, chlorine materials should not be added to culture water or be used as medical treatments. This would be analogous to raising terrestrial livestock in an atmosphere with chlorine gas. Aquatic animals should be raised with adequate space, food, and fresh water to prevent illness, rather than treating the illness with synthetic materials.

Relevant TR for aquatic systems is needed

The most recent TR was written by ICF, in January 2011. This TR was for use in terrestrial crop production. A previous TR was written in 2006, also by ICF, for terrestrial livestock production. These TRs addressed the use of chlorine to disinfect hard surfaces, and the use of chlorine to clean irrigation lines. They did not address aquaculture uses, specifically the use of chlorine in culture water.

The subcommittee evaluation relies heavily on the 2006 TR for terrestrial livestock, written seven years ago. [Note: The proposal refers to the "2006 Crops TR" but the heading for the 2006 TR states "Livestock".] Even the recent TR, from 2011, was written for terrestrial crops. It is not relevant for aquatic livestock.

Reliance on this TR fails to answer several relevant questions. The following are questions that should be answered for aquatic livestock:

1. Are there any alternative substances?
2. Are there any management practices that would make the substance unnecessary?

The subcommittee review answered "no" to both questions. However, there are alternative substances and management practices that render chlorine not essential. A TR to address the use of chlorine in aquatic systems is needed.

Chlorine is not essential

When an item is to be evaluated for the National List, evaluation questions must address the question of essentiality in that particular system, for that particular use, or uses, in this case.

The **first** petitioned use of chlorine is for **disinfection of hard surfaces**. Numerous sanitizers are allowed for disinfection of hard surfaces used for organic processing, as long as residues are removed before organic product is handled. The 2011 TR offers several alternative substances for this use, discussed in depth in lines 532 to 606:

- hydrogen peroxide
- ozone
- electrified water
- alcohols – ethanol and isopropanol
- peracetic (peroxyacetic) acid

The proposal states that there are no alternative substances (category 2, number 8). We request that this petition be rejected, until the subcommittee has an opportunity to thoroughly review the 2011 TR.

The **second** petitioned use of chlorine is in the **culture water** in which fish are living. There is no evidence that it is essential to add chlorine to water in which fish are living. The species of fish raised on aquaculture farms are also found in the wild. They successfully live in lakes, streams, and oceans without the addition of chlorine. Clearly, chlorine is not essential in fish culture water.

The proposal states that there are no other practices that could make this substance unnecessary (category 2, number 9). Based on animal husbandry practices for terrestrial livestock, we believe that a proactive approach to maintaining fish health will make chlorine unnecessary. Adequate space to avoid overcrowding, fresh water, and high-quality food are the primary keys to animal health. There are numerous options for cleaning and purifying the recirculating water in aquatic systems. An updated TR based on aquatic systems is needed, to provide a complete discussion of the practices that make chlorine materials unnecessary.

One solution for aquaculture in open-net pens is the use of electrolytic water treatment systems to disinfect seawater.[46] This process does produce some chlorine, as it causes the salt (NaCl) in seawater to dissociate and liberate the chlorine. However, the authors conclude that this process could be more effective than addition of sodium hypochlorite solutions. This alternative was not discussed in the TR, since the TR was written to address use of chlorine in terrestrial crop production. A new TR for use of chlorine in aquatic ecosystems is needed.

Before voting on this petition, it is necessary to clarify all possible uses of chlorine. Conventional aquaculture uses chlorine to disinfect fish eggs, particularly salmon, as well as shrimp eggs[47]. These uses should be prohibited for organic aquaculture.

Chlorine is harmful to humans

The proposal claims that chlorine materials are not harmful to human health or the environment (category 1, number 7). The 2011 TR paints a different view in Evaluation Question #9: [48]

> *"Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational 411 exposures. Acute exposure to high concentrations can cause eye and skin injury. … Ingestion of small quantities of household bleaches (3-6% hypochlorite) may lead to gastrointestinal irritation. Ingestion of more concentrated commercial bleach … may result in corrosive injuries to the mouth,*

[46] Jorquera, M., et al. 2001. Disinfection of seawater for hatchery aquaculture systems using electrolytic water treatment. *Aquaculture* 207:213-224.
[47] OIE. 2009. Methods for Disinfection of Aquaculture Establishments. Page 32. IN: *Manual of Diagnostic Tests for Aquatic Animals*. Downloaded from http://web.oie.int/eng/normes/fmanual/1.1.3_DISINFECTION.pdf.
[48] ICF International. 2013. Technical Evaluation Report for Chlorine / Bleach (Crops).

throat, esophagus, and stomach with bleeding, perforation, and eventually death."[49, 50]

Chlorine materials are harmful to the environment

The Materials Subcommittee has indicated that there are serious concerns about the environmental impacts of chlorine materials. In their *Proposal: Research Priorities for 2013*, they state:

> *"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."* [emphasis added]

One way to "*move beyond reliance on chlorine-based materials*" is to reject any petitions for adding chlorine materials to the National List.

The subcommittee is aware that there is a lack of data. The proposal states:

> *"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."*

There is no evidence that chlorine materials are harmless in aquatic environments, because the TR does not address that issue. Although one purpose of a TR is to address the question of adverse interactions in the agro-ecosystem, the existing TRs do not consider the aquatic ecosystem. The TR does not provide evidence to reassure us that the chlorine used in aquaculture will be harmless.

To evaluate environmental harm, it is necessary to know the extent to which chlorine materials are released into the environment. The proposal limits the **concentration** of chlorine, but it does not limit the total **amount** of chlorine. There is a significant difference between the release of 10 gallons of chlorinated water and 10,000 gallons. There is a need for data on the quantity of chlorine to be released and the frequency with which it will be released. This data must be collected by an independent contractor. It is not sufficient to rely on statements from the petitioner.

The proposal states that residual chlorine levels must be consistent with the Safe Drinking Water Act (SDWA) levels. The SDWA is completely irrelevant to the release of

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[49] ATSDR. 2002. ToxFAQs™ for Calcium Hypochlorite/Sodium Hypochlorite Available at: 636 http://www.atsdr.cdc.gov/toxfaqs/tfacts184.pdf.

[50] EPA. 1991. R.E.D. Facts. Sodium and Calcium Hypochlorite Salts. Available at: 657 http://www.epa.gov/oppsrrd1/REDs/factsheets/0029fact.pdf.

chlorine into the environment. Chlorine used in open-net pen systems would result in the release of chlorine into the environment, which is not consistent with organic principles.

The proposal, under category 1 (*Adverse impacts to humans or the environment?)*, claims that there are no adverse impacts. This is clearly false. The above discussion indicates that chlorine materials do indeed cause harm, in their manufacture, use, and disposal. We believe this material should not be added to the National List for use in aquaculture.

Synthetic materials for aquaculture should have a firm expiration date.

Cornucopia urges the NOSB to reject this petition, or at least table it until regulations for aquaculture are in place, so that the need for synthetic materials can be evaluated. Due to the NOP's recent changes in the sunset process, we are concerned that the use of synthetic materials in aquaculture systems will never again be subject to a full rigorous review, and a vote by the full Board. If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing. Although this suggestion is placed at the end of the document and it is titled a minority opinion, we believe that the suggestion represents the majority opinion in the organic community.

CONCLUSION

There is no reason to approve the use of synthetic materials in organic aquaculture until **after** the organic standards are available.

The publication of the new sunset process provides ample reason to avoid adding any new materials to the National List. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. Our objections to the new sunset policy are explained in detail in the section on the Policy Development Subcommittee.

Concerns about chlorine materials in particular provide additional reasons to reject this petition. The proposal was brought before the Board without the needed technical evaluation for the proposed uses. The proposed use of chlorine in culture water for medical use is a novel use, not analogous to any current uses in organic production. Chlorine fails the evaluations criteria for addition to the National List. It has not been shown that chlorine is essential for this use. It has not been shown that chlorine is harmless to humans and the environment.

The Cornucopia Institute recommends this petition be rejected.

Tocopherols – animals

SUMMARY

Reject the petition to add tocopherols to the National List at §205.611 Synthetic substances allowed for use in organic aquatic animal production. This petition specifically requests the listing of synthetic tocopherols.

The full text of the listing motion as stated in the proposal is:

> *"Move to list tocopherols on section 205.611 of the National List for use in aquatic livestock production with the following annotation: Tocopherols derived from vegetable oils, not extracted using volatile synthetic solvents, are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative."*

Rationale:

- Organic regulations for aquatic animals have not yet been established.
- Synthetic materials for aquaculture should have a firm expiration date.
- Petitioned use is for a preservative, not a vitamin.
- Synthetic tocopherols are not consistent with organic agriculture.
- Synthetic tocopherols are not essential.

DISCUSSION

Tocopherols are antioxidants that are currently added to commercial fish feed to delay rancidity in fats. Tocopherols are found in many types of plants, in several forms, collectively known as mixed tocopherols. Although there are natural forms of tocopherols found in plants, this petition requests the listing of synthetic tocopherols. Mixed tocopherols are a source of vitamin E.

The proposal, as modified for the Spring 2014 meeting, includes the suggestion for an annotation that sets a five-year expiration date on the listing. The expiration date is needed to address changes in the sunset process.

Organic regulations for aquatic animals have not yet been established

Organic agriculture is a production system that responds to site-specific conditions and promotes ecological balance. The raising of livestock, primarily fish but also aquatic invertebrates, is fundamentally different from the raising of terrestrial livestock. From an organic standpoint, it is essential to take these differences into account when

considering both the regulations and any possible additions of synthetic materials to the National List. The fact that organic regulations have not yet been developed and approved by both the NOP and the NOSB indicates that these differences have not been fully resolved. The first order of business must be the discussion of organic regulations. Until then, it is not possible to verify that tocopherols are harmless to the environment.

The proposal indicates that tocopherols should be reviewed after the regulations for organic aquaculture have been established. The proposal states:

> *"Since, at the time of this checklist there are no rules or policy standards for aquaculture, we believe that once the definitions for closed and open systems in organic aquaculture are defined, this material should be reviewed with an eye to whether it is appropriate for both open and closed systems."*

Since the material should be reviewed after the regulations are in effect, there is no need to review it before regulations are in effect.

Synthetic materials for aquaculture should have a firm expiration date

Cornucopia urges the NOSB to reject this petition, or at least table it until regulations for aquaculture are in place, so that the need for synthetic materials can be evaluated. If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

To ensure a full evaluation, **Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing**. Although this suggestion is placed at the end of the document and it is titled a minority opinion, we believe that the suggestion represents the majority opinion in the organic community.

Petitioned use is for a preservative, not a vitamin

The National List §205.603 allows synthetic vitamins to be used for enrichment or fortification of livestock feed. Tocopherols, being a source of vitamin E, would be allowed to fortify feed with additional needed vitamin E. However, this is **not** the petitioned use of synthetic tocopherols for aquatic livestock.

This petition requests tocopherols as antioxidants to prevent rancidity of the fish oils in feed. The petition states:

> *"Tocopherols are used as a preservative to delay the onset of rancidity in fats and oils, and thereby to extend shelf life."*[51]

[51] ICF International. 2013. Technical Evaluation Report for Tocopherols (Aquaculture – Aquatic Animals).

The tocopherols in this case are not used for enrichment. The petition states that the fish need fish oils and omega-3 fatty acids, but does not state that the fish need additional tocopherols. The tocopherols act as antioxidants, to prevent the other fats from oxidizing (turning rancid).

Synthetic tocopherols are not consistent with organic agriculture

The original proposal for the Fall 2013 Board meeting acknowledged that synthetic tocopherols are not consistent with organic farming and sustainable agriculture. In the checklist, category 3, questions 1 and 2 were checked both *yes* and *no*. The checklist, category 3 question 1, stated that the petitioned use of tocopherols, as a preservative, is not consistent with the current use of vitamins in organic livestock. Tocopherols are "*restricted to use for enrichment or fortification when FDA approved*". They are not allowed to be used as synthetic preservatives in organic livestock feed. **This wording was removed from the current proposal for Spring 2014, with no explanation given. We believe it is still valid.**

The proposal states:

> *"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****."* [emphasis added]

Since this petitioned use is for tocopherols as antioxidants, the above statement is a valid reason why they should not be permitted for organic aquaculture.

Even under conditions where tocopherols are permitted, international organic standards require that they be obtained from natural sources. The TR lines 202–257 reference several international organic standards, all of which require natural antioxidants, not the synthetic tocopherols petitioned here. Canadian regulations for organic livestock feed permit antioxidants from non-synthetic sources only. CODEX allows only antioxidants from natural sources in organic livestock feed. EEC regulations permit only tocopherol-rich extracts of natural origin to be used in livestock feed. Japan permits feed additives only if they are natural substances or derived from natural substances without being chemically treated. IFOAM prohibits the use of preservatives in the diet of organic livestock.[52]

The petition provides additional information. The Canadian Standards allow antioxidants from non-synthetic sources only. Naturland (Germany) allows natural antioxidants. Soil Association (UK) allows antioxidants of natural origin.[53]

Synthetic tocopherols are not essential

[52] ICF International. 2013. Technical Evaluation Report for Tocopherols (Aquaculture – Aquatic Animals).
[53] Lockwood, G. 2012. Petition for Listing: Tocopherols for Aquatic Animals. Page 7.

The petition states that tocopherols are needed to prevent rancidity of fish oils in fish feed. Although carnivorous fish will require those fish oils, we question whether herbivorous fish and other aquatic invertebrates require fish oils preserved with tocopherols. If antioxidants are needed, natural alternatives are available.

Citric acid and rosemary have both been found to be effective antioxidants in fish feed. After testing a rosemary extract, citric acid, and a citric acid/tocopherols mix as possible preservatives for fish feed, scientists concluded that fish feed may be protected with these natural antioxidants.[54] An extract of rosemary, Herbalox®, is commercially available.

Other antioxidants are also available. The TR, in lines 575–576, states: *"Many other substances have shown promise in laboratory studies as possible natural replacements for synthetic antioxidants used to preserve fish oil and fishmeal."*

The TR then lists the following natural antioxidants: boldine (extract from the boldo tree), hard winter wheat extracts, red algal extracts, grape seed extracts, raspberry seed extracts, green tea extracts, oregano, brown seaweed extracts, *Salvia* extracts, and tannic acid.[55]

Regarding the many natural replacements for synthetic antioxidants to preserve fish meal, the TR states, "*no evidence was found of their use in commercial aquaculture*." This is an opportunity for organic aquaculture to differentiate itself from conventional aquaculture. Conventional systems feed synthetic materials because they are less expensive. Organic systems should rely on natural preservatives for fish feed.

The analysis by the Livestock Subcommittee also indicates that synthetic tocopherols are not essential. Under category 2 (*Is the substance essential for organic production?*), the subcommittee responded as follows:

Q6. Is there an organic substitute? YES
Q7. Is there a wholly natural substitute product? YES
Q8. Are there any alternative substances? YES
Q9. Are there other practices that would make the substance unnecessary? YES

CONCLUSION

There are numerous reasons to reject the petition for tocopherols in organic aquaculture.

[54] Hamre, K., Kolas, K., Sandnes, K. 2010. Protection of fish feed, made directly from marine raw materials, with natural antioxidants. *Food Chemistry* 119: 270-278.
[55] ICF International. 2013. Technical Evaluation Report for Tocopherols (Aquaculture – Aquatic Animals).

In general, aquaculture materials should not be placed on the National List because the organic regulations for aquatic livestock have not yet been developed, and the public has been given no indication that the NOSB recommendations will be followed. It is impossible to evaluate the impact of tocopherols on the environment, especially when used in natural waterbodies.

Synthetic tocopherols, in particular, should not be used in aquaculture systems. The petitioned use of tocopherols is as a preservative, to allow shipping and storage of fish feed that contains fish oils and other fats. Synthetic tocopherols are not consistent with organic agriculture. Many organic certifiers allow natural antioxidants, but they do not allow synthetic tocopherols to be used as antioxidants in organic livestock feed. Synthetic tocopherols are not essential, as there are many sources of natural antioxidants.

If there are any reservations in any Board member's mind about the need for tocopherols, it is essential to vote "no" on this petition. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board.

If the motion is passed, we encourage the Board to include the annotation to ensure a complete review in five years.

Trace Minerals – animals

SUMMARY

Reject the petition to add trace minerals to the National List at §205.611 Synthetic substances allowed for use in organic aquatic animal production.

Rationale:

- Organic regulations for aquatic animals have not yet been developed.
- This petition is too broad.
- Addition of minerals may harm aquatic ecosystems.
- Ethanediamine dihydroiodide is not essential.
- International organic standards require natural sources of minerals.
- Synthetic materials for aquaculture should have a firm expiration date.

DISCUSSION

The petition asks the NOSB to allow trace minerals as feed ingredients for aquatic animals. Although a partial list of 11 minerals is provided in the petition, the request is for the allowance of any mineral, including those not listed in the petition.

More importantly, the petition does not define the term "trace" mineral. At least one of the listed minerals, sodium chloride (common table salt), cannot be considered a trace mineral.

The proposal, as modified for the Spring 2014 meeting, includes the suggestion for an annotation that sets a five-year expiration date on the listing. In order to ensure that the tocopherols are subject to a full review, a five-year expiration date must be added to this motion.

Organic regulations for aquatic animals have not yet been established

The raising of aquatic animals is fundamentally different from the raising of terrestrial animals. From an organic standpoint, it is essential to take these differences into account when considering additions of synthetic materials to the National List.

No regulations have been established by the NOP for aquatic animal or plant production. The first order of business, before petitions are approved, must be the establishment of organic regulations. This, alone, is reason enough to vote against any materials petitioned for use in aquaculture. Since federal organic regulations have not yet been established by NOP, it is difficult to evaluate the effects of large quantities of synthetic materials on aquatic ecosystems.

Even if regulations were established, there are several reasons to reject the wholesale approval of minerals in feed.

This petition is too broad

This petition does not provide a complete list of the materials being petitioned for use in aquatic production. This makes it impossible to evaluate the materials. For example, in order for the NOSB to approve the addition of a synthetic substance to the National List, it must be essential. To determine if a substance is essential, the NOSB must know exactly what that substance is. In this case, a complete list of minerals to be added to animal feed is not available; therefore, the NOSB cannot determine if they are essential.

The petition requests that trace minerals be allowed in organic production, but does not even provide a definition for the term "trace minerals." The petition provides examples of macrominerals and microminerals, but does not provide a working definition of those terms. Without a definition of what constitutes a "trace" mineral, we assume that the petition is for the use of any mineral.

Ethanediamine dihydroiodide is not essential

The petition includes ethanediamine dihydroiodide in its list of trace minerals. There is no evidence that this is essential, as it is not even mentioned in the TR. We assume it is intended as a source of iodine. If so, there are other, more natural sources, including potassium iodide and seaweeds, as mentioned in the TR.[56]

Although it is apparent in this case that a synthetic mineral is being used where alternatives exist, there are likely other instances where this will occur if this petition is approved. A wholesale approval of synthetic materials provides no incentive for organic producers to seek natural alternatives.

International organic standards require natural sources of minerals

Although the proposal states that "*[a]ll the major standards for … organic aquaculture allow the use of synthetic minerals*," that is not quite accurate. The standards require natural minerals, unless they are not available.

According to the TR, regulations for aquaculture are as follows:[57]

- Canadian General Standards Board – "synthetic nutrient minerals may be used if non-synthetic sources are not commercially available." (lines 468–469)
- EEC – "feed of mineral origin, trace minerals, vitamins or provitamins shall be of natural origin." (line 488) If these are unavailable, analogous "chemically well-defined" substances may be used. The regulations list the compounds that may be used to supply specific trace elements.
- United Kingdom Soil Association – "mineral diets of natural origin must be used in the diets of farmed fish." (lines 509–510) Supplements not of natural origin may be used only with prior approval.

Regulations for terrestrial livestock, by an organization that does not have aquaculture standards:

- Codex Alimentarius – "trace minerals … can only be used if they are of natural origin." (line 482)

From the above regulations, it appears that use of synthetic minerals should only be allowed after the petitioner requests use of a specific mineral, and provides evidence that a natural form is not available. This petition should be rejected until it is demonstrated that natural minerals are not available.

Natural sources of minerals are available

[56] Pesticide Research Institute. 2013. Trace Minerals (Aquaculture – Aquatic Animals) Technical Evaluation Report. Pages 1, 23.
[57] Pesticide Research Institute. 2013. Trace Minerals (Aquaculture – Aquatic Animals) Technical Evaluation Report.

The petition does not provide adequate evidence that synthetic forms of minerals are essential. The petition states "*[t]race minerals are essential nutrients for all forms of animal life*…."[58] While this statement is true, it does not relate to the petitioned use. The petitioner requests the approval to use **synthetic** trace minerals. Many wild fish (and other animals) survive and thrive without synthetic minerals, because they obtain minerals from the foods they eat. Clearly minerals in a synthetic form are not essential.

The TR lists many natural foods that are sources of trace minerals. Some sources are foods that might normally be found in the diet of a wild fish: kelp, fish, crustaceans (shrimp, crab), and seaweed. Other sources are commonly available products: yeast, molasses, rice, alfalfa, wheat germ, rye grain, sesame seeds, safflower seeds, cottonseed meal, milk, whey, and many others.[59]

The petition states "*there are no known natural alternatives for trace minerals in aquaculture systems*…."[60] Clearly there are natural alternatives. Wild fish survive without synthetic minerals. The TR devotes a full page to listing natural alternatives available in food. Providing minerals through synthetic additives, rather than through food, is not consistent with organic principles. Feed ingredients—not synthetic additives—should provide a well-balanced diet.

Unfortunately, the Livestock Subcommittee changed the answers to questions 5 and 6, category 2, regarding natural and organic substitutes for minerals. Initially, they acknowledged that natural sources exist, as explained in the above paragraph, but the revised checklist ignores these natural sources.

Addition of minerals may harm aquatic ecosystems

This petition does not offer a limit on the concentrations of these trace minerals to be added to feed. Unlimited addition of minerals to fish feed would undoubtedly increase the concentrations in the water, through uneaten food and feces.

One of the minerals listed in the TR is tricalcium phosphate. Although this may be added to feed as a source of calcium, it would also add phosphates to the aquatic environment.

The role of phosphates in causing harm to the aquatic environment has long been known.[61] Adding nutrients, especially nitrogen and phosphorous, to aquatic systems can result in growth of algae, which then die and decompose, leading to anaerobic conditions and death of fish, a process known as eutrophication. More recent evidence indicates that the harmful effects in marine environments can be widespread. Sera, et al.

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[58] Lockwood, G. 2012. Petition for Listing: Trace Minerals for Aquatic Animals. Page 7.
[59] Pesticide Research Institute. 2013. Trace Minerals (Aquaculture – Aquatic Animals) Technical Evaluation Report. Page 23.
[60] Lockwood, G. 2012. Petition for Listing: Trace Minerals for Aquatic Animals. Page 7.
[61] NAS (National Academy of Sciences). 1969. *Eutrophication: causes, consequences, correctives; proceedings of a* 1289 *symposium*. The National Academies Press, Washington, D.C. Retrieved September 25, 2013 from http://books.google.com/books/about/Eutrophication.html?id=wjsrAAAAYAAJ

[62] studied the nitrogen and phosphorous added to the Mediterranean Sea due to aquaculture. They concluded:

> *"This paper demonstrates for the first time ever that off-shore aquaculture may affect the marine ecosystem well beyond the local scale…."*

The TR provides more in-depth explanation: [63]

> *"Excessive amounts of artificial or natural nutrients in aquatic systems may lead to damaging eutrophication. Phosphates … are particularly potent initiators of eutrophication…and trace elements may also contribute to eutrophication and the explosive growth of algal species."*

The original proposal acknowledged the possibility of environmental damage by checking YES in category 1, questions 1, 2 and 5. **This is changed in the current proposal;** however, we believe the original version is more balanced.

Synthetic materials for aquaculture should have a firm expiration date

Cornucopia urges the NOSB to reject this petition, or at least table it until regulations for aquaculture are in place, so that the need for synthetic materials can be evaluated. If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

To ensure a full evaluation, Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing.

CONCLUSION

This petition requests the use of a large class of synthetic materials. Although some materials may eventually be approved, it is important to reject this petition because it does not fully include all the synthetic minerals that may be used if a wholesale approval is given.

This petition includes minerals that are not essential and minerals that can easily be obtained through natural feed sources. These minerals have potential to harm the aquatic ecosystem. Although minerals are essential, minerals in a synthetic form are not consistent with organic principles. Several international certifiers require natural sources of minerals. They do allow synthetic forms of some minerals, but only after it is demonstrated that natural forms are not available.

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[62] Sarà, G, Lo Martire., M, Sanfilippo., M, Pulicanò, G., Cortese, G., Mazzola, A., Manganaro, A., Pusceddu, A. 2011. Impacts of marine aquaculture at large spatial scales: evidences from n and p catchment loading and phytoplankton biomass, Marine Environmental Research, doi: 10.1016/j.marenvres.2011.02.007

[63] Pesticide Research Institute. 2013. Trace Minerals (Aquaculture – Aquatic Animals) Technical Evaluation Report.

Even if there were no reservations about synthetic minerals, it is premature at this time to vote on the use of synthetic materials for aquaculture, because the organic regulations have not yet been developed for aquatic animals.

If this reasoning leads to reservations about the need for synthetic minerals, it is essential to vote "no" on this petition. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. It is imperative that Board members follow the precautionary principle: reject materials until there is abundant evidence to prove their safety.

Please reject this petition.

Vitamins – animals

SUMMARY

Reject the petition to add vitamins to the National List at §205.611 Synthetic substances allowed for use in organic aquatic animal production.

Rationale:

- Organic regulations for aquatic animals have not been established.
- This petition is too broad. The petitioner wants to allow any vitamin, including vitamins that are not even listed in the petition.
- Synthetic vitamins are not essential for fish.
- Natural sources of vitamins are available.
- Addition of nutrients may harm aquatic ecosystems.
- Manufacturing processes are confidential.
- Synthetic materials for aquaculture should have a firm expiration date.

DISCUSSION

This petition requests that synthetic vitamins be allowed for organic aquatic animal production. The petition specifically lists 13 vitamins, but the request is not limited to that list. The petitioner wishes to be allowed to add any synthetic vitamin, purchased from any manufacturer, to organic feed. Manufacturing processes for these synthetic ingredients are proprietary. Approving these vitamins wholesale is analogous to approving a material that contains confidential business information in the petition. There is no mechanism for the Board to fulfil its obligation to carefully review the material.

The proposal from the Livestock Subcommittee included for this meeting states that there are minor formatting revisions only but in actuality there are some rather major revisions.

First, the listing motion has changed slightly: Motion to list vitamins as listed above at §205.611 of the National List. The motion needs to be clarified as to whether it included all vitamins, as the petitioner requested, or only the vitamins specifically listed in the classification motion.

Second, the proposal claims that vitamins used in fish production will not pose environmental harm, despite the ample evidence that addition of nutrients does cause harm to aquatic systems.

Third, the check boxes and the wording were changed under the NOSB evaluation criteria. In category 1, questions 1, 2, 5, and 6 are checked both YES and NO in the original proposal for the Fall 2013 meeting, but only the NO boxes are checked in the proposal for this meeting, suggesting that vitamins for aquatic animals have no adverse impacts to humans or the environment. In reality vitamins in aquatic production do have the potential to harm the environment, by adding nutrients. In category 2, question 9, the original proposal checked boxes YES and NO, but the current proposal only checks box NO. This suggests that there are no alternatives to feeding synthetic vitamins to fish, which is false. Many alternatives sources of whole foods are available to provide vitamins to fish.

In terrestrial systems, under §205.603 (d) (3), vitamins are allowed for livestock feed. This petition is for the use of vitamins in **aquatic** systems, which are fundamentally different from **terrestrial** systems.

Adding nutrients to terrestrial systems may provide a benefit in terms of enhanced plant growth, whereas adding nutrients in aquatic systems can result in excessive plant growth, followed by plant death and decay. The results are anaerobic conditions and environmental degradation.

Organic regulations for aquatic animals have not yet been established

Organic agriculture is a production system that responds to site-specific conditions and promotes ecological balance. The raising of livestock, primarily fish but also aquatic invertebrates, is fundamentally different from the raising of terrestrial livestock. From an organic standpoint, it is essential to take these differences into account when considering both the regulations and any possible additions of synthetic materials to the National List. The fact that organic regulations have not yet been developed and approved by both the NOP and the NOSB indicates that these differences have not been fully resolved. The first order of business must be the discussion of organic regulations.

Even after USDA NOP regulations have been established, there are several reasons to reject this petition for synthetic vitamins.

This petition is too broad

In order for the NOSB to approve the addition of a synthetic substance to the National List, it must be essential. To determine if a substance is essential, the NOSB must know exactly what that substance is. In this case, we do not know what vitamins will be added to animal feed, therefore we cannot determine if they are essential. The petitioner wants to allow any vitamin, including vitamins that are not even listed in the petition.

Synthetic vitamins are not essential

The petition states "*[v]itamins are essential nutrients for all forms of animal life*…."[64] While this statement is true, it does not relate to the petitioned use. The petitioner requests the approval to use **synthetic** vitamins. Many wild fish (and other animals) survive and thrive without synthetic vitamins, because they obtain naturally occurring vitamins from the foods they eat. Clearly, vitamins in a synthetic form are not essential.

Judging from the specific vitamins listed in the petition, there are at least 13 vitamins, and probably more, that will be deficient in the diets of farmed fish. The petition states "*feed ingredients used in animal and/or fish feeds do not contain sufficient levels of vitamins to supply their dietary requirements*…."[65]

It appears that the aquaculture industry intends to provide nutritionally deficient feed for farmed fish, and compensate for the inadequacy with the addition of synthetic vitamins. Providing vitamins through synthetic additives, rather than through food, is common in conventional aquaculture, but it is not consistent with organic principles. Feed ingredients—not vitamins—should provide a well-balanced diet. There is evidence that plant foods are not well digested by carnivorous fish. Soy foods, in particular, are not easily digestible for fish, and can cause fish to produce excess waste.[66]

Natural sources of vitamins are available

Natural sources of vitamins are abundant in whole foods, such as: eggs, meat, brewer's yeast, whole grains (wheat, rice), seeds (peanuts, safflower seeds, sunflower seeds), milk, alfalfa, fruits (citrus, berries), and vegetables (peppers, leafy greens, cabbage).[67] The TR devotes a full page to a detailed listing of the natural sources of vitamins, and many of these sources are available in organic form. If organic regulations require natural sources of vitamins, it will provide incentive to develop fish feeds based on whole foods. This would also provide incentive to search for additional vitamin sources, such as kelp and spirulina, which are already available as ingredients for aquarium fish foods.

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[64] Lockwood, G. 2012. Petition (Revised) for Listing: Vitamins for Aquatic Animals. Page 5.
[65] Lockwood, G. 2012. Petition (Revised) for Listing: Vitamins for Aquatic Animals. Page 5.
[66] Food and Water Watch. 2012. Factory-Fed Fish: How the soy industry is expanding into the sea. 18 pp.
[67] Pesticide Research Institute. 2013. Vitamins (Aquaculture – Aquatic Animals) Technical Evaluation Report

Addition of nutrients may harm aquatic ecosystems

At first glance, providing vitamins to aquatic animals may appear to be similar to providing vitamins to terrestrial animals. In actuality, the ecosystems are fundamentally different. Organic principles specify that the differences of unique ecosystems must be carefully considered. Organic production practices "must maintain or improve the natural resources of the operation, including soil and water quality."[68]

Although addition of vitamins is intended for consumption by fish, the vitamins will also find their way into the environment through uneaten fish food and through the feces of farmed fish. This increases nutrient levels of the aquatic ecosystems, particularly when fish are confined at high stocking densities in open-net pens in natural waterbodies.

Adding nutrients to terrestrial systems may provide a benefit in terms of enhanced plant growth, because animal manures act as plant fertilizers. In contrast, adding nutrients to aquatic systems can result in growth of algae, which then die and decompose, leading to anaerobic conditions and death of fish and other aquatic organisms.

The TR, in lines 1075–1079, explains this phenomenon:

> *"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."*[69]

The proposal notes that the TR states that risks of environmental contamination ("large-scale eutrophication") are low. The reference supplied for this statement was written in 1995. Certainly much has been published on the effects of marine aquaculture in the past 18 years! We provide some recent references that indicate the threats of environmental contamination.

Food and Water Watch, in a report on the open ocean fish farming industry,[70] concluded: "*evidence indicates that offshore fish farms … will threaten the marine environment in a variety of ways.*" One of the most important results will be the production of large amounts of nitrogenous waste (feces) that is released into the ocean.

[68] USDA NOP Organic Regulations. Subpart C - Organic Production and Handling Requirements. §205.200 General.
[69] Pesticide Research Institute. 2013. Vitamins (Aquaculture – Aquatic Animals) Technical Evaluation Report
[70] Food and Water Watch, 2011. *Fishy Farms, The Government's Push for Factory Farming in our Oceans*. 24 pp. Downloaded on Aug. 27, 2013 from http://www.foodandwaterwatch.org/reports/fishy-farms/

Studies have shown that the uneaten feed and fish wastes cause nutrient loading that can be significant on a local scale. Changes in benthic communities (the ocean floor) can occur even at low stocking rates for salmon.[71]

Sera, et al. [72] studied the nitrogen and phosphorous added to the Mediterranean Sea due to aquaculture. They concluded:

> *"This paper demonstrates for the first time ever that off-shore aquaculture may affect the marine ecosystem well beyond the local scale and provides an additional element of concern to be kept into consideration when allocating oceans' space for new fish farming activities."*

The petition states that vitamins released into the environment will have a positive impact.[73] No scientific references are provided to substantiate this claim. We request that the NOSB ignore this statement, because abundant scientific evidence is available to refute it.

Manufacturing processes are confidential

The petition specifically states on page 2, "Manufacturing processes are proprietary."[74] With no information as to the proprietary manufacturing process, it is impossible to determine whether a particular vitamin is being produced with the use of genetically modified organisms. Many vitamins are currently produced through industrial fermentation methods, often by GMOs. Certainly we can expect this trend to continue in the future, but the proposal does not specifically address the issue of vitamins made by GMOs.

It is also impossible to assess the possibility of environmental contamination, both from the manufacturing process and from ingredients in the final vitamin formulations. The TR line 945 states, "The potential exists for environmental contamination resulting from the industrial production of several vitamin compounds." This is noted in the proposal, but the subcommittee argues that no specific examples are given. Specific examples are not given because manufacturing processes for the vitamins are proprietary—they are not available in the petition.

We can assume that manufacture of synthetic vitamins will have adverse impacts on the environment but we cannot determine what those impacts will be, because the petition has confidential business information. Since most vitamins are currently manufactured

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[71] Naylor, Rosamond and Marshall Burke. 2005 "/Aquaculture and Ocean Resources: Raising tigers of the sea. *Annual Review of Environmental Resources,* vol. 30:185-201.
[72] Sarà, G, Lo Martire., M, Sanfilippo., M, Pulicanò, G., Cortese, G., Mazzola, A., Manganaro, A., Pusceddu, A. 2011. Impacts of marine aquaculture at large spatial scales: evidences from n and p catchment loading and phytoplankton biomass, Marine Environmental Research, doi: 10.1016/j.marenvres.2011.02.007
[73] Lockwood, G. 2012. Petition (Revised) for Listing: Vitamins for Aquatic Animals. Page 3.
[74] Lockwood, G. 2012. Petition (Revised) for Listing: Vitamins for Aquatic Animals. Page 3.

through chemical synthesis, it is likely that residues of those chemicals will appear in the vitamin formulations.

Synthetic materials for aquaculture should have a firm expiration date

Cornucopia urges the NOSB to reject this petition, or at least table it until regulations for aquaculture are in place, so that the need for synthetic materials can be evaluated. If Board members have any reservations about the use of a petitioned material, or their subsequent ability to rigorously review materials at sunset, we urge them to vote against any additions to the National List at this time.

If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years. To ensure a full evaluation, **Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing**.

CONCLUSION

This petition requests the use of a large class of synthetic materials that are not essential and have potential to harm the aquatic ecosystem.

Even if this material were benign, it is premature at this time to vote on the use of synthetic materials for aquaculture, because the organic regulations have not yet been developed for aquatic animals.

If this reasoning leads to reservations about the need for synthetic vitamins, it is essential to vote "no" on this petition. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. It is imperative that Board members follow the precautionary principle: reject materials until there is abundant evidence to prove their safety.

Please reject this petition.

Vaccines – animals

SUMMARY

Reject the petition to add vaccines in aquatic animal production to the National List at §205.611: Synthetic substances allowed for use in organic aquatic animal production. The listing motion is:

Motion to list Biologics: Vaccines for Aquatic Animals at §205.611 with the following annotation: except those produced with excluded methods.

Rationale:

- Organic regulations for aquatic animals have not yet been established.
- Modified live vaccines are capable of infecting other aquatic organisms and wild fish.
- Many **toxic chemicals are used in producing fish vaccines**, such as formaldehyde and oil-based adjuvates, which are still present in small quantities in the final vaccine and are not approved on the National List.
- The method of vaccine administration can injure or cause disease in some fish.
- **Many vaccines are produced using excluded methods** such as genetic engineering and the final products are not always clearly labeled as such.
- Aquaculture **increases disease pressure on wild aquatic organisms** and may not be compatible with the principles of organics.
- New NOP sunset process may prevent future reviews by the full Board.

DISCUSSION

At the present time, organic livestock producers are allowed to use vaccines as provided in §205.603(a)(4) Biologics-vaccines. However, vaccines made with excluded methods (genetically engineered) are prohibited as provided in §205.105(e). Nevertheless, 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.

On 6/12/2012 the Aquaculture Working Group submitted a petition requesting that vaccines, including those made with excluded methods, be added to the National List at §205.611 for use in aquatic animal production. The Livestock Subcommittee then motioned to list vaccines for aquatic animals in their meeting on 2/18/2014, except those vaccines produced with excluded methods. However, there is a minority opinion that should be heard, asking for an annotation to the motion of "Until May 1, 2019 (or sunset date)" due to some of the concerns around vaccines described in more detail below.

Organic regulations for aquatic animals have not yet been established

Organic agriculture is a production system that responds to site-specific conditions and promotes ecological balance. The raising of aquatic animals, primarily fish but also aquatic invertebrates like bivalves and crustaceans, is fundamentally different from the raising of terrestrial livestock. From an organic standpoint, it is essential to take these differences into account when considering both the regulations and any possible additions of synthetic materials to the National List. The fact that organic regulations have not yet been adopted by the NOP indicates that these differences have not been

fully resolved. The first order of business must be the discussion of organic regulations for aquaculture. Despite the NOSB recommendations to develop aquaculture standards—voted on in 2007, 2008, and 2009—the NOP has yet to develop standards.

Instead of voting on what organic and synthetic materials should be added to the National List, we should be developing and approving the standards for the rapidly growing aquaculture industry. Otherwise we run the risk of allowing an input-substitution model of aquaculture farming to develop that looks nearly identical to conventional aquaculture—not the ecologically based management system that people expect from organics.

Vaccines could be harmful to the native aquatic species

Even though modified live vaccines are more desirable and effective than inactivated vaccines in closed aquaculture systems, their potential to cause viral infections in non-target species is documented in open systems.[75] Indeed, because farmed fish are not usually kept in isolation from their wild counterparts, the use of live modified or attenuated products has not been approved in UK aquaculture.[76] However the Aquaculture Working Group petition makes no distinction around live vaccines being used in open environments, and yet this practice is banned in the UK. Potential transmission of viruses to non-target and wild aquatic animals is possible in open systems and in the waste-water of closed systems and is therefore environmentally risky.

Vaccines may contain chemicals not on the National List

Formaldehyde is the most widely used agent for inactivating viral, bacterial, and parasitic pathogens. Additionally, adjuvants are added to help the vaccine persist for a longer time within the body cavity of the fish to increase the duration of the vaccine's protection. Adjuvants are produced from a wide range of synthetic substances, such as oil-water emulsions and aluminum compounds. None of these materials are approved on the National List and yet they may be present in small quantities in the vaccine itself.

Vaccine administration may cause injury or disease to the fish

Although vaccines can reduce certain diseases in aquaculture species, they can also present adverse health effects to those same animals. Injection of vaccines can result in injection site injury and surface and intra-abdominal lesions. Oil adjuvated vaccines can cause autoimmune disease in farmed salmon. Anesthetic risks are small but present a potential area for loss of fish and in addition the overall stress of the procedure can in

[75] Responsible Use of Medicines in Agriculture (RUMA). 2006. "Responsible Use of Vaccines and Vaccination in Fish Production." *National Office of Animal Health (NOAH), UK*.
[76] Responsible Use of Medicines in Agriculture (RUMA). 2006. "Responsible Use of Vaccines and Vaccination in Fish Production." *National Office of Animal Health (NOAH), UK*.

some cases trigger other diseases such as fungal infections which are opportunistic pathogens and are ubiquitous in the fresh water aquatic environment.[77]

There is no standardized labeling to tell which vaccines have been produced with excluded methods

According to the Technical Report, there are some challenges in determining whether or not a vaccine was produced using excluded methods such as genetic engineering. Therefore, even if the listing motion excludes certain vaccine production methods, it may be impossible for aquaculturists to know if the vaccine products they are using were produced using approved or excluded methods. Certifiers as well will not be able to determine if excluded methods were used in vaccine production.

"Although recent vaccine products produced with excluded methods may be named so their method of production and origin is recognizable**, it may not always be possible to differentiate them** solely upon the true name assigned by the Center for Veterinary Biologics of the USDA, Animal and Plant Health Inspection Service (CVB). CVB has recently begun updated its naming convention for vaccines containing recombinant organisms (Table 2—APHIS, 2013b). Historically, naming of recombinant vaccines has been variable and names previously assigned to vaccines containing recombinant organism may not be accurate."

Disease should be prevented through management practices, not reliance on vaccines

Disease in wild aquatic species is increasing as a result of aquaculture. Vaccines are only marginally effective in reducing disease pressure in farmed species because they wear off over time. Therefore, other management practices must be implemented that reduce the transfer of disease from farmed species to wild ones. There are still too many unanswered questions and more research is needed.

Recent research published in the journal *Veterinary Research* described the increasing spread of viral fish and shrimp diseases around the globe. The authors conclude that "…during the past century, the rise of novel forms of intensive aquaculture, increased global movement of aquatic animals and their products, and various sources of anthropogenic stress to aquatic ecosystems have led to the emergence of many new diseases in fish and shrimp."[78] For example, three rhabdoviruses- IHNV, VHS, and SVC- are spreading quickly amongst wild finfishes due to the spread of intensive aquaculture raising of similar species.[79] While vaccinating farmed fish can reduce the spread of disease between farmed fish and their wild counterparts, it is not foolproof and it masks

[77] Responsible Use of Medicines in Agriculture (RUMA). 2006. "Responsible Use of Vaccines and Vaccination in Fish Production." *National Office of Animal Health (NOAH), UK*.
[78] Walker, Peter and James Winton. 2010. "Emerging Viral Diseases of Fish and Shrimp." *Veterinary Research* 41:51.
[79] Ibid.

the underlying management problems that promote the spread of disease in the first place. Indeed, the Technical Report pointed out this issue:

"Host density plays a role in the spread of fish diseases in the environment amongst farmed and wild fish. Low host density reduces the rate of encounter between susceptible hosts and pathogen. **Increased host density will favor more rapid disease spread**. In any population, there is a density threshold where disease spread can become epizootic. Effective aquaculture increases host density. Vaccines are effective at reducing the density of susceptible hosts and their use can lead to disease eradication. However, vaccination can be imperfect and lead to virulence evolution, potentially affecting wild and farmed fish and other species." [emphasis added]

Because aquaculture increases the density of species beyond what would occur in nature to the point where disease can become epizootic, should we be masking that problem with intensive vaccination programs? That practice would be akin to masking livestock disease transmission through the use of aggressive antibiotic programs. While it is true that vaccines are allowed in organic livestock and poultry production, that practice is more for the protection of those animals from disease and less so about preventing the spread of those diseases to wild animals. In farmed aquatic organisms, vaccination is also about preventing disease amongst individuals but it is also to contain those diseases from spreading to wild stocks.

Due to the precarious population of the majority of the world's fisheries, we need stronger protections to prevent disease transmission. Vaccination programs are ineffective alone— they must be combined with a strong set of management practices such as closed systems, appropriate stocking densities, and proper waste-water disposal. We need to go back to the foundation of aquaculture to see if it is compatible with the organic philosophy and understand whether or not the stocking densities utilized in commercial aquaculture will work with an organic approach. Approving medical crutches such as vaccines before we develop a system for aquaculture is shortsighted and will hinder the development of a system based on ecological methods.

New NOP sunset process may prevent future reviews by the full Board

Cornucopia urges the NOSB to reject this petition. If vaccines are reviewed and voted on at this time, Board members must consider what may happen in the future. Due to the NOP's recent changes in the sunset process, we are concerned that vaccines, if approved at this meeting, will never again be subject to a full rigorous review, and a vote by the full Board.

Cornucopia agrees with the suggestion for an annotation that sets a five-year expiration date on the listing. Although this suggestion was placed at the end of the document, and it was titled a minority opinion, we believe that the suggestion would represent a majority opinion within the organic community.

CONCLUSION

It is imprudent to approve the use of synthetic materials such as vaccines in organic aquaculture until **after** the organic standards are available.

The publication of the new sunset process provides ample reason to avoid adding any new materials to the National List. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board.

The Cornucopia Institute recommends this petition be **rejected**.

Micronutrients – plants

SUMMARY

Reject the petition to add micronutrients to the National List at §205.609, Synthetic substances allowed for use in organic aquatic plant production.

The listing motion is:

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

Rationale:

- Organic regulations for aquatic plants have not yet been established.
- This petition is too broad.
- Natural sources of micronutrients are available.
- Addition of micronutrients may harm aquatic ecosystems.
- Manufacturing processes of micronutrients are proprietary and have been withheld from scrutiny by the NOSB.
- The Technical Report is not adequate to assess use of micronutrients in aquatic systems.

DISCUSSION

The petition asks the NOSB to allow micronutrients for aquatic plant production. Although a partial list of six trace elements is provided in the petition, the request is not limited to those listed in the petition.

The petition does not define the term *micronutrient*, rather the petitioner states that the term is interchangeable with the terms *trace element*, *trace metal*, and *trace mineral*.

Organic regulations for aquatic plants have not yet been established

It is essential to understand how a material will be used in its specific organic system before adding synthetic materials to the National List. The NOSB developed regulations for organic aquatic plants that required *"culture media shall be disposed of in a manner that does not adversely impact the environment*." With this regulation in place, there would be assurance that the nutrient-fortified culture water would not be released into natural ecosystems. The NOP has not yet put these recommendations into law; therefore, it is possible that these added nutrients could be introduced to aquatic ecosystems—with unknown and possibly adverse impacts.

The TR states that this proposal is based on the NOSB recommendations voted on in 2007, 2008, and 2009. We urge the NOSB to not base their evaluation of this motion on those recommendations, because there is no evidence that they will be fully accepted by the NOP. In fact, there is a strong indication that those recommendations will be ignored, as five years have passed since those recommendations were written, and no action has been taken by the NOP.

In practice, production of organic aquatic plants is already allowed. The NOP issued a policy memorandum on Production and Certification of Aquatic Plants in 2012, stating that "aquatic plants and their products may be certified under the current USDA organic regulations."

Even if the NOSB recommendations are accepted, there are several reasons to reject the wholesale approval of micronutrients for plants.

This petition is too broad

The petition requests that micronutrients be allowed in organic plant production, but it does not provide a complete list of the micronutrients that may be used, which makes it impossible to evaluate the materials. For example, in order for the NOSB to determine if a substance is essential, the NOSB must know exactly what that substance is.

The proposal attempts to remedy this situation, by providing a list of six elements that they consider micronutrients. This is a good start; however, the proposal only uses the term micronutrients, which can be very broadly interpreted. In addition, the listing of specific micronutrients in the proposal will not become part of the final regulations.

We suggest that this proposal should be sent back to the subcommittee to craft a motion that includes the specific names of every micronutrient that the industry would like to use in aquaculture systems. Then, with the specific nutrients listed, it will be possible for the organic community to evaluate essentiality, possible environmental harm, and compatibility with organic production.

Natural sources of micronutrients are available

The petition does not provide adequate evidence that **synthetic** forms of micronutrients are essential. Certainly plants need micronutrients; however, many types of aquatic plants survive and thrive by obtaining nutrients from natural sources.

The petition specifically states that a natural source of nutrients has been used in the past: aqueous extracts of soil. The purpose of the petitioned material is to replace this natural option with a mix of synthetic nutrients. That purpose is not consistent with organic principles.

Addition of minerals may harm aquatic ecosystems

This petition does not offer a limit on the total amounts of micronutrients to be used, just the concentrations. Facilities that grow a large quantity of aquatic plants would use a large quantity of nutrients, even if the concentrations were small. The petitioner claims that the added nutrients would not affect natural ecosystems, but we find this argument inconsistent. The petitioner claims that the nutrients enhance the growth of the cultivated plants, but those same nutrients do not enhance the growth of native plants in natural systems. The evidence indicates otherwise: the addition of nutrients to aquatic ecosystems will increase growth of native aquatic plants, which can harm overall ecosystem function. This effect has been seen repeatedly in algal blooms that occur when nutrients are abundant.

The extent of harm to aquatic ecosystems is hard to predict because there is no context on the ecological system. The petitioner states that these will be used in contained systems, but that restriction has not been included in the motion. There is no prohibition that prevents the nutrient-enhanced culture water from being released into rivers, lakes, or other natural waterbodies. This release would likely damage those ecosystems.

Manufacturing processes of micronutrients are proprietary

One of the fundamental factors in the evaluation of synthetic nutrients is the probability of environmental contamination during manufacturing. The proposal checklist states that there is no possibility of environmental damage, but we strongly disagree. The TR states "commercial micronutrients are generally manufactured as by-products or intermediate products of metal mining and processing industries,"[80] which suggests that there is some environmental degradation during the manufacturing process.

The petition states that "various trace minerals are obtained from sources in a number of countries, including China. Manufacturing processes are proprietary." This gives the Board no information on how to evaluate environmental damage done during manufacture. With a proprietary manufacturing process, it is not even possible to determine whether micronutrients are contaminated with harmful substances.

[80] Technical Services Branch. 2010. TDR Micronutrients - Crops. Lines 323-324."

Essentiality for aquatic systems has not been established

Micronutrients should not be allowed for aquatic plants, because the conditions under which they will be used are not compatible with organic principles. As a comparison, some micronutrients are allowed for terrestrial crops, but only under specific conditions. First, the farmer must have an approved organic system plan to build and maintain the soil, which provides natural sources of micronutrients. Second, the farmer must monitor the system, typically by soil testing, and may add only the specific micronutrients, in appropriate quantities that have been shown to offset deficiencies. These precautions ensure that addition of synthetic micronutrients is minimized.

Aquatic systems should also be based on the organic principle of obtaining nutrients from soil-based solutions, or other natural sources of fertility. Instead, aquatic systems will be based on routine use of synthetic nutrients. The proposal states, *"In aquatic plant production, micronutrients are generally added to culture media at the outset and supplemented occasionally…".* There will be no testing to determine the need for these nutrients; they will simply be added indiscriminately. This is not consistent with organic agriculture.

The Technical Report is not adequate

The TR was written for terrestrial systems, not aquatic. **The word "aquaculture" does not appear in the TR**. The word "aquatic" appears only once, in line 726, to explain that nickel in aquatic systems eventually appears in the sediment. **The question of essentiality for aquatic plants is not addressed at all**. Possible **harm to aquatic environments is not addressed**. A new TR, or at least a modified TR, is needed to address these issues in aquatic systems.

We question whether the contractors who wrote the TR have sufficient expertise. The NOSB Policy and Procedures Manual, revised in 2011, describes the Technical Advisory Panel Contract Procedures:

> *"Contractor(s) shall utilize qualified individuals or organizations who have specialized knowledge of the petitioned substances. Contractor(s) must have demonstrable expertise in organic production and handling or scientific disciplines such as veterinary medicine, chemistry, food technology, microbiology or toxicology. Contractor(s) must be familiar with the requirement for technical advisory panels described in the Organic Foods Production Act of 1990."*

This TR was prepared by the Technical Services Branch of the USDA, in 2010. Based on the TR, it appears that the contractors are not familiar with organic agriculture or the needs of the NOSB. For example, under the section *Status: International*, the preferred response would be to list the regulations of the materials according to international organic standards, including IFOAM, CODEX, EU, MAFF, Canada, etc. This was not done in the TR. None of the above words exist anywhere in the document. Instead, they discuss U.S. regulations unrelated to organic standards.

CONCLUSION

This petition requests the use of a large class of synthetic materials. Although micronutrients are essential to all growing plants, the reliance on synthetic forms of micronutrients as a routine input is not consistent with organic principles. Although some materials may eventually be approved on a case-by-case basis, it is important to reject this petition at this time because it does not specifically name all the synthetic micronutrients that may be used if the stated motion is passed.

If this reasoning leads to reservations about the need for synthetic minerals, it is essential to vote "no" on this petition. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. It is imperative that Board members follow the precautionary principle: reject materials until there is abundant evidence to prove their safety.

Please reject this petition.

Carbon Dioxide – plants

SUMMARY

Reject the motion to list carbon dioxide at §205.609 with the following annotation: for use in contained systems such as tanks and ponds.

Rationale:

- Organic regulations for aquatic plants have not yet been established.
- A technical report for use in aquatic plant production is needed.
- Carbon dioxide is not essential to control pH.
- Synthetic CO_2 as a macronutrient is not compatible with organic principles.
- An expiration date offers a compromise.

DISCUSSION

The petition asks the NOSB to allow carbon dioxide gas in the culture of aquatic plants as a nutrient and for maintaining pH (acidity), on §205.609 Synthetic substances allowed for use in organic aquatic plant production.

Although the majority of the livestock subcommittee voted in favor of this petition, the minority opinion offers valid reasons to delay the vote or reject the petition outright.

Organic regulations for aquatic plants have not yet been established

Although this proposal is based on the NOSB recommendations voted on in 2007, 2008, and 2009, the NOP has not yet put these recommendations into law. We urge the NOSB to not base their evaluation of this motion on those recommendations, because there is no evidence that they will be fully accepted by the NOP. In fact, there is a strong indication that those recommendations will be ignored, as five years have passed since those recommendations were written, and no action has been taken by the NOP.

The first priority should be to table petitions for new aquaculture materials until regulations are in effect. This will allow NOSB members to fully evaluate petitioned materials within the context of their proposed use.

A Technical Report for aquatic plant production is needed

Evaluation of carbon dioxide is based on a TR for use in processing and handling—a completely different application from aquatic plant production. Information from that TR is not applicable for this petitioned use.

Information is needed to answer questions on the essentiality of CO_2 for pH control, alternative substances available, and the environmental harm caused by CO_2 used in large quantities.

The possibility of environmental harm is particularly difficult to evaluate at this time. The use of small quantities of CO_2 in processing poses little risk to the environment, per the 1995 TR, because it will not release much CO_2 gas into the environment. The use of large quantities of CO_2 in aquaculture systems may result in significant addition of CO_2 into the atmosphere. The proposal does include an annotation for use in contained systems, however the term "contained" applies only to liquids. Carbon dioxide is a gas that will bubble through the water and be released into the atmosphere. Information is needed on the amount of CO_2 that will likely be used, and the amount that is not taken up by plants, but is released into the environment.

These questions should be addressed in a new TR, given that the 2006 TR is eight years old, or at minimum a supplemental TR.

Carbon dioxide is not essential to control pH

Although the petitioner claims that synthetic CO_2 is needed to decrease pH in water, in reality there are acids already approved for that purpose.

There are several acids that are allowed as pH adjusters for crops if used in their nonsynthetic form:

- Acetic acid
- Citric acid
- Vinegar

Other nonsynthetic acids are allowed as fertilizers:

- Fulvic acid
- Humic acids—alkali extracted

In practice, these acids are already available, because production of organic aquatic plants is already allowed (and is presumably being executed without the use of CO_2).

The NOP issued a policy memorandum on Production and Certification of Aquatic Plants in 2012, stating:

"[A]quatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use … the National List … CFR 205.601 – 205.602, as the basis for the production and certification of cultured and wild crop harvested aquatic plants."

Synthetic macronutrients are not compatible with organic principles

The petition states that "*CO_2 gas is used in the culture of aquatic plants as a nutrient …*" The application *CO_2,* as proposed, would constitute the use of a synthetic fertilizer/growth promotant in organic production.

Synthetic macronutrients are not compatible with organic principles. A synthetic substance used for organic crop production must be placed in a category defined in category 3, question 7 of the proposal. No boxes are checked in the proposal, therefor CO_2 cannot be approved.

An expiration date offers a compromise

Cornucopia urges the NOSB to table this petition until regulations for aquaculture are in place, and the need for synthetic materials can be properly evaluated. Due to the NOP's recent changes in the sunset process, we are concerned that carbon dioxide, if approved for use in aquaculture at this meeting, might never again be subject to a full rigorous review, and a vote by the full Board. If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

To ensure a full evaluation, in the future, Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing.

CONCLUSION

This petition should be rejected because the use of synthetic macronutrients (carbon) is not consistent with organic principles, and the use of carbon dioxide for pH control is not essential. In addition, dioxide has not been subject careful review with a current TR

applicable to aquaculture systems. Potential harm to the environment cannot be determined until a technical report is available to explain the use of carbon dioxide in aquaculture systems and the release of the gas into the environment.

Chlorine – plants

SUMMARY

Reject the petition to add chlorine materials to the National List at §205.609 *Synthetic substances allowed for use in organic aquatic plant production*. The listing motion is:

> *"Motion to list chlorine materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) to §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 disinfecting limit under the Safe Drinking Water Act."*

Rationale:

- Organic regulations for aquatic plants have not yet been developed.
- A TR that is relevant for aquatic systems is needed.
- Alternative materials are available.
- Chlorine is not essential for the growth of aquatic plants.
- Chlorine is harmful to humans.
- Chlorine materials are harmful to the environment.
- Synthetic materials for aquaculture should have a firm expiration date.

DISCUSSION

Currently, chlorine is on the National List as a synthetic material allowed for organic crops, livestock, and handling, as a disinfectant for hard surfaces. This petition for aquatic plants also includes the addition of chlorine to the culture water in which the plants are grown, a fundamentally different application. The motion explicitly mentions only the use of chlorine on hard surfaces; however, the stated intention in aquaculture is to use the chlorine to disinfect culture water.

The NOP has clarified the use of chlorine; however, that clarification is in the form of a guidance document.[81] As such, it is not part of the regulations, and is subject to change at the whim of current or future administrations at the USDA. It is essential that the NOSB clearly state the annotations needed for chlorine use in water.

[81] NOP 5026. 2011. Guidance: The Use of Chlorine Materials in Organic Production and Handling.

Cornucopia agrees with the suggestion for an annotation that sets a five-year expiration date on the listing. Although this suggestion was placed at the end of the document, and it was titled a minority opinion, we believe that the suggestion would represent a majority opinion within the organic community.

The expiration date is needed to address changes in the sunset process. When chlorine was first added to the National List, a robust sunset process was in place. This ensured that the Board would conduct a thorough review of the chlorine materials every five years, and that the entire Board, all 15 members, would be required to vote on whether the materials should be retained. This widely respected system is no longer in place. In order to ensure that the chlorine materials are subject to a full review, a five-year expiration date is essential.

Organic regulations for aquatic plants have not yet been established

No regulations have been established for aquatic animal or plant production. The first order of business, before petitions are approved, must be the establishment of organic regulations. This, alone, is reason enough to vote against any materials petitioned for use in aquaculture.

The proposal states that it is based on NOSB recommendations of standards voted in 2007, 2008 and 2009. The fact that NOSB recommendations have not yet been approved, five years after they were developed, suggests that there will be significant differences between the NOSB recommendations and the final NOP regulations. When considering whether to approve petitioned materials for aquaculture the board needs to consider their original recommendations may be ignored or even directly contradicted.

In the past the NOP has directly contradicted Board recommendation. For example, in 2010 the Board passed a recommendation that hydroponic systems are prohibited for organic production. However, the current statement recently put on the NOP website specifically states that hydroponic production is allowed—in direct contradiction to the NOSB recommendations.

Two different uses for chlorine materials have been petitioned

The petitioner requested the use of chlorine as a disinfectant for both hard surfaces, which is analogous to current organic regulations for crops. Currently, crop producers may use chlorine for "disinfecting and sanitizing facilities and equipment." Typically, chlorine used in crop production is for the purpose of disinfecting irrigation lines.

The petitioner also requested the use of chlorine to be added to culture water, which is fundamentally different from current use in crops. These uses should be clarified in the listing motion. For aquatic plants, chlorine materials should not be added to culture water.

Relevant TR for aquatic systems is needed

The most recent TR, written by ICF in 2011, addressed chlorine use in terrestrial crop production. A previous TR, written by ICF in 2006, concerned chlorine use in terrestrial livestock production. These TRs addressed the use of chlorine to disinfect hard surfaces, and the use of chlorine to clean irrigation lines. They did not address aquaculture uses, specifically the use of chlorine in culture water. Growing crops in chlorinated water is fundamentally different from the accepted use of chlorine for cleaning irrigation lines.

The subcommittee evaluation relies heavily on the 2006 TR for terrestrial livestock, written seven years ago. [Note: The proposal refers to the "2006 Crops TR" but the heading for the 2006 TR states "Livestock".] Even the recent TR, from 2011, was written for terrestrial crops. It is not relevant for aquatic crops.

Reliance on this TR fails to answer several questions as they relate to aquatic crops:

3. Are there any alternative substances?
4. Are there any management practices that would make the substance unnecessary?

The subcommittee review answered "no" to both questions. However, there are alternative substances and management practices that render chlorine not essential. Since there have been recent TRs, a limited-scope TR to address these specific questions may be sufficient to allow NOSB members to render a more informed decision about alternatives to the use of chlorine in aquatic systems.

Alternative materials are available

When an item is evaluated for the National List, evaluation questions must address the question of essentiality in that particular system and for that particular use. The proposal states that there are no alternative substances or other practices (category 2, numbers 8 and 9). In reality, there are many alternative substances and practices.

The **first** petitioned use of chlorine is for **disinfection of hard surfaces**. Numerous sanitizers are allowed for disinfection of hard surfaces used for organic processing, as long as residues are removed before organic product is handled. The 2011 TR offers several alternative substances for this use, discussed in depth in lines 532 to 606. The following materials are already on the National List for crops, at *§*205.601:

- hydrogen peroxide
- alcohols—ethanol and isopropanol
- peracetic (peroxyacetic) acid

We suggest that hydrogen peroxide may be an excellent alternative, because it decomposes into water and oxygen. It is far more benign for the environment than chlorine.

Chlorine to disinfect culture water is not essential

The **second** petitioned use of chlorine is in the **culture water** in which crops are grown. An alternative practice is to grow aquatic crops without chlorine. There is no evidence that it is essential to add chlorine to water in which crops are growing. Aquatic plants successfully live in lakes, streams, and oceans without the addition of chlorine. Presumably, the aquatic plants that will be grown organically are the same ones that grow naturally in chlorine-free waters.

Alternatively, chlorine may be added to culture water that will later be used to grow aquatic crops. . Comments submitted to the NOSB describe this use: "*In aquaculture, culture water is sometimes disinfected with chlorine and then de-chlorinated …*".[82] Used in this way, high levels of chlorine may be used, as long as the chlorine levels are later decreased, typically by allowing toxic chlorine gas to be dispersed into the air. Chlorine is not essential for this purpose. There are many ways to disinfect water without chemicals: boiling, autoclaving, ultraviolet light, and filtering are effective. The EPA recommends boiling over bleach to disinfect drinking water.[83]

Chlorine is harmful to humans

The proposal claims that chlorine materials are not harmful to human health or the environment (category 1, number 7). The 2011 TR paints a different view in Evaluation question 9:[84]

> *"Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational exposures. Acute exposure to high concentrations can cause eye and skin injury. … Ingestion of small quantities of household bleaches (3-6% hypochlorite) may lead to gastrointestinal irritation. Ingestion of more concentrated commercial bleach … may result in corrosive injuries to the mouth, throat, esophagus, and stomach with bleeding, perforation, and eventually death."*[85] [86]

Chlorine materials added to culture water can be harmful to humans, due to their rapid dissociation in water and the formation of chlorine gas.

Chlorine materials are harmful to the environment

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[82] Lockwood, G. 2014. AWG Comments to the NOSB, March 17, 2014.
[83] US EPA. Emergency Disinfection of Drinking Water. Downloaded from http://water.epa.gov/drink/emerprep/emergencydisinfection.cfm.
[84] ICF International. 2011. Technical Evaluation Report for Chlorine / Bleach (Crops).
[85] ATSDR. 2002. ToxFAQs™ for Calcium Hypochlorite/Sodium Hypochlorite Available at: 636 http://www.atsdr.cdc.gov/toxfaqs/tfacts184.pdf.
[86] EPA. 1991. R.E.D. Facts. Sodium and Calcium Hypochlorite Salts. Available at: 657 http://www.epa.gov/oppsrrd1/REDs/factsheets/0029fact.pdf.

The Materials Subcommittee has indicated that there are serious concerns about the environmental impacts of chlorine materials. In their *Proposal: Research Priorities for 2013*, they state:

> *"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."* [emphasis added]

One way to "*move beyond reliance on chlorine-based materials*" is to reject any petitions for adding chlorine materials to the National List.

There is no evidence that chlorine materials are harmless in aquatic environments, because the existing TRs do not consider the aquatic ecosystem. The TR also does not consider the quantities that may be used in aquaculture operations.

To evaluate environmental harm, it is necessary to know the extent to which chlorine materials are released into the environment. The proposal limits the **concentration** of chlorine, but it does not limit the total **amount** of chlorine. There is a significant difference between the release of 10 gallons of chlorinated water and 10,000 gallons. There is a need for data on the quantity of chlorine to be released and the frequency with which it will be released. This data must be collected by an independent contractor. It is not sufficient to rely on statements from the petitioner.

The petition states, "Residual chlorine levels **in the facility effluent water** shall not exceed the maximum residual disinfecting limit under the Safe Drinking Water Act."[87] The proposal states that residual chlorine levels must be consistent with the Safe Drinking Water Act (SDWA) levels. The SDWA is completely irrelevant to the release of chlorine into the environment. A more appropriate standard would be the effluent standards set under the Clean Water Act (CWA), if effluent is released directly into natural waterbodies.[88]

Chlorine materials do indeed cause harm, in their manufacture, use, and disposal. We believe this material should not be added to the National List for use in aquaculture.

Synthetic materials for aquaculture should have a firm expiration date

If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years. To ensure a

[87] Lockwood, George. 2012. Petition for Listing: Chlorine materials in aquaculture. P. 2.
[88] US EPA web site, http://cfpub.epa.gov/npdes/cwa.cfm?program_id=45

full evaluation, **Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing**.

CONCLUSION

There is no reason to approve the use of synthetic materials in organic aquaculture until **after** the organic standards are available.

The publication of the new sunset process provides ample reason to avoid adding any new materials to the National List. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board.

Concerns about chlorine materials in particular provide additional reasons to reject this petition. The proposal was brought before the Board without the needed technical evaluation for the proposed uses. The proposed use of chlorine in culture water for medical use is a novel use, not analogous to any current uses in organic production. Chlorine fails the evaluations criteria for addition to the National List. It has not been shown that chlorine is essential for this use. It has not been shown that chlorine is harmless to humans and the environment.

The Cornucopia Institute recommends this petition be rejected.

Lignin Sulfonate – plants

SUMMARY

Reject the petition to add lignin sulfonate to the National List at §205.609 Synthetic substances allowed for use in organic aquatic plant production.

Rationale:

- Organic regulations for aquatic plants have not yet been developed.
- The petition for lignin sulfonate for aquatic animals was rejected by the Livestock Subcommittee.
- Lignin sulfonate is not essential; it merely facilitates use of synthetic micronutrients.
- A Technical Review that addresses aquatic production is needed.
- Lignin sulfonate can harm native aquatic animals by removing dissolved oxygen from natural waterbodies.
- If this material is approved, an expiration date is essential to ensure re-evaluation in the future.

DISCUSSION

Lignin sulfonate is a by-product of the paper pulp industry. It is a derivative of lignin, a molecule that provides strength to wood.

The petition asks the NOSB to allow lignin sulfonate as a chelating agent for micronutrients supplied to aquatic plants. The listing motion is:

> *"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"*

Lignin sulfonate was petitioned for use in aquatic production of both animals and plants. The Livestock Subcommittee rejected the petition for aquatic animals, by a vote of 0 (yes) to 6 (no).

The available TR was written for use of this material in terrestrial crops; it does not mention aquatic plant or animal production.

Organic regulations for aquatic plants have not yet been established

It is essential to understand how a material will be used in its specific organic system before adding synthetic materials to the National List.

The NOSB recommendations for organic aquatic plants required that "*culture media shall be disposed of in a manner that does not adversely impact the environment.*" This provided assurance that nutrient-fortified culture water would not be released into natural ecosystems. The NOP has not yet put these recommendations into law; instead, the NOP has specifically stated that aquatic plants may be certified organic in the absence of this precaution.

The first order of business must be the clarification of organic regulations. Even if regulations were established, there are several reasons to reject the wholesale approval of lignin sulfonate.

Lignin sulfonate was rejected for aquatic animals by the Livestock Subcommittee

The Livestock Subcommittee reviewed a petition for the use of lignin sulfonate for aquatic animals and rejected the petition by a vote of 0 (yes) to 6 (no). Notes from July 30, 2013:

> *"Lignin sulfonate (feed binder) (Jean Richardson - JR) – The lead reviewer summarized the proposal for the group, indicating that* ***the material fails all review criteria*** *and there are several alternatives. … JR briefed the members about*

the Maine aquaculture tour and noted that one producer in Maine did not use lignin sulfonate as a feedbinder, but used two alternatives instead. JR asked several experts (fish nutritionists, aquaculturists etc.) about the need for this material and got consistent answers about the lack of essentiality and necessity."

From these notes, it appears that the subcommittee unanimously decided that lignin sulfonate was harmful to humans and/or the environment, not essential, and not compatible with organic production practices. This is true for aquatic plants as well as animals.

Lignin sulfonate is not essential for aquatic plant production

Certainly this petitioned use is slightly different from the use for animals, but there is no evidence that it is essential, other than the claim of the petitioner. Lignin sulfonate is only to be used to facilitate the routine addition of synthetic nutrients to organic plants. Our comments on micronutrients explain why we oppose this use:

- Natural sources of micronutrients are available.
- Addition of micronutrients may harm aquatic ecosystems.
- Manufacturing processes of micronutrients are proprietary

The possibility of alternative chelating agents has not been fully reviewed. Non-synthetic amino acids and non-synthetic citric acid are allowed for use as chelating agents in organic agriculture. The only evidence to dismiss them as alternatives comes from the petitioner's claim that they simply have not yet been used in plant aquaculture. In regards to question 9 (*Are there other practices that would make the substance unnecessary?)*, the checklist notes that none are provided in the TR. Alternatives to lignin sulfonate for use in aquaculture are not listed in the TR because the TR was written for terrestrial crops, not for aquatic crops. There may be other possibilities for aquatic crops, including the use of natural sources of micronutrients. A supplemental TR is needed to fully address the question of essentiality, rather than simply relying on the word of the petitioner.

Lignin sulfonate is harmful to the environment

The TR specifically states that lignosulfonates may be harmful when discharged into waterways.[89] Lignin sulfonate has a high biological oxygen demand, which means that the microbial breakdown of lignosulfonates requires a large amount of dissolved oxygen. As a result, oxygen is depleted from waterbodies, which is harmful to fish and aquatic animals.

The proposal ignores the possibility that lignin sulfonate may be released into natural water bodies. The proposal claims that these micronutrients chelated to lignosulfonate will be used only in completely closed systems such as on-shore tanks and ponds. <u>There</u>

[89] ICF international. 2011. Technical Evaluation Report, Lignin Sulfonate (crops).

is no guarantee that lignosulfonate will only be used in closed systems because the motion as listed above does not specify only closed systems. Moreover, there is no assurance that the wastewater from onshore tanks or ponds will not be released into natural rivers, streams, or lakes. As was mentioned above, the NOSB Recommendations includes a requirement that the water should be disposed of in a way that does not adversely impact the environment, but there is no guarantee that those recommendations will be implemented.

Including an expiration date offers a more robust approach to protecting the interests of organic stakeholders

If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years. Although it was not mentioned in the proposal, Cornucopia suggests that a five-year expiration date should be included on the listing motion. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. It is imperative that Board members follow the precautionary principle: reject materials until there is abundant evidence to prove their safety.

CONCLUSION

There are many reasons to oppose this petition. Lignin sulfonate facilitates the use of synthetic micronutrients, and it can harm native fauna if released into waterbodies. With a TR that is not relevant for the petitioned use, it is premature to consider approval of this material. Even if there were no reservations about lignin sulfonate, it is premature at this time to vote on the use of synthetic materials for aquaculture, because the organic regulations have not yet been developed for aquatic plants.

The Cornucopia Institute recommends this petition be rejected.

Vitamins – plants

SUMMARY

Reject the petition to add vitamins to the National List at §205.609 Synthetic substances allowed for use in organic aquatic plant production.

Rationale:

- Organic regulations for aquatic plants have not been established.
- Manufacturing processes were withheld as proprietary.
- Addition of synthetic nutrients may harm aquatic ecosystems.
- New NOP sunset process may prevent future reviews by the full Board.

DISCUSSION

This proposal requests that synthetic vitamins be allowed for organic aquatic crop production. The listing motion is:

> *Motion to list vitamins (B1, B12 and H) at §205.609 of the National List.*

Vitamin B1 is also called thiamine. Vitamin B12 is also called cobalamin or cyanocobalamin. Vitamin H is also called biotin, vitamin B7, or coenzyme R.

The petition states "*Vitamins B1, B12, and H are essential for aquatic plant life*…."[90] While this statement is true, it does not relate to the petitioned use. The petitioner requests the approval to use **synthetic** vitamins.

These vitamins might very well be "essential" for plant growth. But the synthetic forms of these vitamins are not necessarily essential in organic production if the nutrients can be obtained through different management practices or supplementation with natural substances.

The vitamins will be dissolved in the growing media in tanks and ponds.

Organic regulations for aquatic plants have not yet been established

Organic agriculture is founded on the principle of ecological balance. Before adding synthetic materials to the National List, it is essential to understand how the material will be used in the proposed environment. Cultivation of aquatic plants is fundamentally different from the cultivation of terrestrial plants.

[90] Lockwood, G. 2012. Petition for Listing: Vitamins for Aquatic Plants. Page 6.

The NOSB recommendations for organic aquatic plants required that "*culture media shall be disposed of in a manner that does not adversely impact the environment.*" This provided assurance that nutrient-fortified culture water would not be released into natural ecosystems, but the NOP has not yet put these recommendations into law. Instead, the NOP specifically stated that aquatic plants may be certified organic in the absence of this precaution.

The proposal ignores the possibility that vitamins may be released into natural water bodies. The petitioner claims that these vitamins will be used only in completely closed systems, but this is not guaranteed because the motion does not specify closed systems.

Even if closed systems were included in an annotation, the term "closed system" is not well-defined. The pond may be a closed system if the pond has an impermeable bottom and sides. In contrast, ponds constructed of soil may allow pond water to drain into the groundwater. During periods of unusually heavy rain, ponds may overflow, and drain into natural waterbodies. Moreover, there is no assurance that the wastewater from onshore tanks or ponds will not be released into natural rivers, streams, or lakes. The motion listed above should include annotations to clarify protection of the environment.

The first order of business must be the clarification of organic regulations. Even after USDA NOP regulations have been established, there are several reasons to reject this petition for synthetic vitamins (in essence, synthetic nutrients/fertilizer).

Manufacturing process is confidential

Manufacturing processes for these synthetic vitamins are not described in the petition because they are proprietary. This confidential business information does not allow the legally required full review, which is itself a valid reason to reject the petition. Manufacturing processes, along with possible synthetic additives, are likely to remain confidential, because the vitamins "*are* ***obtained from sources in a number of countries, including China***"[91] [emphasis added].

The TR, with general descriptions of the manufacturing processes, presents additional reasons for concern.

Many vitamins, including all of the petitioned vitamins, can be produced through industrial fermentation methods. **Typically the fermentation is done using genetically modified bacteria**. Certainly we can expect this trend toward fermentations by GMOs to continue in the future. Before approving this petition, it is necessary to clarify manufacturing methods.

Addition of nutrients may harm aquatic ecosystems

[91] Lockwood, G. 2012. Petition for Listing: Vitamins for Aquatic Plants. Page 2

At first glance, providing vitamins to aquatic plants may appear to be similar to providing vitamins to terrestrial plants. In actuality, the ecosystems are fundamentally different. Organic principles specify that the differences of unique ecosystems must be carefully considered, and the practices "must maintain or improve the natural resources of the operation, including soil and water quality."[92]

The petition states that vitamins released into the environment will have a positive impact.[93] Abundant scientific evidence is available to refute this claim.

Adding nutrients to terrestrial systems may provide a benefit in terms of enhanced plant growth. Adding nutrients to aquatic systems can enhance plant growth, but the effect can be detrimental rather than beneficial. When the aquatic plants die and decompose, it leads to anaerobic conditions, death of fish, and environmental degradation.

The TR, in lines 1075–1079, explains this phenomenon:

> *"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."* [94]

An expiration date offers a compromise

Cornucopia urges the NOSB to reject this petition, or at least table it until regulations for aquaculture are in place, so that the need for synthetic materials can be evaluated. Due to the NOP's recent changes in the sunset process, we are concerned that the use vitamins in aquaculture systems will never again be subject to a full rigorous review, and a vote by the full Board. If the Board chooses to vote on aquaculture materials at this meeting, it is prudent to ensure that every synthetic material should be fully evaluated in five years.

To ensure a full evaluation, **Cornucopia agrees with the suggestions for an annotation that sets a five-year expiration date on the listing**. Although this suggestion is placed at the end of the document and it is titled a minority opinion, we believe that the suggestion represents the majority opinion in the organic community.

CONCLUSION

This petition requests the use of synthetic materials that may cause harm to aquatic ecosystems. Even if this material were benign, it is premature at this time to vote on the

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[92] USDA NOP Organic Regulations. Subpart C - Organic Production and Handling Requirements. §205.200 General.
[93] Lockwood, G. 2012. Petition (Revised) for Listing: Vitamins for Aquatic Animals. Page 3.
[94] Pesticide Research Institute. 2013. Vitamins (Aquaculture – Aquatic Animals) Technical Evaluation Report

use of synthetic materials for aquaculture, because the organic regulations have not yet been developed for aquatic plants.

If this reasoning leads to reservations about the need for synthetic vitamins, it is essential to vote "no" on this petition. With the new sunset process, this material may never again be subjected to independent technical evaluation and open discussion by the full Board. It is imperative that Board members follow the precautionary principle: reject materials until there is abundant evidence to prove their safety.

The Cornucopia Institute recommends this petition be rejected.

COMPLIANCE, ACCREDITATION, CERTIFICATION (CAC) SUBCOMMITTEE

Guidance on Retail Certification

The vision of the NOP asserts "*Organic Integrity from Farm to Table.*" Since retailers are often the final step in the journey from farm to table, the NOSB discussion document, "Voluntary Retail Certification Requirement Clarification and Guidance," is an important step in protecting organic integrity.

As the discussion document points out, "*Consumers expect to be able to track every ingredient listed on a product back to the organic certificate.*" From a consumer perspective, we would add that consumers expect the label to indicate the name of the final handler of the product, as well as the name of the handler's certification agency. Stakeholders who initially developed the Organic Foods Production Act assumed that an audit trail would be available to track products and ingredients back to the original producers.

The broad question to be addressed is: What procedures must be in place to ensure that consumer expectations are met in terms of trust in the organic labeling and retail process?

The process followed during inspections of organic operations is to identify the **organic control points**, i.e., any point or procedure where loss of control may result in a loss of integrity.

Just as inspectors look for these organic control points (OCPs) and verify that adequate procedures are in place, the NOP and NOSB must look at the organic control points that occur as food travels from the farm to the table. At any time that organic food is removed from its original container and put into a different package, that procedure is considered "handling." The operation, whether it is a retailer or a processing facility, must be certified organic. This does use the broad definition of "processing" as noted in the discussion document: "any act of packaging or enclosing food in a container." This broad definition is needed because many retailers re-package foods, but are not familiar with organic regulations. Labels on the retail packages are not always clear.

We realize that the burden of certification rests heavily on small operations. For that reason, the NOSB may want to consider an exemption for small retailers similar to the existing exemption for small producers and handlers. For retailers, a limit higher than $5,000 may be appropriate.

The discussion document also asks questions about signage. The consumer should have access to information about the certifier for any organic product. The bulk bins can be labeled, meats in the meat department can be labeled, salad bar items can be labeled. Alternatively, a file can be made available in the store near the organic items, for review by customers. This level of consumer information should be feasible even for very small retailers.

Retailers may be allowed to choose a method that is most appropriate in their store, as long as information is available in a public place, and consumers have easy access to the information. This is particularly important when organic and non-organic items are sold in close proximity, as often occurs in a salad bar.

Organic food must maintain organic integrity through the entire process from farm to table. The consumer must be able to find out who certified the final handler.

Sound and Sensible Initiative

Cornucopia's comments on the "Sound and Sensible Initiative" discussion document are presented as informal general comments on the certification process.

The goal of simplifying the certification process, especially for the organic farming community, is meritorious. We feel it is incumbent upon us to convey to the NOSB multiple comments we have received from Cornucopia farmer-members regarding their experience going through the certification process. With approximately 9,000 members, reflecting a high percentage of the nation's certified organic producers, we think their anecdotal reports are worth paying attention to.

Before simplifying the current process, the USDA should contract with an outside research organization to gauge the sentiments of farmers regarding the efficiency of the current system. Many of the observations in the discussion document we are confident will be borne out. But many concerns of farmers are not articulated at all.

Current Inspection/Certification Weaknesses

We have received numerous accounts of unqualified inspectors, individuals whom farmers report have no experience in production agriculture, let alone organic farming. They have no context, other than some rudimentary training that they may have participated in, to filter their observations through. Farmers who have reported on these inspections are individuals who hold the ideals inherent in the organic farming movement sacred and are highly disturbed by their experiences. They worry that unscrupulous operations will be able to operate outside of the regulations as a result of less than competent inspection staff.

The lack of ACA personnel with production agriculture experience could also explain why, according to the discussion document, many farmers perceive the present verification process to be "redundant" and "out of touch with how the operation works."

What exacerbates this problem are reports that all too often, instead of using experienced and trained in-house staff, certifiers are hiring independent contractors on the basis of the lowest bid. Many of these individuals are economically undercutting sustainable fees collected by experienced independent inspectors.

As a result of the low bids, we have reports from farmers of inspectors who are doing numerous farm inspections in a given day, what can be called "drive-by inspections." Sometimes these individuals are sleeping in the back of their car or truck because of the low compensation rates.

Coming to our final concern in terms of the quality of current inspections, we have been told all too often about inspectors who never bothered to look at the audit trail of documents maintained by the farmer. As expressed in the discussion document,

encouraging increased observational reviews by inspectors is no doubt important. The backbone of the audit process needs to be a rigorous review of documents in order to act as an internal check to assure that non-organic commodities are not being marketed. For example, if someone is farming 400 acres of cash grain, there should be a reconciliation between appropriate inputs on that acreage and yields. That can only be accomplished via a rigorous document review.

Having experienced and creditable inspectors is the backbone of the organic certification process. We will remind members of the NOSB that one of the largest, if not *the* largest, scandals in the history of the organic movement took place at Aurora Dairy; USDA auditors found that the giant chain of industrial-scale dairies violated 14 tenets of the organic regulations (including bringing on illegal conventional cattle, confining animals without grazing, and using an uncertified contractor to raise replacement animals).

In that case, an inspector from the Colorado Department of Agriculture, with no experience whatsoever in organic inspection, was allowed to inspect one of the largest organic livestock facilities in the United States. That individual, knowing his limitations, asked for support from his supervisors to either bring in an experienced independent inspector or to visit another state, such as Wisconsin, where he could observe numerous dairy inspections. We support the comments of the National Organic Coalition regarding increasing the opportunities for mentoring and apprenticeship in raising the level of professionalism within the community of organic inspectors.

We applaud removing redundancy and streamlining the recertification process. No farmer should have to fill out the same reports every year; instead, ACAs (and the NOP through a standardization process) should develop systems so the referenced *abbreviated updates* can be quickly and simply executed.

Targeting Inspection/Certification Infrastructure

It might be time to acknowledge that, given the present fee structures and the loss of cost-sharing, a new model might be necessary in order to maintain the highest level of organic integrity through the certification/inspection process at the farm level.

The Internal Revenue Service does not audit every taxpayer on an annual basis. Perhaps the National Organic Program should consider a basic annual review, which could include random, unannounced annual inspections (along with unannounced residue testing). This could free up budget dollars commensurate for a more thorough document audit/inspection, conducted by a higher level of seasoned and experienced inspectors, every three to five years.

Since these in-depth reviews could be randomly rotated, farm operators would have to maintain their document trail on an annual basis not knowing if they are going to be audited or not in any particular year.

Cornucopia policy staff have discussed this concept with a broad array of organic industry participants. Just like some of the concepts presented in the Sound and Sensible proposal, any deviation from the current standard of an annual, theoretically thorough inspection would need wide organic community input and refinement.

Notices of Noncompliance and Other Remedies

While retooling, it is important to be cognizant of the fact that there is an inherent conflict of interest between ACAs and certified entities. All noncompliances, even if handled in a less formal manner than presently exists, need to be documented with the NOP. Otherwise, "customers" of the ACA could be exonerated of more serious violations of the regulations in an effort to maintain friendly business relations. Besides for the inherent integrity of most certifiers, the NOP accreditation program is the only oversight to assure the public that collusion in the process is not taking place.

Materials Review

The dependence, without oversight, of the organic community on one nonprofit entity, and informal decision-making by scores of individual certifiers, with or without the technical expertise to make these determinations, is unsettling.

The Organic Materials Review Institute (OMRI) is widely viewed as being a reputable organization, with many respected and learned organic community participants, in both leadership and review roles. However, the OMRI committee that reviews materials used in processing includes many of the same industry-related consultants whom Cornucopia found, during its *Organic Watergate* investigation, produced inappropriate and inadequate Technical Reviews for the NOSB. Some of these TRs were deficient, biased, and in some cases left out published research which would have made approval of synthetics less likely by the Board.

That is not to say that The Cornucopia Institute lacks confidence in OMRI's ability to make impartial decisions regarding materials. But the NOP needs to provide oversight in this process, and in the review by certifiers themselves, to assure credibility and impartiality.

Then, the suggestion to have a national database, to serve as a clearinghouse for farmers and ACAs alike, deserves serious investigation.

Peer Review

We agree with the comments of the National Organic Coalition regarding instituting a Peer Review Panel, a requirement of the Organic Foods Production Act of 1990. This body should have been constituted long ago to legally comply with the provisions of OFPA.

CONCLUSION

Our comments here are not intended to be a comprehensive response to the discussion document on the Sound and Sensible Initiative. Rather, we hope needed refinements in the National Organic Program, to better serve the farming community, will be carefully considered in the context of weaknesses in the current program. And we would direct the attention of NOSB members to the thoughtful comments prepared by the National Organic Coalition.

HANDLING SUBCOMMITTEE

Ammonium Hydroxide

SUMMARY

Comments on the petition to add ammonium hydroxide (NH4OH) to the National List at §205.605.

Ammonium hydroxide is an alkaline chemical used as a boiler water additive to reduce corrosion in steam lines. Justification for removal of other more toxic boiler additives, at sunset, will be easier if ammonium hydroxide is already on the National List. However, The Cornucopia Institute questions whether boiler water additives are necessary given that it appears certain practices can be taken to use pure water and maintain and protect steam lines.

Points of consideration:

- Ammonium hydroxide is affirmed as GRAS (21 CFR 184.1139) with no upper concentration limit. However, ammonium hydroxide at concentrations greater than 1,000 parts per million (ppm) is toxic to humans when ingested. In its concentrated form, ammonium hydroxide is highly alkaline and must be handled with care.
- Ammonium hydroxide is an environmental pollutant. It degrades to ammonia, a greenhouse gas, and is a contributing factor to climate change. Spillage or other misuse is a threat to the environment, especially to aquatic ecosystems.
- There are a number of strategies for reducing corrosion in steam pipes that do not require boiler additives, although these may be cost prohibitive.
- Ammonium hydroxide is a safer alternative to boiler additives currently on the National List.

DISCUSSION

Ammonium hydroxide is petitioned for use as a boiler water additive to counteract carbon dioxide in steam lines, which causes corrosion. Steam is widely used in food processing, including applications that bring it into direct contact with food. Ammonium hydroxide is seen as the most cost effective way to clear steam lines, though many other alternatives exist including additives that are currently on the National List.

Ammonium hydroxide (ammonia in water) neutralizes the corrosive carbonic acid (carbon dioxide) in steam to form ammonium carbonate and ammonium bicarbonate. These are the chemicals that come in contact with food ingredients through steam. Ammonium carbonate and ammonium bicarbonate are commonly used in food as leavening agents. Ammonium carbonate is on the National List §205.605 for use as a leavening agent in baked goods and as an alternative yeast food. Ammonia is formed naturally in the body as a result of protein digestion by bacteria that live in the intestines. The ammonia is carried in the blood (as ammonium hydroxide) to the liver where it is converted to urea, which exits the body in the urine.

The use of ammonium hydroxide as a boiler additive is safer than the toxic amines currently on the National List: cyclohexylamine, diethylaminoethanol, and octadecylamine. These volatile amines are approved for use only in packaging sterilization because of their known volatility and toxicity. It is well understood that boiler additives may persist in steam that has contact with the organic product.

International regulations

Ammonium hydroxide is not permitted in organic production anywhere in the world, with the exception of Europe where it is permitted only in gelatin production.

Environmental concerns

According to the Technical Advisory Panel (TAP) review from 2001, when ammonium hydroxide was last petitioned for addition to the National List, there are a number of environmental hazards associated with its production and use. The production of synthetic ammonia and ammonium hydroxide (the Haber-Bosch process) requires the use of natural gas, a fossil fuel. As a boiler additive, ammonium hydroxide works by volatilizing into ammonia, a greenhouse gas, which is then discharged with the steam. Both the production and use of ammonium hydroxide contributes to climate change.

While normal usage of ammonium hydroxide, other than in the release of steam, should not result in direct releases to the environment, the risk of misuse and accidental discharges exists. It is both an air and water pollutant, and it poses special risks to aquatic ecosystems where it can raise pH and be a source of eutrophication.[95]

Human health concerns

The petition and TAP review state that ammonium hydroxide "is toxic by all routes (inhalation, ingestion, and dermal contact)" and requires careful handling by workers.[96] The Material Safety Data Sheet lists both acute and chronic health effects resulting from exposure to ammonium hydroxide including burns to the skin, damage to the mucous

[95] Technical Advisory Panel Review: Ammonium Hydroxide. February 15, 2001. Compiled by OMRI. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066965&acct=nosb
[96] Theurer, Richard. 2012. Petition to add Ammonium Hydroxide as a boiler water additive to the National List.

membranes of the lungs, organ damage, an increased susceptibility to bronchial infections, and possible death.[97] It is important to note that these symptoms are from the concentrated form (for example, eye damage occurs at 90,000 ppm). Concentrations of ammonia in the steam are in the range of 5-25 ppm and then further diluted once added to the food.

Not essential as numerous alternatives exist

Many alternatives are available. There are numerous substances, devices, and practices that can be employed to reduce corrosion in steam-generating systems instead of using ammonium hydroxide as a boiler additive:

- Several boiler water additives that are already approved for use in organic production exist, including caustics like potassium hydroxide and sodium hydroxide, as well as amines specifically designated for use as boiler additives in packaging sterilization.
- Water used in boilers can be pre-treated so as to avoid the need for chemical additives. Water can be treated to soften and deionize it, and can also be filtered.
- Steam pipes can be flushed more frequently.
- Steam systems can be made of stainless steel piping that resist corrosion.[98]

The petition states that while these alternatives are feasible, "the alternatives entail extra expense and extra effort that increases the cost of organic foods for the consumer." This is not sufficient reason to add ammonium hydroxide to the National List (because economic considerations are not part of the criteria) although it may be necessary temporarily due to the cost of water purification systems and stainless steel piping.

The FDA excludes the use of toxic volatile amines from all dairy plants. There is no reason why synthetic cyclohexylamine, diethylaminoethanol, and octadecylamine should be on the National List as boiler additives for packaging, when conventional dairies operate without them. If ammonium hydroxide is effective for proper maintenance of dairy steam lines, there is no reason to assume that it wouldn't be a good replacement for the toxic amines currently used as boiler additives in organics.

Technical Report is not current

Typically, The Cornucopia Institute requests a new Technical Evaluation Report (TR) be performed for every material that is up for review. Further, we request that subcommittee discussions and proposals should be based on information in the current TR. The most recent TR for ammonium hydroxide is dated 2001. A new TR is needed to provide the most recent scientific data for discussions by the Board. Older TAP reports are often incomplete, as compared to the newer TRs, in part because they do not explicitly list the evaluation questions and the answers to those questions. If Board

[97] Material Safety Data Sheet for Ammonium Hydroxide
[98] Technical Advisory Panel Review: Ammonium Hydroxide. February 15, 2001. Compiled by OMRI.

members are inclined to approve ammonium hydroxide, please table the petition until a new TR can be prepared.

CONCLUSION

Ammonium hydroxide is a synthetic chemical that appears to be non-toxic at concentrations less than 1,000 ppm. The Cornucopia Institute recognizes that ammonium hydroxide is the most cost-effective method to prevent corrosion in boilers. It is also a safer alternative to the toxic amine boiler additives currently on the National List. However, our position remains that if ammonium hydroxide is approved it should be considered for sunset in five years if adequate research concludes corrosion can be prevented by altering production practices, such as filtering and pre-treating water and maintaining steam lines.

Glycerin

SUMMARY

Support the petition to remove glycerin as an allowed synthetic material for handling at §205.605(b) of the National List.

Rationale:

- Per the petition, organic glycerin can now be produced in sufficient quantities with only the "mechanical and biological processes" required in §205.270.
- The transition from synthetic glycerin to organic glycerin is an example of organic regulations pushing industry toward safer practices. Removing synthetic glycerin from the National List (i.e., glycerin produced by hydrolysis of fats and oils) will encourage additional glycerin production consistent with organic principles.

DISCUSSION

The removal of glycerin as an allowed synthetic is petitioned by Draco Natural Products, a company that produces organic glycerin by means of fermentation of organic corn. This product is agricultural in nature and all the inputs can be acquired from organic sources.[99] The synthetic glycerin that is currently used in organic handling is produced by the application of steam or permitted synthetic alkalis such as sodium hydroxide, sodium carbonate, and potassium hydroxide.[100]

[99] Draco Natural Products. 2013. Petition to remove glycerin from the National List.
[100] Draco Natural Products. 2013. Petition to remove glycerin from the National List.

Synthetic glycerin is not essential

The petition will cause an allowed synthetic to be replaced by something that is truly organic. A large number of producers currently manufacture organic glycerin at purportedly competitive prices, thus making the listing of synthetic glycerin unnecessary.[101]

There are many sources of certified organic glycerin. Table 5 (line 673) of the TR includes 21 certified organic operations that manufacture or source organic glycerin. The Organic Trade Association's directory of organic producers lists four additional companies.[102] They are Daabon Organics USA, Inc., Earth Supplied Products, LLC, Materia Organica, and Jedwards International, Inc. A web search produced even more sources.[103] While there may not have been organic alternatives to synthetic glycerin when it was originally added to the National List, that is not the case anymore. Synthetic glycerin is no longer essential given the wide availability of organic glycerin in the marketplace.

No incentive for processors to use non-synthetic glycerin

Glycerin produced by fermentation of organic corn, as opposed to synthetic glycerin, is available to organic processors in sufficient quantities. However, because there is no requirement under §205.605 to use listed materials "only when the product is not commercially available in organic form," as in §205.606, there is no incentive for processors to use the organic glycerin. Removing glycerin from the National List of allowed synthetics will incentivize the market to use glycerin consistent with §205.270, which requires mechanical or biological methods of production.

CONCLUSION

The removal of synthetic glycerin from the List will provide incentive for processors to use organic glycerin, which is commercially available. The organic handling industry is expected to adjust as organic sources for materials become available. The Cornucopia Institute supports the majority opinion on the Handling Subcommittee to remove glycerin from the National List.

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[101] USDA AMS Agricultural Analytics. 2013. Glycerin Technical Evaluation Report.
[102] http://www.theorganicpages.com/topo/commercialactivity.html?ca=ingredients&commid=36&keyw=1726. Viewed September 9, 2013.
[103] From Nature with Love (https://www.fromnaturewithlove.com), Essential Wholesale and Labs (http://www.essentialwholesale.com/), Allyson Enterprises, Inc. (http://www.allysonenterprises.com/)

Polyalkylene Glycol Monobutyl Ether (PGME)

SUMMARY

The Cornucopia Institute **opposes** the use of polyalkylene glycol monobutyl ether (PGME) in organic food without adding it to the National List. PGME should be considered by the full Board based on the evidence that it **does** come into contact with organic food.

The Handling Subcommittee's recommendation to allow the use of PGME without adding it to the List is based on a potentially flawed Technical Review. The TR states that PGME when used as a boiler additive does not come into contact with food. The Cornucopia Institute documents evidence below indicating that PGME likely contacts food when used as a boiler additive and therefore must be approved by the full NOSB through the petition process.

§205.605 of the National List includes synthetic materials "allowed as ingredients in or on processed products…". Polyalkylene glycol monobutyl ether was petitioned to be added to the National List, based on the petitioner's assumption that it may be present in organic foods when used as a boiler additive. However, the authors of the TR indicated that PGME will not be present in organic food when used as a boiler additive.

We are concerned about the quality of the TR, which was prepared by the USDA AMS Agricultural Analytics Division for the NOP in June of 2013.

The petition, submitted by a manufacturer of a product containing PGME designed to be used in livestock food mills, states that the mode of action is through direct contact of the product with food. The TR states this does not occur, but does not provide a citation for this assertion that can be independently verified.

Rationale:

- The quality of the TR does not provide sufficient information to evaluate PGME.
- Used as a boiler additive, it is likely that PGME would come into contact with organic food through entrainment of liquid water by steam.
- While PGME itself has relatively low toxicity, it is manufactured from highly toxic petrochemicals that have adverse effects on human health and the environment.
- PGME is not essential as a boiler additive in the production of pellet feeds, which is the intended use in the petition.

DISCUSSION

PGME was petitioned for inclusion on the National List by Pellet Products, Inc., a manufacturer of water treatment chemicals.

PGME is a synthetic substance petitioned for use as a boiler additive to improve steam quality used for animal feed pellet production. PGME is a liquid polymer synthesized from butanol, propylene oxide, and ethylene oxide by Dow Chemical Corporation and other international manufacturers. PGME is a lubricant and the predominant uses are as automotive transmission, brake and hydraulic fluid, heat transfer fluid, and as an inert solvent for processing operations.

PGME is unique in that it completely dissolves easily in cold water but is insoluble at temperatures above 104 degrees F (inverse solubility). The temperature at which PGME is completely insoluble in water (greater than 104 F) is called the "cloud point" because PGME precipitates out of water. The intended use is as a boiler additive to reduce foaming, reduce scale, and increase the quality of culinary steam used in the production of animal pellet feed, and to lubricate the feed, or "mash," as it passes through the rollers and die that turn the feed into pellets.

PGME is used at concentrations of 0.15 to 1.7ppm. The petitioners are requesting to use the high molecular weight form (greater than 1,500). PGME toxicity is highest for the lower molecular weight polymers. Higher molecular weight PGME polymers are toxic in animals upon inhalation of mechanically generated mists. The products of thermal degradation are also toxic.

The Technical Review found that PGME as a boiler water additive would not be transferred to the feed through the steam, and so is not eligible for inclusion on the National List because it doesn't come into contact with food.

Substandard quality of Technical Review

The TR was prepared by the USDA AMS Agricultural Analytics Division for the NOP. In general, we question whether this contractor was fully vetted for technical expertise and knowledge of organic regulations. Specifically, PGME likely comes into contact with food when used as a boiler additive through water droplets in the steam (entrainment). **The TR does not include citations, which would allow verification of its findings**—findings that directly contradict those of the petitioner and manufacturer of the product. PGME should not be allowed in organics until this question is settled by provision of a supplemental TR from a knowledgeable contractor.

Mode of action

There appears to be a significant disagreement between the petition and the TR regarding the way PGME acts in steam-generating systems, and specifically the way the petitioned substance lubricates the mash.

The petition states:

> *"PGME functions as both a lubricant and as a surfactant within the pelleting process. With an approximate application rate of 1-3.5 fluid ounces per ton of feed produced, the consistent use of PGME causes reduced friction of the material moving through the die which can result in up to 60% longer die life."*
>
> *"When the PGME is brought into contact with a hot die or cutting tool, it is heated to a temperature above the cloud point of the polymer. The PGME then comes out of solution.* ***The resulting PGME droplets coat the surfaces of the hot die or cutting tool, forming a lubricant film that provides excellent hydrodynamic lubricity****."*[104] [emphasis added]

According to the TR:

> *"Steam conditioning with uniform, high quality steam brings natural oils present in the mash to the surface lubricating and extending the longevity of the pellet mill dies."*[105]

The TR does not include a citation for this assertion, nor is such an action mentioned anywhere in the petition. The TR further states that, because of its chemical properties, PGME is non-volatile at temperatures found inside boilers, and so is not delivered to the mash when steam is applied. This is the basis for the proposal to remove the petition from the NOSB work plan. However, the TR denies the potential of entrainment (water droplets) in steam, a common mechanism for boiler additives to come into contact with the food.

Entrainment of droplets

Although PGME is non-volatile, contact with organic food is likely through condensation/entrainment in water droplets in steam from boilers. Therefore, PGME should be evaluated through the petition process before it is allowed in organic handling**.**

The Handling Subcommittee found that, despite the stated mode of action in the petition, PGME is not required to be on the National List because it has no direct contact with organic products.

This does not accurately reflect what was stated in the TR:

> *"At high temperatures characteristic of culinary steam boiler operating temperatures, PGME solubility in water is significantly reduced. Thus, there is* ***little***

[104] Pellet Products, Inc. 2012. Petition for the addition of Polyalkylene Glycol Monobutyl Ether to the National List.
[105] USDA AMS Agricultural Analytics Division. 2013. Technical Review of Polyalkylene Glycol Monobutyl Ether.

carryover of PGME from boiler water to steam and negligible transfer of PGME to food."

*"…in **properly operating boilers**, PGME is neither a component or [sic] has a direct effect on the pellet mash or the pellet"*

*"Carryover into steam of substances present in boiler water is caused both by entrainment of small droplets of water in the steam leaving the boiler drum and by volatilization of salts that are dissolved in the steam. Mechanical entrainment, which **can occur in all steam generators**, can be **minimized** through mechanical or operational changes."*[106] [emphasis added]

The NOSB has emphasized the importance of boiler additives not contacting organic food.[107] While the risk of contamination may be low, entrainment of PGME or any other boiler additive is likely; thus PGME should be assessed as are other boiler additives already on the List.

PGME poses risks to human health, the environment, and is not essential

While not highly toxic itself, PGME is a synthetic chemical manufactured from ethylene oxide, propylene oxide, and butylene oxide, all petrochemicals of high toxicity both to humans and the environment. The fact that PGME is not readily biodegradable is of utmost concern when assessing its environmental impact, given its environmental persistence.[108]

PGME is not essential to the maintenance of boilers or to the manufacture of animal feed pellets. There are boiler additives on the National List that reduce scale build-up, and the TR lists a number of naturally occurring substances that act as anti-foaming agents.[109]

Furthermore, boiler additives are non-essential. Foaming can be prevented for steam infusion or injection by the mechanical culinary steam piping design. In Canada, where some boiler additives are prohibited (PGME is not mentioned), they recommend dual trap culinary steam piping assemblies to provide for airspace heating and defoaming. EEC standards require that feeds should not be processed with the aid of chemically synthesized solvents, and IFOAM requires all additives to be declared. Finally, this material is regulated by the FDA as a secondary direct food additive, and is not considered a GRAS substance.

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[106] USDA AMS Agricultural Analytics Division. 2013. Technical Review of Polyalkylene Glycol Monobutyl Ether.
[107] NOSB Final Recommendation Addendum Number 7, Good Manufacturing Practices. 1995
[108] USDA AMS Agricultural Analytics Division. 2013. Technical Review of Polyalkylene Glycol Monobutyl Ether.
[109] Ibid.

CONCLUSION

Due to the likely chance that PGME would come into contact with organic food, the substance is eligible for petition and should proceed through the petition process. Furthermore, a supplemental TR conducted by a knowledgeable contractor should be prepared to definitively settle how PGME acts in steam boilers. The TR should also include the potential animal health effects of PGME and its breakdown products.

Sunset Materials

SUMMARY

The following sunset materials are listed as discussion items:

- Gellan gum
- Tragacanth gum
- Marsala (fortified cooking wine)
- Sherry (fortified cooking wine)

They are all due to sunset in 2015. The Cornucopia Institute **does not support** these substances under review for continuation on the National List, for the following reasons:

Rationale:

- Technical Reports are either missing or inaccurate.
- Gellan gum should be considered a synthetic substance.
- An organic alternative (gum arabic) to tragacanth gum is available.
- Organic versions of marsala and sherry are now available.
- The new NOP sunset process may prevent future reviews by the full Board.

DISCUSSION

The Cornucopia Institute requests that Technical Reviews be completed on all of these materials before they are considered for relisting.

No TR was ever prepared for non-organic marsala or sherry, though the heavy use of pesticides in the production of conventionally grown wine grapes is well known as well as the use of synthetic preservatives (sulfites) and other additives. No TR was ever prepared for tragacanth gum, so its impact on human health and the environment cannot be ascertained. Gellan gum appears to be wrongly listed as a non-synthetic, as the 2006 TR states that it is manufactured in part by a chemical process that removes an acetyl group and affects the functional properties of the gum.[110] A new TR is warranted to help settle this issue.

Cornucopia requests a new TR be performed for every material that is up for sunset review. Further, we request that subcommittee discussions and proposals should be based on information in the new TR.

[110] ICF Consulting. Technical Review of Gellan Gum. February 10, 2006

First, new TRs are needed because we cannot always rely on the work of past TRs/TAP reviews. While some TRs have been objective, others have revealed bias—for example, failing to identify serious human health and environmental impacts of the petitioned material.

Second, new TRs will provide the most recent scientific data for discussions by the Board. Older TAP reports are often incomplete, as compared to the newer TRs, in part because they do not explicitly list the evaluation questions and the answers to those questions. New TRs can include new information, published subsequent to the material's last review, on health effects as well as on advances in the development of alternative materials.

When Cornucopia conducts our own, independent evaluation of materials proposed for the National List, we use the TR as a starting point for our investigations. For that reason, we believe that thorough comments on these sunset materials would be premature at this time.

New Sunset Review Policy

According to the new sunset review guidelines, the Handling Subcommittee must vote to remove these materials in order for the full NOSB to consider them in a public forum. The Cornucopia Institute considers the public debate and the involvement of the full NOSB in decision-making to be a cornerstone of organic regulations and critical to maintaining public trust in the label. **All materials scheduled for relisting should be voted on by the full NOSB**. We urge the Handling Subcommittee to vote not to relist materials as long as this new policy is in effect so that a full and open debate can take place.

Gellan Gum - Sunset

Gellan gum is a polysaccharide produced by the bacterium *Pseudomonas elodea* and currently considered to be a nonagricultural *natural* substance by the NOP. The low-acyl form is extracted with isopropyl alcohol and chemically altered by alkali treatment to increase firmness. Therefore, low-acyl gellan gum should not be considered for listing under §205.605a. Instead, it should be considered for relisting under §205.605b as a synthetic substance. The Cornucopia Institute recommends allowing only the high-acyl native form of gellan gum. The Handling Subcommittee should propose not to relist gellan gum so that the full NOSB can consider these issues with adequate public comment.

Note: Since the extraction of ingredients using volatile solvents, such as hexane or isopropyl alcohol, is specifically prohibited in organic production, the review of this material should be moot.

Tragacanth Gum - Sunset

Tragacanth gum is made from the dried root sap of several species of the legume *Astragalus*. Another organically available emulsifier, thickener, and stabilizer is gum arabic, which is nearly identical to tragacanth gum, according to the original petitioner. Organic gum arabic is readily available from organically produced acacia trees. Therefore, tragacanth gum is not essential as a non-organically produced product allowed in organics.

Marsala and Sherry - Sunset

The Cornucopia Institute contacted the original petitioners of marsala and sherry, Fairfield Farm Kitchens, and they are no longer using these cooking wines in their products. Organic sources of marsala- and sherry-like wines (like Organic Wine Company in San Francisco) exist to meet any change in demand for marsala and sherry in organic products. Therefore, marsala and sherry should not be relisted under §205.606 because they are not essential and organic alternatives are available. If marsala and sherry are relisted, Cornucopia recommends an annotation to prohibit fortified wines that contain added sulfites such as sulfur dioxide or potassium metabisulfite.

CONCLUSION

Materials should not be relisted without up-to-date Technical Reviews. The Handling Subcommittee should request TRs for these four materials prior to considering them for relisting. Discussion of sunset materials at NOSB meetings should be postponed until after the new TRs are available for public review. Finally, the Handling Subcommittee does not have the authority to act on behalf of the full NOSB; therefore, it should propose that all materials NOT be relisted.

MATERIALS SUBCOMMITTEE

Update of Petition & Technical Review Process

This proposal has two parts:

Part 1. Procedures for Submitting National List Petitions
Part 2. NOSB PPM Proposed Revisions

Cornucopia supports the changes as detailed in Part 1 and Part 2.

We suggest that additional procedures should be established to facilitate collaboration between the NOP and the NOSB in the choosing of third-party experts to provide technical reviews. For example, one part of the procedure is "*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*." This is an excellent procedure, but additional explanation covering the following questions would be helpful:

- Are there specific questions that the subcommittee answers to complete this assessment?
- Is this review shared with other members of the NOSB?
- Is the review shared with the NOP?
- How does the NOP use the information?
- If the report by a third-party expert is deemed inadequate, what are the consequences?

We believe it is extremely important to ensure that the technical experts have the required expertise, both in their specific technical field (such as food additives, poultry production, etc.) and in organic certification. The USDA has recently reviewed the expertise of contractors for the technical reviews. It is not clear whether the NOP has reviewed the expertise of employees from other USDA agencies.

The PPM states:

Third party experts can consist of the following:
• Employees from other USDA agencies such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed.

If the expertise of these USDA agencies has not been rigorously established, in a manner similar to the process used for review of contractors, then it is essential that their

reports be thoroughly reviewed by NOSB subcommittees, and those reports should be sent to the NOP.

OFPA gives the NOSB authority to procure a technical review (TR). The Board should take control of the selection process to ensure that contractors are qualified and impartial.

Confidential Business Information in Petitions

Cornucopia supports Recommendation 1 of the Materials Subcommittee:

CBI [confidential business information] 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.

It is the responsibility of Board members to have all the information needed to fully evaluate petitions and proposals. As stated in the PPM:

It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board.

The only way that Board members can fulfill this responsibility is to prohibit CBI in petitions.

We do not support the modified version of this recommendation—to allow back-up research and references to be submitted as CBI to assist the TR development. If research is confidential, the TR will not be able to use it. They will not be able to identify the source, except perhaps as confidential information submitted by the petitioner. Since the technical experts are expected to provide unbiased, scientifically verified information, any conclusions based on CBI should not be part of a technical review.

Research Priorities

We agree with the research priorities presented in the proposal.

Due to recent increases in the planting of genetically engineered crops, and the difficulty of obtaining unbiased scientific information about the effects of those crops, we suggest that research on genetic engineering be given a high priority.

Fate of Genetically Engineered DNA in the Environment

Organic farmers are allowed to use compost from conventional crops. Does the transgenic DNA survive the composting process?

Organic farmers are allowed to apply manure from conventionally raised livestock. Do the bacteria in conventional manure carry the transgenic DNA from conventional feed? Even if this fresh manure is applied 90 or 120 days before harvest, is it possible that the GE DNA remains active? What times and temperatures would be needed to inactivate GE DNA, for example in the process of heat-treatment of poultry manure?

Currently there is a three-year transition period from conventional to organic agriculture. If a conventional farmer has been growing GE crops, and now has a field infested with herbicide-tolerant weeds, is a three-year transition sufficient? Clearly the genetically engineered traits are heritable, and have been transferred from the crop to weeds. Can those traits be transferred from the weeds back to organic crops?

There is a clear understanding that pollen from GE crops can contaminate non-GE crops. What isolation distances are needed? Should organic inspectors and ACAs verify that the isolation distances are maintained?

POLICY DEVELOPMENT SUBCOMMITTEE

The following comments were submitted for the Fall 2013 NOSB meeting. This is an in-depth analysis of the NOP-directed changes to the NOSB Policy and Procedures Manual (PPM). They provide insight into the fundamental changes made by the NOP. We strongly believe that all changes should be made only by the NOSB with public input. According to meeting notes from the Executive Subcommittee, the Policy and Procedures Manual remains the guiding document for the NOSB.

The Policy Subcommittee has an extremely important responsibility to ensure the integrity of the process by which the NOSB makes decisions. The organic industry was built with grassroots support, and continues to benefit from broad stakeholder involvement. The NOSB, because it represents a diversity of organic stakeholders, must be the driving force behind any fundamental policy changes. Comments made at meetings of the Policy Subcommittee indicate that the members of the Board are willing to assume this responsibility for direct involvement when significant changes are proposed.

From the Policy Subcommittee meeting notes on July 9, 2013:

"Three participants emphasized that the NOP be direct about changes and reasons for changes, and work collaboratively with the NOSB."

It's unclear from the notes whether this refers to the overall changes to the Policy and Procedures Manual (PPM), or whether it refers only to subcommittee work plans. It is clear, however, that three of the six members are requesting collaboration with the NOP, and transparency in all interactions. Our interpretation of OFPA is that the NOP should be **asking** the NOSB for advice, not **directing** their activities. Indeed, we believe that the NOP is required by law to ask for and accept the recommendations of the NOSB.

Additional comments from the Policy Subcommittee meeting notes on July 9, 2013 related to the recent changes to the Sunset review process echoed the same theme:

"Members feel that any amendments to NOSB procedures should be developed collaboratively and must be vetted through the Subcommittee, Board and public. A member noted that there appears to be a departure from the collaborative process with regard to changing Board policies."

Cornucopia fully agrees with the sentiments expressed by NOSB members above. We appreciate their willingness to honestly and clearly articulate their viewpoints.

PPM Updates – Administrative

The Policy Subcommittee Proposals available on the NOP website list Administrative Updates and Miscellaneous Updates as two separate proposals. The changes proposed under Miscellaneous Updates are clear, because they have been highlighted. The changes proposed under the Administrative Updates are not clear, because they have not been highlighted in the PPM included in the proposal.

The proposal before the full NOSB states:

"The Policy Development Subcommittee (PDS) proposes to update and revise various administrative components of the PPM, including organization, formatting, sentence structure, grammar and syntax."

According to this statement, none of the proposed revisions should be a change in policy or change in meaning of the text in the PPM. Unfortunately, without a complete listing of the revisions, it is difficult to independently verify that there is no change in meaning.

Clearly, the Policy Subcommittee has done an extraordinary amount of work in revising the PPM, and we applaud their efforts. Now, as the full Board prepares to vote on these changes, it is imperative that the Board fully understand those changes. The only way to verify changes would be to compare the original document available on the NOP website with the revised document attached to the proposal. Until this is done, the Board should not approve this proposal.

Reject this proposal. Review and vote on changes item by item.

Rationale:

- The full Board must be made aware of each revision.
- The proposal does not have unanimous support from the Policy Subcommittee.

Although the proposal in its entirety should be rejected, it is possible to review the changes item by item. Accept those changes to the PPM that adequately capture the original intent. Reject the changes that change the meaning of the PPM.

The full Board must be made aware of each revision

We believe that the Policy and Procedures Manual is fundamentally sound. The sentence structure, grammar, and syntax are clear. However, in respect for the work of the Policy Subcommittee, we support revisions that do not change the meaning of the original document. We agree with the subcommittee's proposal in that there are a few places where the organization of the document can be improved, and we support those changes.

Specifically, we support the revisions listed in the proposal in Examples 1, 2, and 3. These changes should be considered eligible for voting because they have been clearly communicated to the entire Board and the public. Other changes should not be voted on at this time—especially without the opportunity for stakeholder review.
We oppose any revisions that do change the meaning of the document.

The Proposal does not have unanimous support from the Policy Subcommittee

The subcommittee vote on this proposal was:

Yes: 4
No: 1
Absent: 1

Only 4 members of the 15-member NOSB voted in favor of this proposal. If the changes are merely cosmetic, there should be unanimous support, but clearly a member has some reservations about these revisions. The full NOSB, and the public, should be privy to these concerns before a vote takes place. As this proposal comes before the Board for a vote, we urge you to listen carefully to the opinion of the dissenting member.

PPM Updates – Miscellaneous

The proposal before the full NOSB states:

> *"The NOSB Policy Development Subcommittee (PDS) proposes to update and revise various sections of the Policy and Procedures Manual (PPM)…."*

After review of the proposed revisions, it appears that substantive changes have been made that significantly affect the meaning of the PPM.

Reject this proposal.

If the proposal cannot be rejected in its entirety, then the changes must be reviewed item by item. Accept those changes to the PPM that adequately capture the original intent. Reject the changes that change the meaning of the PPM. Approve those that improve clarity.

Section III

Role of the Designated Federal Officer (DFO)/Advisory Board Specialist (ABS)

Election of Officers

Approve the proposed changes in Section III of the PPM. Minor changes were made in the above sections.

Section IV

Task Forces

Approve the listing of responsibilities in a bulleted list. Approve the clearly articulated list of responsibilities.

Reject the changes to the first sentence, because the proposed revision is not clear.

The proposal states that the revised version is:

"As determined by the Board or Executive Subcommittee and with approval/support from the NOP, task forces …"

The attached PPM states that the revised version is:

"With approval from the NOP, Task Forces may be appointed" (page 88 of 268)

This revised version should be rejected. It suggests that the NOP is taking undue control of the independent activities of the NOSB. The original wording of the first sentence

clarifies the fact that task forces should be first initiated by the Board, and then approved by the NOP:

"As determined by the Board or Executive Subcommittee and with approval/support from the NOP …"

Section V

Procedures for Completing Subcommittee Proposals and Discussion Documents

We agree with the majority of the proposed wording, but we suggest that step 4 needs to be removed. The proposed wording is:

"4. At any point in the process prior to the Board's vote a Subcommittee may convene and, by simple majority, vote to withdraw its proposal."

The proposed wording is substantially similar to the current wording in step 4:

"4. At any point in the process prior to the Board's vote on the status of the recommendation, the presenting committee may convene and vote to withdraw its recommendation, based on approval of this action by the majority of the members of the committee."

The intention of having a 15-member NOSB is to allow all members of the Board to vote on all proposals. We suggest that both current and proposed language may allow decisions to be made by a subcommittee, without approval from the full Board.

Allowing a subcommittee to withdraw a proposal may prevent the majority of the Board from voting on a proposal—for example, if an individual submits a petition to remove Substance X from the National List. The current procedure is that a Technical Report is commissioned, the subcommittee evaluates the substance, then votes on the substance, then finally brings their recommendation to the NOSB. The proposal may contain a recommendation in favor of or against the petitioned material.

The subcommittee should not be allowed to withdraw its proposal after they vote. This may result in subcommittees withdrawing proposals merely to prevent the full Board from overriding their position. For example, if a petition to remove a substance is discussed in a subcommittee, and they vote that the material should NOT be removed from the National List, the subcommittee can then vote to withdraw that petition, effectively making the decision for the entire Board.

Cornucopia understands that step 4 of these procedures was not part of the proposed changes. However, as the PPM is being revised, it is helpful to consider all changes that may be useful.

Section VII

Invited Speakers

Reject the revised wording to the Invited Speakers section of the document:

- The meaning of some statements has been changed.
- The statement "Invited Speakers must provide objective information" should be retained.
- The original Conflict of Interest statement should be retained.
- The original bulleted list is clearer than the revision.

Invited speakers must provide objective information

Despite the wording in the introduction of this proposal, the revised section on Invited Speakers has significantly changed the meaning of the PPM. The revised version **omits** this important statement:

"Invited speakers must provide objective information."

Further, we recommend that all Board members be instructed that the invited speakers are required to present objective information. If the speaker attempts to persuade the Board by expressing a personal opinion, any Board member may interrupt the speaker by saying "point of order," and may express objections to the speaker's bias.

We believe it is important to insist on the objectivity of invited speakers. The meeting information on Miscellaneous Updates includes this statement:

"The sentence 'Invited speakers must provide objective information' was struck from this section as the NOP noted that there are situations in which speakers are invited because they hold a differing view."

The above statement is objectionable for three reasons.

First, it appears that the impetus for changing the policy came from the NOP, not the NOSB. <u>The NOP should not attempt to direct the NOSB to change the policies in the PPM.</u>

Second, the objectivity of the invited speakers maintains a professional atmosphere focused on impartial research and investigation. When providing speakers with extended time to present information, such as 20 minutes or a full hour, asking them to be objective seems a minimum requirement.

Third, the NOP stated "*speakers are invited **because** they hold a differing view*." We hope that speakers are invited because they have in-depth knowledge of the subject matter, not because of their individual viewpoints on a particular subject. It may be necessary to remind invited speakers that members of the public are allowed only a brief time (3

minutes) to publicly express their views, despite the fact that public citizens may "*hold a differing view*." Invited speakers are welcome to express their differing views during the public comment period, but not during their invited speaking slot.

Please reject the revised wording. **Retain** the original statement *"Invited speakers must provide objective information".*

Speakers must disclose Conflict of Interest

The original wording in the PPM states:

"Speakers must disclose any actual or perceived conflict-of-interest including information about who may have provided funding for the presentation."

This statement is clear and unambiguous; it should not be changed. It is important for members of the NOSB, and the public, to know who provides funding for the invited speakers' research and presentation. This is consistent with the expectations of those providing limited public comment.

In contrast, the proposed statement is ambiguous. The proposal does not define the term *reasonable*, as in "*financial interests that … can reasonably be assumed to influence his or her presentation content.*" Our definition is that **any** financial support can reasonably be assumed to influence the speaker's presentation content; therefore, any funding must be disclosed.

All speakers before the NOSB are asked to provide their affiliation, even when they only provide 3 minutes of public comment. In the past, Board members have asked for the affiliations of speakers who are members of the public when these individuals have neglected to provide the information. Clearly, this is important for Board members, and invited speakers should be willing to be completely transparent in their interests.

Speakers must be approved by the NOSB

The PPM makes it clear that the NOP must approve all invited speakers, as noted in statement 3. The PPM does not clarify that the NOSB must approve all invited speakers. Several of the proposed revisions appear to suggest that the NOP may invite speakers without consulting the NOSB. We believe that requests for speakers **should** be initiated by the NOSB, although the request **may** be initiated by the NOP. Regardless of who initiates the request, all speakers require approval by the NOSB.

We recommend that the following statement be added to the PPM:

Speakers must be approved by the NOSB.

PPM Updates – Conflict of Interest

The proposal states:

> *"The current policy and practice in force for the disclosure of an interest (DOI) for a determination of a conflict of interest (COI) for the National Organic Standards Board (NOSB) are contained in a National Organic Program (NOP) memo entitled 'Conflict of Interest Guidelines' dated March 29, 2013."*

We urge the NOSB to reject any attempts to include these guidelines in the PPM.

Cornucopia has several concerns with this memo:

- The NOSB must be given authority to determine conflicts of interest.
- The NOP failed to collaborate with the NOSB in publishing that memo.
- The COI process must be transparent.

For clarity in this discussion, we refer to the policy in the recent memo as the "NOP Policy." We refer to the policy that has been used in the past by the NOSB, the policy currently in the PPM, as the "NOSB Policy." We avoided using the term "current policy" as there appear to be two different current policies: one in the NOP memo and another in the NOSB PPM.

NOSB must be given authority

The proposal states:

"Option A gave decision authority to the NOSB, whereas the voted-upon Option B acknowledges NOP as the sole decision-maker. Those who supported Option A felt that it provided clearer guidance to the COI process and left determinations less to the discretion of the NOP. They also supported a procedure that required disclosure of interests to the full Board and the public, rather than only the NOP, in the belief that decision making of a board of representatives requires input from all perspectives, but also the recognition by other Board members of the perspectives from which differing opinions come."

Clearly, the NOSB prefers to accept the responsibility for determining conflicts of interest.

NOP failed to collaborate with NOSB

The NOP memo was written without the input from the NOSB, and is contrary to their express opinions. For that reason, we believe the memo should be redacted, and replaced by a policy that does reflect NOSB support. At the current time, the procedures in the PPM should be followed.

It is clear that the NOSB wants to have input in the COI determination. The proposal states, "*The majority of the PDS members preferred Option A"* [which gives authority to the NOSB].

At this time, it appears that the NOP continues to prevent collaboration. According to the proposal:

"[T]he NOP noted that the PDS would be precluded from putting forth option A for public consideration and NOSB determination (because of its conflict with the NOP memo)…"

In other words, the Board is given no opportunity to advise the NOP. The responsibility of the NOSB is to evaluate information and make recommendations to the NOP. The NOP should not prevent the NOSB from initiating a public discussion and public vote on an item where they clearly desire to have input.

The COI decisions must be transparent

The proposal states:

"The updated COI policy upon a DOI should provide greater transparency and confidence in Board decisions by the organic community."

We agree that any updates to the COI policy **should** provide transparency. The policy in the NOP memo **removes** transparency; thus, it should not be included in the PPM.

The NOSB policy allows any potential COI to be discussed publicly—all NOSB members understand the interests and conflicts of other members. The information is available to Board members and organic stakeholders, through the transcripts of the NOSB meetings. The NOSB policy is transparent.

The NOP policy states that potential conflicts are reported to the NOP Associate Deputy Administrator. The NOP will determine whether a conflict exists. This process is not transparent. Only the final decisions are announced.

Although the NOSB is being administered under FACA rules, this merely provides an operational framework. The NOSB was established by Congress through OFPA and endowed with specific statutory authority. Thus, the FACA rules cannot legally override responsibilities given to the NOSB through OFPA.

Comments on Individual Recommendations

#1 - Approve

#2 - Modify
We suggest the following addition (in bold):

(2) a former employer or a prospective employer **or your current employer**
(6) **You, or** a close family member

#3 - Reject
We believe that the individual Board members do have a responsibility to the organic community and the public at large, as well as to the interests of the group they serve. This explains why there is a conflict of interest. We prefer the existing PPM language that states:

"The Duty of Loyalty requires Board members to exercise their power in the interest of the public and not in their own interest or the interest of another entity or person. A Board member's loyalty is to the organic community and the public at large."

#4 - Reject
Retain the current wording under Conflict of Interest in the PPM:

"Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote."

We understand that this is contrary to the NOP memo. It is the responsibility of the Board to determine their own COI policies that allow members to fulfill their duties as Board members.

#5 - Reject
This recommendation merely repeats the wording of the NOP policy. We support the NOSB in retaining the NOSB policy.

#6 - Approve
We support the disclosure of names of technical review authors:

"All technical reviews should disclose the names and address of all authors on the first page of the TR below the TR title."

We suggest that the "address" might be replaced by "work address" or "employment affiliation," but the current wording is acceptable.

#7 - Reject
Keep the original language. It clearly advises Board members to "[a]ddress conflicts of interest". The suggested language change is not clear.

#8 - Reject
Keep the original language, which requires Board members to disclose any "direct financial interests" to the Board. The suggested language change merely states that

Board members must follow the procedures in the NOP memo. Since the Board did not develop the NOP guidelines, the Board should not, in good conscience, vote in favor of adding them to the PPM.

#9 - Reject
The paragraphs currently in the PPM provide an excellent discussion of conflict of interest, based on years of experience. The statements are still valid:

"Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain."

There is no value in deleting this statement, and the accompanying explanation, from the PPM. Please **retain** all four paragraphs on COI that are currently in the PPM.

It may be desirable to expand the definition of COI beyond a direct financial gain, based on the guidelines in the NOP memo. We suggest that the Policy Subcommittee should prepare a suggested language change, based on the NOP memo, to be included in the PPM in addition to the above language.

In all cases, we suggest that it is preferable to include all explanations in the PPM, rather than referring to NOP memos. The prospective reader, a Board member recently appointed to the NOSB and inundated with new information, will be more likely to read an explanation included with the PPM, rather than referring to a separate document (NOP memo).

#10 - Reject
The existing PPM language states that members with a potential or perceived conflict of interest **must** disclose that to the Board. This maintains transparency.

#11 - Approve
The recommendation appears to suggest that the existing language should not be changed. We support retaining the existing language.

CONCLUSION

We believe that it is important to preserve transparency on the question of conflicts of interest. The following items are requirements to maintain transparency:

- The NOSB should determine policy at full Board meetings that are open to the public.
- Potential or perceived conflicts should be disclosed to fellow members of the Board before discussions or voting occurs.

Since the NOSB members are the people who are most affected, they should be the ones who write and implement the policy. We ask that the NOP abide by the opinions of the NOSB.

Nothing we are stating here should suggest that having a conflict of interest, in itself, is an ethical problem. It has been long established that certain stakeholders are expected to have conflicts from time to time on the NOSB. But not disclosing these conflicts, in a transparent manner, publicly, is a problem. And members voting on materials and issues that directly benefit them personally, or their employers, should not hesitate to remove themselves from the process if conflicts, or the impression of conflicts, exist.

PPM Updates – Sunset Process

On September 16, 2013, a notice was published in the Federal Register entitled *National Organic Program – Sunset Process.* The National Organic Program (NOP) sunset policy published in the Federal Register violates OFPA, because it does not subject National List materials to the required reassessment. The policy was a reversal of long-standing accepted procedures. This change in policy was undertaken without public comment and without the participation of the NOSB.

The NOP additionally requested that the Board support this unilateral decision. In a memorandum dated September 13, 2013, the NOP requested that the NOSB take the following action:

"…update the NOSB Policy and Procedures Manual so that the manual reflects the Sunset Process published in the Federal Register."

Cornucopia urges the Policy Subcommittee to **retain** the sunset process as it stands in the Policy and Procedures Manual (PPM). The Board is not required to support a sunset policy that violates the intent of Congress (OFPA). Indeed, it is the Board's responsibility to act in accordance with OFPA.

We agree with the following statement by Beyond Pesticides:

"We urge NOSB members to oppose petitions for new synthetic chemical uses at this Fall 2013 NOSB meeting and until the sunset process is reinstated. We are especially concerned about the lack of public transparency and input on all decisions related to organic and the long-term viability of the USDA organic label as consumers begin to increasingly distrust the process and the lack of NOSB authority to conduct a public assessment to determine whether materials should be relisted every five years."[111]

Rationale:

The Sunset Process published in the Federal Register was a reversal of accepted procedures for maintaining the National List. This change in policy was undertaken without public comment and without the participation of the NOSB.

The NOSB was established to advise the NOP

The purpose of the NOSB according to the Organic Foods Production Act*:*

Sec. 2119. [7 U.S.C. 6518] National Organic Standards Board:

[111] Beyond Pesticides. Downloaded on Sept. 20, 2013 from http://www.beyondpesticides.org/organicfood/action/Fall2013-action.php

(a) In General.-The Secretary shall establish a National Organic Standards Board … to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title.
(k)(1) The Board shall provide recommendations to the Secretary regarding implementation of this title.

This indicates that it is the responsibility of the NOSB, not the NOP, to determine sunset review procedures. OFPA does not give authority to the NOP to advise the NOSB.

This responsibility is restated in the PPM:

NOSB-NOP COLLABORATION
The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the Act. In 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution responsible for this and is the means through which ***the NOSB provides advice and assistance to the Secretary of Agriculture****. (emphasis added)*

Policy established in 2005 should be retained

Previous policy allowed materials to be removed from the National List if they were not approved by the full Board. The NOP stated, in a memorandum dated March 4, 2010:

"If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited."

This policy should remain in effect.

In order to retain materials on the National List, a vote of two-thirds of the members present has been required. This policy should remain in effect.

Previous policy required the entire Board to discuss and review each material during the sunset procedure. As stated in OFPA, the NOSB has a responsibility to review materials. In other words, the entire Board must review each material, not just the subcommittee. This policy should remain in effect.

The review of materials for the National List must be conducted with the most up-to-date, impartial scientific information. Previous Boards have often requested a current technical evaluation report, and that TR has been available for public review, before voting on the material. This practice should be continued.

In their meetings, the Policy Subcommittee has expressed reservations about the process of altering a fundamental NOSB policy.

The minutes of the Policy Subcommittee from July 9, 2013 include the following:

"The Subcommittee is not clear about how to proceed with regard to the materials the NOP shared about modifying the Sunset review process. The NOP indicated that the program is interested in the NOSB's informal feedback about this, but that if the Subcommittee wants to work on it as a Discussion Document, the Executive Subcommittee would first need to approve it for addition to the workplan.

Members feel that any amendments to NOSB procedures should be developed collaboratively and must be vetted through the Subcommittee, Board and public. A member noted that there appears to be a departure from the collaborative process with regard to changing Board policies and the intended Discussion Document was a way to begin those conversations.

Opinions about this were mixed; one member noted that his preference would be to wait until any NOP policy is released and respond then, while another member added that it would be advantageous for the NOSB to weigh in prior to the release of anything. **With regard to the Sunset process, the member felt that it would have been useful to have a group conversation so the NOSB could have provided input.**

The NOP indicated that both the NOP and NOSB have responsibilities under OFPA, and that some NOP policies are independent of NOSB procedures. A member felt that the Sunset process was initially built collaboratively and they would like to have further discussions about this before it is implemented. The Chair noted that the topic will be revisited on the Executive call on Friday." (emphasis added)

We believe that the NOP's notice in the Federal Register should be retracted.

Appendix 1.

Antibiotic Use in Organic Apples and Pears

Results of a survey conducted by The Cornucopia Institute
April 2013

The Cornucopia Institute conducted a survey of 764 organic apple and pear producers in February and March of 2013 to determine their practices for control of fire blight. The survey was sent to all Cornucopia organic farmer-members producing tree fruit and all identifiable growers on the USDA's National Organic Program database. We received 85 responses (11%). Of those, 72 were apple growers; 32 were pear growers (some farmers grow both). The responses from apple and pear growers were tabulated separately.

The survey respondents represented a diversity of farm sizes, organic experience, and geographic locations. The acreage under organic cultivation ranged from 1 to 800 acres of apples, and from 1 to 600 acres of pears. Some farmers grew up to 800 acres of conventional tree fruits, in addition to their organic acreage.

Table 1. Overview of respondents

	Apples	Pears
Number of responses	72	32
Acres of organic fruit	1 to 800	1 to 600
Percent with conventional tree fruit	31%	28%
Acres of conventional fruit	Zero to 800	Zero to 800
Years of organic certification	2 to 30	1 to 25

Responses were received from the following states: California, Colorado, Illinois, Iowa, Maine, Massachusetts, Michigan, Montana, New York, North Carolina, Oregon, Pennsylvania, Tennessee, Vermont, Washington, and Wisconsin.

Results
When growers were asked if they used tetracycline or streptomycin, the majority of growers responded that they used only one antibiotic, although some used both antibiotics. The following questions are paraphrased from the survey. Results are indicated as percent of respondents. (The number in parentheses is the number of respondents.)

Do you use antibiotics on your organic apple or pear trees?

	Apples	Pears
Yes (streptomycin or tetracycline)	44% (32)	66% (21)
Tetracycline	24% (17)	53% (17)
Streptomycin	32% (23)	22% (7)

No	56% (40)	34% (11)

How often do you spray antibiotics to control fire blight?

	Apples	Pears
Never	56% (40)	34% (11)
Once every few years, only if needed	25% (18)	31% (10)
Every year	7% (5)	3% (1)
Several times a year	13% (9)	34% (11)

What practices do you use to prevent fire blight?

	Apples	Pears
Biological controls	21% (15)	34% (11)
Blossom thinning	39% (28)	34% (11)
Resistant rootstocks	31% (22)	28% (9)
Resistant apple or pear varieties	32% (23)	19% (6)
Bordeaux mix (copper sulfate / lime)	36% (26)	19% (6)
Limited nitrogen fertilizer	35% (25)	44% (14)

How would a prohibition of antibiotics affect you?

	Apples	Pears
No effect	44% (32)	31% (10)
Use more biological and cultural controls to prevent fire blight	19% (14)	25% (8)
Stop growing organic fruit, switch to conventional fruit production	28% (20)	25% (8)
Stop growing organic fruit, but grow other organic crops	0%	0%
Stop growing certain varieties of organic fruit	15% (11)	19% (6)
Stop farming altogether	1% (1)	0%
Lose money	15% (11)	25% (8)

DISCUSSION

The purpose of this survey was to provide information as to whether antibiotics are essential for fire blight control in apples and pears. The data strongly indicates that antibiotics are not essential, because 56% of apple growers and 34% of pear growers responded that they do not use these antibiotics. More specifically, the data indicate that antibiotics are not essential for organic apple production, because only 24% of apple growers reported using tetracycline and 32% streptomycin.

Recent research has indicated that a combination of blossom thinning and biological controls are as effective as antibiotics in managing fire blight[112]. Yet, only 21% of apple

[112] Johnson, K. 2013. *Research Update on Non-antibiotic Control of Fire Blight.* Webinar date March 19, 2013. www.extension.org/organic_production

growers and 34% of pear growers indicated that they use biological controls. This indicates that effective controls are available, but they are not being widely adopted by organic growers. Orchardists simply prefer to use antibiotics, perhaps due to lower cost or the need for fewer sprays. Orchardists who were previously engaged in conventional production may simply be continuing to use techniques that they have found successful in the past.

The discussion of antibiotics in tree fruits has parallels with antibiotics in livestock. When the abolition of antibiotics was first proposed in organic dairy production in the early 1990s, organic farmers claimed it would be impossible to produce milk without their arsenal of antibiotic drugs (mostly to treat mastitis). After the prohibition against antibiotics went into effect, dairy producers concentrated on preventing mastitis and, when necessary, treating cows with herbs and other alternative measures. Today, a thriving organic dairy sector exists without the use of antibiotics.

What will happen if antibiotics are prohibited in organic apples and pears? At this time, 63% of apple growers and 56% of pear growers will continue to grow organic fruit, based on the respondents who stated that the ban will have no effect or will require them to use more organic and cultural controls. As research on alternative fire blight management continues for the next two years, this percentage will likely increase. Based on these numbers, we question whether antibiotics are essential for organic tree fruit production.