October 1, 2013

National Organic Standards Board  
Attn: Ms. Michelle Arsenault, Special Assistant  
1400 Independence Ave. SW, Room 2648-S  
Washington, DC 20250  

Docket: AMS-NOP-13-0049 (submitted via regulations.gov)

Center for Food Safety Comments to the NOSB

The Center for Food Safety (CFS) is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our membership has rapidly grown to include over three hundred and fifty thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

Our comments address the following issues: sunset policy; streptomycin; synthetic methionine in organic poultry feed; aquaculture synthetic materials (chlorine, tocopherols, trace minerals, and vitamins); conflict of interest; and confidential business information.

Introduction

Over the course of the last six months or more, the Center for Food Safety (CFS) has been surprised and disappointed to witness the National Organic Program's (NOP) increasing efforts to limit the powers of the National Organic Standards Board (NOSB). Its usurpation of control has been most notably demonstrated in the NOP's recent Policy Memos on the "Sunset" Review of the National List of Allowed and Prohibited Substances. These actions, issued as edicts via “NOP policy memos,” were made in the absence of any public input, undermining the participatory bedrock of organic policy-making since the Organic Foods Production Act’s (OFPA) inception in 1990. They not only restrict NOSB’s authority to deliberate and make recommendations on behalf of organic stakeholders, but they also have created a veil of opacity in organic policy-making that contravenes the spirit and intent of OFPA.

Organic food and farming practices that often predate and inform OFPA emanated from the wider organic community with stakeholder interests in pursuing the growth and development of a healthy, environmentally sustainable, humane, and transparent food system. They sought to define organic as an alternative model for securing our nation’s food future. While not everyone supported codifying organic practices into law, there was a strong stakeholder drive to collaborate in the creation of unified standards that would ensure the organic industry’s authenticity as it grew. Passage of OFPA, and the establishment of a stakeholder advisory board (NOSB) charged with continuously improving organic, have helped to maintain organic’s authenticity and integrity.

The ongoing success of this unique public/private partnership model depends upon the unprecedented authority and autonomy given to the NOSB Federal Advisory Committee Act (FACA) Board, under OFPA. An NOP need to “streamline” NOSB decisions is no excuse for undermining that foundational intent of the law. On the contrary, it is the unbridled public participation, transparency in policy-making, and stakeholder buy-in to the organic policy development process that keeps organic strong and authentic. Announcing that organic policies are “on display for public inspection” in the Federal Register hardly meets the public participation requirement of notice and comment under OFPA. Moreover, moves to “streamline” the National List petition process, based upon NOP decree rather than a robust public participation process serve to undermine organic farmer, consumer, and wider organic community confidence in the National Organic Program.

We urge the NOSB to reclaim its authority over conflict of interest decisions at its biannual meeting in Kentucky in October. We further urge the Board to reassert its authority over the National List (NL) and the review of materials destined for inclusion or sunset, in conversation with the NOP. The integrity of organic policy making depends upon it, as is further described and illustrated in these comments.

**Sunset Policy**

Given the recent and surprising NOP Sunset Policy announcement that completely alters the existing sunset process, CFS felt compelled to share our thoughts on this issue during the public comment period for the upcoming NOSB meeting.

CFS strongly urges the NOSB to request that the NOP rescind its latest Sunset Policy. Not only does it contravene OFPA’s robust public participation provisions, it also inappropriately takes authority over the National List (NL) away from the full NOSB. Any other significant Sunset Policy changes should be subjected to public review and comments, as is expected by the organic stakeholder community. Placing a new and final Policy in the Federal Register “on display for public inspection” rather than for soliciting

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public comment, as is the case with the NOP’s recent Sunset Policy Memo, reduces public confidence in the fair and transparent operations of the NOP.

**NOP Changes Sunset Policy from Materials Removal to Materials Renewal**

The new NOP policy reverses the sunset process, which had been in effect since the implementation of this section of OFPA in 2005. Instead of strengthening the sunset procedures to facilitate expeditious removal of synthetics from organic, the new policy makes it even easier for synthetic and non-organic chemicals to remain on the National List indefinitely.

The new policy directly contradicts NOP’s longstanding sunset policy presumption that the reliance on synthetic and non-organic materials will, for the most part, decrease over time. As recently as 2010, NOP stated: “NOSB has the responsibility and authority to add substances to the National List... Both approved and prohibited substances that appear on the National List are reviewed every 5 years by the NOSB to either renew the listing or recommend that the substances are removed from the List.”

The intent of the policy was that producers would work to phase out NL materials as alternative practices are developed or organic substitutes become available.

As correctly explained by the NOP in a 2010 memorandum:

The NOSB has the responsibility to review materials in a timely manner. The NOSB is responsible for making a recommendation regarding whether the listing of an exempted material should be **renewed or removed** during the sunset review. In the absence of a recommendation, the NOP will initiate rulemaking to **remove** [emphasis added] the substance from the National List.6

If the **renewal** process was not completed by the sunset date, the use of the material automatically became prohibited. Now that processes has been completely reversed.

**Subcommittees Gain More Influence than Full NOSB**

NOP’s latest Sunset Policy has turned this decision-making process on its head. First, it changes the default position from removal to renewal. “If the Subcommittee determines that a substance should remain on the National List, and there are no proposals to remove the substance, then the Subcommittee’s preliminary review moves to the next step in the process. The Subcommittee does not vote on a motion to retain a substance on the National List.”7 Instead, the material, by default, remains on the NL without any review, public comment, or full NOSB member deliberation. Yet, Subcommittee deliberations are

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6 McEvoy M. 2010.
an important part of the documentation trail that informs the NOSB when a given material is again reviewed prior to the next sunset.

If Subcommittee members decide to recommend removal of the substance from the NL, only then is the full Board given a chance to evaluate the material. But, if the Subcommittee decides to take no action, then the material is silently renewed without announcement or solicitation of public comment. Even if the Subcommittee recommends the removal of a given material, then a two-thirds majority must vote to remove the material. This directly contrasts with the former Sunset Policy whereby the full Board votes on whether to retain the substance on the NL with a two thirds majority.

Unfortunately, this results in effectively reversing the long-standing policy of limiting synthetics and non-organic substances. It also puts the authority over the National List in the hands of Subcommittees instead of the full Board. This new policy does not promote a full review of materials from the full range of board members and their stakeholders, thus missing an important component of NOSB reviews and violating OFPA.

CFS finds this policy to be highly irregular in that it directly contradicts OFPA, which designates the NOSB—not a subsection thereof—as the final arbiter of the National List and the materials review process.\(^8\)

**Burden is Removed from Material Users**

The NOP’s supposed “streamlining” of the sunset process no longer requires those promoting synthetics to prove, *inter alia*, that synthetics “will not have adverse impacts on the environment,” and that they are “essential for the handling of organically produced agricultural products.”\(^9\) It also places a heavy burden on environmental groups, consumer groups, and Subcommittee members to bring forth new information and prove that synthetics have negative impacts warranting their removal. This eliminates the financial incentive for producers to seek organic alternatives by providing them with the security of having synthetics languish on the NL indefinitely. Changing the policy in this way undermines the spirit of continuous improvement that has positively characterized the evolution of the National Organic Program.

The other major shortcoming of the new policy is that it now forces annotations to be made through the petition process, not during sunset, making it even more difficult to phase out materials. Annotations at sunset have been used effectively by the NOSB to ratchet down or restrict the use of certain materials while alternatives are developed or become available. This process is a useful mechanism to provide some flexibility to organic producers while also responding to concerns about materials in particular products or the way they are used.

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\(^8\) 7 U.S.C. § 6517 (e).
\(^9\) 7 C.F.R. §§ 205.600(b)(2) & (6).
**NOP Sunset Policy Must be Rescinded**

Framing sunset review as a “renewal” process rather than a “removal process” changes the way sunset has worked since the inception of OFPA. This attempt to streamline sunset actually distorts the system of checks, balances, and robust public participation created by Congress. CFS strongly urges the NOSB to request that the NOP rescind its latest Sunset Policy and immediately commence discussions with the NOP about how they can work together to create a policy that honors the public participation tradition and intent of OFPA with respect to the Sunset process.

**Streptomycin**

Center for Food Safety opposes an extension for the use of streptomycin in apple and pear orchards beyond the current expiration date of October 2014. Streptomycin does not meet the review criteria required under OFPA for substances to be added to the National List (NL). In fact it never has, but now the evidence is even stronger to support sunsetting streptomycin once and for all.

In 2011, the Materials Subcommittee determined that streptomycin failed to satisfy all three review criteria. Even though the Subcommittee recommended against its extension, the full NOSB voted to extend its use until 2014. That decision included an explicit expectation that the industry would work to identify alternatives. Despite the NOSB’s clear intent to end its use, the current Crops Subcommittee has recommended yet another extension. What is even more perplexing is the fact that the Subcommittee now decided that streptomycin does satisfy all the materials review criteria, even in the face of mounting evidence about the environmental and health risks of continued spraying in orchards. Subsequently, the Subcommittee has again recommended extending the approval, again with the caveat that its use should end, saying that they are “committed to the phase out of this material.” This type of contradictory policy-making does little to bolster consumer confidence in the National Organic Program or the organic label.

**Streptomycin Must Be Phased Out Now**

Streptomycin use in organic orchards should not be extended because it is incompatible with organic systems and because it poses unnecessary threats to human health. The use of streptomycin contravenes the NOSB’s stated Principles of Organic, which emphasize promoting and enhancing “biological cycles” and “the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials.” The risks of using streptomycin are even clearer than those from using tetracycline, which the NOSB voted to allow to sunset at its April 2013 meeting. Scientists have shown that the mechanism for

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11 NOSB. 2011. Formal Recommendation by the NOSB to the NOP: Streptomycin Sunset.
streptomycin resistance in fire blight is directly applicable to human pathogens, meaning that the same gene gives both types of bacteria resistance. Fire blight resistance to streptomycin is also already widespread in orchards, so this resistance gene is present as a result of spraying. These two details are less clear for tetracycline. With the phase out of tetracycline scheduled for October 2014, it is especially important to maintain consistency by not extending the allowance for streptomycin. If streptomycin use is permitted beyond October 2014, some growers in areas without streptomycin resistance could turn to using it instead of tetracycline for fire blight control, enhancing resistance opportunities and streptomycin use.

The Crops Subcommittee acknowledged the differences between tetracycline and streptomycin by including a section in their report describing the contrasts. Every point raised emphasized that the adverse impacts of streptomycin are even stronger than tetracycline. Given the extensive debate at the April 2013 NOSB meeting that led to a vote to phase out tetracycline, it is clear that the NOSB agrees that antibiotics do not belong in organic and it should phase out the use of streptomycin as well. Organic systems should not be furthering the non-essential use of this important antibiotic.

**Antibiotic Resistance Develops and Spreads**

The use of streptomycin is inconsistent with organic principles and practices, predominantly because it inevitably contributes to incidences of antibiotic resistance in bacterial populations. Streptomycin resistance to fire blight is widespread in orchards where it has been used, rendering it ineffective in those locations. Its impacts are long-lasting as well. In fact, such resistance has been detected in orchards up to ten years after the spraying has stopped.

Resistance to streptomycin can occur either as a random mutation or as acquired resistance from another bacterium. Horizontal gene transfer -- a process by which bacteria can pass on plasmids or other traits that confer resistance to one another -- allows for resistance that develops in orchards to move out into the wider bacterial population. It occurs readily between various species of bacteria and is the primary means by which antibiotic resistance is spread. This mechanism means that any use of antibiotics contributes to the pool of resistance by selecting for resistance and then allowing it to move between different bacteria. When bacteria are exposed to antibiotics, susceptible bacteria die and those with resistance survive and increase their incidence of conjugation (gene transfer) with other bacteria, enhancing the spread of antibiotic resistance. For this reason, infectious disease experts worldwide have called for an end to any unnecessary

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uses of antibiotics to retain their effectiveness in treating human diseases.\textsuperscript{19}

Resistance to streptomycin has already been identified in the fire blight pathogen, \textit{Erwinia amylovora}, in many orchards, including plasmid-borne resistance across the U.S.\textsuperscript{20} Genes carried on a plasmid are very susceptible to horizontal gene transfer between bacterial species. Several researchers have documented how streptomycin resistance spreads through bacteria, contributing to our certainty that resistance can spread from orchards.\textsuperscript{21} Use of streptomycin is likely to result in a greater diversity of mobile resistance genes in orchards that can be transferred amongst bacteria.\textsuperscript{22} This means that there are more genes available to other bacteria, and potentially pathogens, that confer resistance to streptomycin.

\textit{Antibiotic Resistance Negatively Impacts Human Health}

Antibiotic resistance has been identified as a major human health concern by many health-based organizations, including the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).\textsuperscript{23}

The CDC recently issued a report on antibiotic resistance, stating that its purpose is “to increase awareness of the threat that antibiotic resistance poses and to encourage immediate action to address the threat.”\textsuperscript{24} Unnecessary uses of antibiotics in all sectors contribute to the development of antibiotic resistance. Since streptomycin is considered a critically important antimicrobial for treating human infections, it is vital to curtail non-therapeutic uses of this drug.\textsuperscript{25} Organic operations absolutely should not be contributing to the development of antibiotic resistance and the loss of effectiveness of this important medical tool in any way.

The plasmid genes for resistance to streptomycin in the fire blight pathogen, \textit{Erwinia amylovora}, are the same as the genes that cause antibiotic resistance in many human pathogens.\textsuperscript{26} Thus, development of resistance within an ecosystem can and does contribute to resistance in human pathogens. This critical link in our knowledge of how streptomycin use can affect resistance among human pathogens is acknowledged in the Crops Subcommittee report.\textsuperscript{27} Horizontal gene transfer between unrelated bacteria can pass resistant genes between orchard species and human pathogens or simply create a

\textsuperscript{25} World Health Organization. 2011.
reservoir of resistance in the environment that can later be passed on to pathogenic species. There are a number of mechanisms that can move microbes out of the orchards and into human communities, including dust on fruit, airborne dust, and dirt on workers’ shoes. These clear linkages between orchard microbes and human pathogenic communities exist, even when they are not directly exposed to antibiotics.

**Streptomycin Impacts Soil Microbial Ecosystems**

Spraying antibiotics in orchards may disrupt the microbial ecology of soils and agroecosystems, which runs contrary to organic’s mandate to ‘maintain or improve’ ecosystems and build healthy soil. The bioavailability of streptomycin in any given location will vary depending on local environmental factors including physical soil type, nutrient availability, and others. Therefore, streptomycin may have a stronger effect or be more persistent in certain areas than others. In several laboratory studies, streptomycin was found to have negative effects on microbial ecology ranging from inhibiting nitrification to significant reductions in total bacterial count and the elimination of several bacterial species. While this suggests that streptomycin use in orchards could have a negative effect on the microbial ecology of soil systems, no field studies have yet confirmed this finding.

Streptomycin is moderately persistent and highly mobile in aerobic soils, so its biological activity can continue to impact soils after spraying has occurred. Streptomycin is a strong algicide and is labeled to prevent application to water bodies. However, algae may be present in soils and streptomycin is vulnerable to leaching, so it could impact nearby water bodies from orchard use. These potential effects from use of streptomycin in orchards are incompatible with the philosophy that underpins organic systems, namely to build soil fertility and biodiversity.

**Alternative Management Techniques Exist**

Phasing out streptomycin will remove only one of the available tools farmers can use to manage fire blight. The severity of fire blight varies in different years and regions depending upon weather patterns, rain, and humidity; thus requiring a range of techniques for control. No one tool, including antibiotics, can fully control it. With widespread resistance to streptomycin already present in orchards, growers have already had to find alternative controls. Combinations of techniques, including biological controls, limiting soil

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29 7 CFR 205.200
35 NOP. 2011. Lines 225; 294-299.
moisture and the use of manure, pruning, thinning orchards, and planting new orchards with wider tree spacing and disease-resistant varieties can be utilized to manage fire blight damage.\textsuperscript{36}

New biological control products are also entering the market place. While some growers reported mixed success with Blossom Protect during the 2013 growing season, apparently this was due to an unusually warm season in those regions, which increases the activity of fire blight. Unusually harsh weather conditions in a given year will impact crops with different disease pressures and possibly curtail yields. But, any one control strategy should not be dismissed in light of a particularly challenging growing season. The most effective alternative controls require an integrated approach including cultural practices, attention to fire blight prediction models, and alternative biological control products.

One clear example of the success of alternative management techniques is demonstrated in orchards that produce fruit without using antibiotics. There are a number of US orchards that supply organic markets (such as the European Union and Canada) that prohibit the use of antibiotics. These orchards have been successful in mitigating fire blight damage, proving that alternative control techniques can be effective in the absence of antibiotics.\textsuperscript{37} This information must be documented and circulated to organic and pear growers across the country to aid them in the control of fire blight. Once all organic growers cease using antibiotics, they will have the added advantage of accessing those markets as well.

\textbf{Consumers Do Not Expect Antibiotic Use in Organic}

Consumers do not expect antibiotic use in any sector of organic production, especially given the clear and widely marketed prohibition of their use in livestock rearing. Consumers choose to buy certified organic food because they want to support systems of production that protect and enhance human health and the environment. They also expect their organic food to be grown without the use of antibiotics, growth hormones, genetically engineered organisms, and synthetic herbicides and pesticides.\textsuperscript{38} Continuing to allow streptomycin, which has even clearer adverse impacts than tetracycline, will only cause confusion and disillusionment among consumers when they learn that their tree fruit is still being treated with antibiotics. Consumers have made it clear that they do not support the continued use of antibiotics in organic tree fruit, with 30,498 signatories to our petition on the public record calling for NOSB to oppose another extension to the sunset date for streptomycin.\textsuperscript{39}

In addition to concerns about antibiotic resistance development, residues of streptomycin have been identified on treated fruit.\textsuperscript{40} This represents an added concern for consumers.

\textsuperscript{36} NOP. 2011. Lines 601-617.
\textsuperscript{37} NOP. 2011. Lines 671-701.
\textsuperscript{39} Please see the text of our petition, attached as Appendix A and submitted to the public record docket.
that even goes beyond the concerns they already had about the use of tetracycline in orchards, because tetracycline residues have not yet been found in fruit from those orchards. The highest concentrations of streptomycin were found in the apple core and skin. Although the residues identified are below EPA limits, organic consumers do not expect any residues of antibiotics in the organic fruit they buy.\textsuperscript{41}

In order to maintain the integrity of the organic label and its unique position in the marketplace, the NOSB must not extend the use of streptomycin. A strong commitment from the NOSB to uphold the 2014 expiration date would send a meaningful signal to organic consumers that the NOSB is committed to continual improvement, as per the regulatory charge of the National Organic Program.\textsuperscript{42} We strongly urge the NOSB to reject an extension for the use of streptomycin in apple and pear orchards and vote to eliminate the use of antibiotics in organic once and for all.

**Synthetic Methionine in Organic Poultry Feed**

CFS opposes the methionine proposal put forth by the Livestock Subcommittee. Contrary to its conclusion that the overall usage of methionine will be lowered with this approach, overall methionine use will largely remain the same. Moreover, if this recommendation is implemented, the sunset clock will be reset, allowing methionine to languish on the National List for another 5 years.

Methionine users have already had 12 years to identify alternative, natural sources of this essential amino acid. Its run on the sunset treadmill must come to an end. Methionine use is a symptom of a larger problem—some organic egg and poultry production facilities may just be getting too big to adhere to organic principles. Yet, the NOP has been turning a blind eye to the problem as evidenced by its failure to promulgate animal welfare regulations with provisions requiring poultry to spend time outdoors. This situation serves to further perpetuate the use of synthetic methionine. Instead of continuing to allow this synthetic feed additive that props up over-crowded organic poultry and egg production systems, it is incumbent upon the NOSB to force an end to its use. We urge the NOSB to vote against additional modifications to the synthetic methionine listing.

**Methionine Usage Will Not Decrease With This Proposal**

There is no disputing the fact that methionine is an essential amino acid vital to proper cell growth in omnivores. Nonetheless, it is only absolutely necessary for maintaining maximal growth, and not entirely necessary in and of itself for maintaining animal health and well-being.\textsuperscript{43} Synthetic methionine provides a cheap alternative to an omnivorous diet rich in

\textsuperscript{41} NOP. 2011. Lines 242-244.
\textsuperscript{42} 7 CFR §205.200.
natural methionine from insects, worms, or alternative protein sources, but as explained by CFS in past comments and reiterated here, methionine use is controversial. Nevertheless, the Livestock Subcommittee’s recommendation continues to indulge poultry producers’ desires for more methionine rather than push the industry to find ways to live without it.

It is disheartening to see that just one year after the NOP codified and implemented the “step down” rates, the Livestock Subcommittee is still promoting high amounts of synthetic methionine by altering the way methionine rates are expressed, rather than allowing for its use to end. While the current methionine listing sets a maximum level in poultry feed, the Subcommittee is now recommending that feed rates are expressed as an average per ton of feed over the life of the flock instead of just per ton of feed. CFS disagrees with the Subcommittee’s conclusion that “[o]verall usage of [methionine] will be lowered. Producers can only add [methionine] to the average cap, not consistently add [methionine] at the maximum rate.” In fact, this is not the case. Producers could add methionine to feed at the maximum rate consistently throughout the flock’s life. And, if a producer uses feed lower in methionine during a portion of a flock’s life, then they could use feed with more methionine at a later date.

**Congress Intended Sunset to Phase Out Materials on the National List**

Approval of this petition would extend methionine’s sunset date, directly contradicting the NOSB’s step down approach and the purpose of OFPA’s sunset provision. If the subcommittee’s recommendation is approved, methionine will not be subject to removal until 2018—another five years. At that point, synthetic methionine would have resided on the National List for 17 years.

Congress intended the National List to handle the “few limited exceptions” in organic production. Accordingly, it created the sunset provision to guarantee that these limited exceptions were reviewed every five years and cycled off the list when organic alternatives were found. The drafters of OFPA created the sunset review process to ensure materials are removed unless, after extensive review, two-thirds of the NOSB votes to renew the materials for another five years. Then, after those additional five years, the material would sunset. Imposition of a firm sunset date drives innovation and research by members of the organic community and promotes the common goal of continuous improvement of organic products.

Yet, the sunset provisions are not working the way Congress intended. Instead of promoting innovation and advancing research, the sunset process is now akin to a recycling program, promoting repetitive renewals and very limited removals. For example, methionine has been on the National List for 12 years and it will have been on the List for

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44 Rack et al. 2009, at 55; Goldfarb et al. 1981. Organic Chemicals Manufacturing Hazards (Ann Arbor Science Publishers Inc.) (Methionine is commercially synthesized by condensing acrolein and methyl mercaptan. The resulting compound is reacted with ammonia and hydrogen cyanide to form a racemic mixture of the d and l isomers of methionine.).

16 years by the time it is currently scheduled to sunset. If it takes organic innovators more than 15 years to implement a natural alternative to synthetic methionine, then the sunset provisions of the National Organic Program are clearly no longer functioning.

To add insult to injury, the NOP’s new Sunset Policy issued September 19, 2013 makes it even easier for synthetics like methionine to languish indefinitely on the National List. As discussed elsewhere in these comments, the default of the new policy is to keep materials on this list instead of taking them off, as per the original intent under OFPA. This supposedly streamlined process allows substances to stay on the National List unless Subcommittee members take action to advocate for their removal by bringing the material before the Board for a vote.

Methionine’s continual renewal on the National List represents a classic example of the sunset process gone awry. It also contravenes Congress’s intent of establishing the National List in the first place. The NOSB’s role vis a vis the sunset process must be to promote research and innovation in order to keep the organic program alive and continually improving. One clear way to do this is to follow through with sunset dates which will force the market to step in to create solutions. This is especially true in cases such as methionine where there are proven, feasible alternatives for organic producers. If there is a culture of constantly renewing chemicals sunset after sunset, this will never happen.

The Organic Community Must Make Research a Priority

CFS applauds NOSB for not giving organic producers the option to feed omnivores animal by-products or meat scraps after last year’s debate. However, the conversation does not end there. We strongly believe that the NOP must eliminate synthetic methionine in poultry production without compromising organic integrity. In order to do so, poultry feed must be supplemented with natural sources of methionine such as meat, worms, insects, organically certified fish meal (if it becomes available), organic milk powders, organic corn-gluten meal, organic sunflower meal, organic potato meal, and natural-based dietary supplements, which need further study. Animal welfare regulations are urgently needed as well to ensure that poultry are required to go outdoors and have access to pasture. CFS recommends that the Livestock Subcommittee work with the NOP to develop clear research goals and a timeline for finding any additional natural and safe alternatives to synthetic methionine that the larger producers may need. This will allow NOSB to permanently eliminate synthetic methionine from organic production within the next four years at sunset.

CFS remains in favor of both government and privately-funded research on the efficacy and availability of naturally-derived methionine sources but we are not aware of any recent government-funded research projects that promote natural methionine alternatives, despite the demonstrated need and the impending sunset. Consumer groups are not responsible or capable of brokering the necessary relationships with researchers to develop lasting solutions. NOSB and NOP must coordinate and collaborate with USDA to
encourage the allocation of government research dollars to finding natural alternatives to the use of synthetic methionine that enhance organic integrity in poultry production.

As CFS and others have repeatedly expressed, there are several alternatives to synthetic methionine that must be explored. CFS urges NOSB and NOP to promote all efforts to research the efficacy and availability of these natural sources, including:

- Research worms and insects as alternative protein feed sources
- Research on increasing production of organic corn-gluten meal
- Research on increasing production of organic potato meal
- Research on increasing production of organic sunflower meal
- Research on natural methionine supplements such as the herbal supplement produced in India
- Research on the recently discovered African plant sources high in methionine
- Research on sources of organic fish-based amino acids once they become available
- Research on shifting feed rations to balance amino acids
- Research on the optimum space/methionine complement that can work for US poultry producers

These alternatives are by no means new ideas. They have existed and been used by farmers for generations. It is time that the NOSB and NOP promote these tried and true methods along with other innovative ideas instead of creating excuses for producers because they are resistant to implementing alternatives.

**Large Scale Flock Production Requires Chemicals—This is Not the Intent of OFPA**

The continuous use of synthetic methionine is a symptom of a larger problem that is increasingly seen in organic egg and poultry production. Some operations are simply too big to comply with the National Organic Regulations let alone adopt proposed improvements to animal welfare standards. Large-scale production facilities often house more than 100,000 birds, severely limiting the animals’ opportunity to engage in natural pecking and rooting behaviors or access the outdoors, shade, shelter, exercise areas, and fresh air. In order to preserve the integrity of organic animal production, standards must be set now that keep practices on organic farms consistent with the spirit and intent of OFPA.

Isolating the use of synthetic methionine in a fishbowl glosses over the big picture. Feeding animals synthetic amino acids to promote maximum growth is not consistent with the spirit and letter of OFPA. It also does not promote optimal animal welfare in organic animals. Using synthetic methionine as a crutch to promote large-scale industrialized production of poultry is plainly antithetical to organic principals. Organic agriculture is a systems approach and, therefore, the NOSB cannot isolate and promote synthetic methionine without looking at the system it supports. Increasing pressure to raise more
poultry on less space drives producers out of the pasture and into animal factories. This hurts the organic brand and label.

For years, CFS has promoted the introduction of animal welfare standards in organic poultry production. Now, it has become clear that after years of deliberation and public comment the NOP does not plan to move ahead with the implementation animal welfare regulations for organic poultry anytime soon. The NOP has stated that “[g]iven other urgent priorities at this time, we do not anticipate addressing the NOSB proposals on animal welfare in the near future.” But, we disagree with the prioritization of the NOP. Animal welfare is a priority and one of the pillars of organic animal production systems. The adoption of stringent standards for animal welfare would force better poultry management practices by requiring ready access to the outdoors, soil contact for animals, vegetative cover, and more space per bird, etc. These very minimal changes would have an enormous impact not only on the welfare of poultry by encouraging them to roam on pasture but also by helping producers transition away from their current dependence on synthetic methionine.

As a strong champion of organic, CFS is discouraged by the continued allowance and reliance upon synthetic methionine in poultry production. We urge NOSB to deny the petition for an extension of methionine use and urge the greater organic community in the interim to implement and continue to develop novel solutions to provide poultry greater nutritional quality without the use of synthetic amino acids.

**Aquaculture Synthetic Materials**

**(Chlorine, Tocopherols, Trace Minerals & Vitamins)**

In the absence of final regulations in place to govern organic aquaculture systems, CFS strongly urges the NOSB to deny all petitions to add materials to the National List (NL) for use in organic aquaculture systems. Approving substances for use in an organic aquaculture system that does not yet exist would be arbitrary and capricious, unlawful agency action.

Evaluating substances within the context that they are used is key to the NOSB materials review process. Without final regulations to govern organic aquaculture, it is impossible to meaningfully assess the necessity or essentiality of synthetic tocopherols, trace minerals and vitamins in fish feed, which are the subject of three of the Aquaculture Working Group’s (AWG) petitions. If you don’t know which species of fish are being grown, where, or whether the system is open or closed, how can you possibly begin to determine their feed requirements? The fourth AWG petition, for the use of chlorine, also has little meaning outside of the systems context. For all of these materials, it is impossible to judge the environmental and human health impacts without knowing the system within which they are being used. Therefore, the NOSB must not consider any petitions for organic aquaculture materials until regulations have undergone public review and comment and they have been finalized.
The implementation of the NOP’s new Sunset Policy will make it even more difficult to remove materials from the NL or annotate them in the future if the Board finds it necessary. This provides yet another argument for denying the petitions and for being even more cautious about allowing new materials on the NL.

While eventually there may be vital synthetic or non-organic materials that are approved for use in organic aquaculture systems, at this point it is premature to make those types of decisions. We urge the NOSB to deny any petitions for aquaculture materials before aquaculture regulations are finalized. The risks to the organic label and markets are far too great to get it wrong.

**Fukushima Radioactivity Casts Further Doubt on Organic Open Ocean Aquaculture**

A required aspect of organic production systems is the ability of farmers to control inputs and outputs. Yet, the presence and unpredictability of toxic pollutants in the marine environment makes any attempt to implement and regulate organic aquaculture in the open ocean exceedingly difficult. In addition to the well-documented presence of PCBs and mercury in ocean sediments and fish, the threat of radionuclides in the ocean environment has emerged from the recent Fukushima nuclear disaster. Farmed fish can be exposed to these radionuclides via ambient ocean water and contaminated food sources. What is most concerning for ocean-based aquaculture systems is that the radioactive plume is moving towards the U.S.

Radiation from Fukushima continues to leak into the ocean. Cesium-134, cesium-137, and cobalt-60 from Fukushima have been detected in fish, soil, and marine plant samples from Japan. Tritium and strontium-90 have leaked into the ocean in sizable quantities as well. With half-lives ranging from 5-30 years for the more hazardous cobalt, strontium, and cesium, these radionuclides will be present in the Pacific for decades to come.

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47 Personal communication. 9/11/2013. Marco Kaltofen. Boston Chemical Data Corp.


51 According to the EPA, if swallowed or inhaled, cobalt-60 is absorbed in the blood, liver, kidneys, and bones.

52 According to the EPA, strontium-90 is linked to bone cancer, cancer in the soft tissue near bone, and leukemia.

53 According to the EPA, exposure to cesium-137 resulting from nuclear accidents results in cancer risks much higher than typical environmental exposures.
come. Models of radiation transfer in the ocean have predicted that radiation will reach the U.S. West Coast by 2014 and mix to depths of 1500 meters.

Fish can absorb radionuclides from both the surrounding water and contaminated food sources. Farmed fish in open-ocean net pens fed diets consisting of wild-caught species are therefore doubly susceptible to contamination. Research has demonstrated that contamination in larger fish species occurs most significantly through the food chain, as radiation is readily absorbed from the surrounding water by sediments, seaweeds, and plankton. Studies have also concluded that is possible for concentrations in fish tissue to exceed that of the ambient water as radiation bioaccumulates in the food web. Predatory fish species near Japan continued to contain cesium levels exceeding regulatory limits more than one year after the event. Also, contaminants may remain in the feces or other detrital particles that settle to the seafloor, again accumulating in sediments and potentially reentering the food chain.

Although radionuclides are excreted rapidly at first, a significant percentage may persist in tissues for much longer. Concentrations of Fukushima-derived radioactivity have persisted longer than researchers initially hypothesized, even in fish that left Japanese waters. For example, blue fin tuna caught near California were unable to completely eradicate radioactive cesium from their tissue despite their journey across the Pacific.

Other large, carnivorous, and migratory fish species will likely have similar difficulty.
excreting Fukushima radioisotopes, especially as the marine food web and ambient water continue to be sources of contamination.

The presence in the marine environment of these artificial radioisotopes—by-products of human-made nuclear reactions—means that farmed fish in open-ocean net pen facilities may concentrate low levels of radiation in their bone, blood, organs, muscle, and other tissue. This is even more likely if farmed fish are fed wild-caught marine fish meal and fish oil, further compounding the difficulties of strictly regulating organic aquaculture systems. It also makes it harder to ensure the differentiation of organically farmed fish from its conventional counterpart in the marketplace.

**Aquaculture Regulations Must Support Organic Integrity**

These concerns about contamination from radioactive particles only exacerbate the importance of creating strong organic aquaculture regulations. For over a decade, the government has solicited public input and internally debated about what constitutes a certified organic aquaculture system. Critical questions asked of the organic community include: Where should such systems be allowed to operate? Should they be open or closed? What are the underlying requirements of the system? What types of fish should be allowed or prohibited? What types of feed would be appropriate for organic fish? And the list goes on.

CFS has been consistent in its response about what is required by OFPA and in line with good governance:

- **Open ocean nets and facilities must be prohibited** because fish escapes are inevitable, as we have documented in our past comments to the NOSB. Exposure to toxic pollutants is unpredictable and unpreventable. Concentrated feeding and excrement loads in the marine environment from such facilities adversely impact local ecosystems and alter the natural feeding behavior of marine life in the vicinity of the facility.

- **Farmed fish must be fed only 100% organic feed**, the gold standard that OFPA requires for all other certified organic livestock, as reflected in the Organic Rule.

- **No wild fish meal or oil can be fed to organically farmed fish** because it may be contaminated with toxic chemicals. Harvesting wild fish also negatively impacts marine ecosystems because species used for fish meal and oil provide an important food source for marine mammals, birds, and other fish.

- **Migratory fish such as salmon can never be farmed organically** because closed facilities severely inhibit their natural behavior to migrate and spawn in inland waters.

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64 7 USC §6509 (c)(1)

65 7 CFR §205.237
• **Recirculating, closed-loop, inland facilities should be tested** first to see if it is possible to manage them as certifiable organic systems. They are preferable to open ocean-based systems because they allow fish farmers to manage inputs and outputs and minimize impacts on natural ecosystems. Nonetheless, these systems are diverse and complex and their regulation must be carefully crafted and tested.

This position is also supported by our National Organic Coalition colleagues and 14,882 signers of our petition calling for NOSB to deny the aquaculture materials. Unfortunately, this call has fallen on closed ears thus far. In addition to denying the AWG petitions, we are again urging the NOSB and NOP to reconsider the former Board’s recommendation, which allows open ocean facilities, wild fish meal and oil, and even salmon to be grown in pens. That former NOSB recommendation, in addition to being contrary to good public policy, is unlawfully contrary to the organic standard’s plain language and requirements. It also runs counter to the high organic integrity that we believe should be upheld by organic policymakers and the organic industry.

Upholding organic integrity means **not** allowing the certification of organic aquaculture systems that:

- clearly degrade the marine environment,
- violate of the basic requirements of OFPA and,
- undermine consumer expectations about organic.

It is impossible and unlawful for the NOSB and NOP to assess the inclusion of particular substances for use in organic aquaculture unless and until specific USDA organic aquaculture regulations have been promulgated. Attempting to approve any substances in the absence of a regulatory frame for their use would be plainly unlawful. For these reasons, we urge the NOSB to reject the petitions for tocopherols, vitamins, trace minerals and chlorine for use in organic aquaculture systems.

**Conflict of Interest**

CFS strongly disagrees with the NOP’s decision to remove all discussions and decisions about NOSB members’ potential conflicts of interest (COI) out of public view and behind closed doors. This runs counter to the transparent culture and tradition of organic policy-making and the intent of OFPA. Holding COI discussions in private undermines the purpose of requiring COI disclosures in the first place—namely to ensure public accountability and checks and balances on NOSB decisions.

CFS does not support the Option B recommendation of the Policy Development Subcommittee (PDS), but rather urges the Board to vote in favor of its originally preferred Option A, which retains NOSB control of COI disclosures and discussions. We strongly believe that bi-annual NOSB public meetings are the appropriate venue for having this

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66 Please see the text of our petition, attached as Appendix B and submitted to the public record docket.
conversation and settling these issues. Moreover, we support requiring COI disclosures to also take place during all Subcommittee meetings where votes are taken, prior to voting.

As an organic stakeholder, CFS has been highly supportive of the PDS’ ongoing efforts to update its COI policy and procedures in direct response to the stakeholders’ requests. We are also appreciative of the PDS’ acknowledgement of the need to ensure COI disclosures by Technical Report authors, an issue that CFS has repeatedly raised in its comments on COI.67

**Potential Vested Interests Must be Publicly Discussed**

CFS agrees with the PDS’ statement that “disclosures of interest to the full board and the public, rather than only the NOP,68” is the appropriate course to follow. We further support their observation that “decision making of the board of representatives requires full input from all perspectives, but also the recognition by other Board members of the perspectives from which differing opinions come.”69 Well-informed and transparent, public policy-making has always been the foundation of organic rulemaking and an important aspect of maintaining organic integrity.

People within the organic community who regularly participate in the NOSB process understand that the very nature of this stakeholder Board is that its representatives are comprised of individuals with direct expertise, experience, and personal, organizational, and/or corporate stakes in the outcomes of Board decisions. Within this context conflicts of interest are bound to arise, yet it is the personal or corporate economic gain that is most relevant for deciding what constitutes a conflict of interest and the need for a vote recusal.

CFS strongly supports open, public discussion during Board meetings about potential conflicts of interest, even if the discussion does not lead to a recusal from a vote. This should be required of all NOSB members, regardless of their affiliation (corporate, NGO, university, government, etc.). It is worth emphasizing that disclosure of COI is not intended, and does not render the comments of those with an announced COI less important, it merely ensures member transparency and fairness in the decision-making.

We view the process of requiring each Board member to voluntarily and publicly disclose potential conflicts of interest as the best way to ensure the highest possible integrity in organic policy-making. It allows members to show respect for the decision-making process and to maintain trustful, collegial relations in a supportive environment where everyone lays their cards on the table before a vote. It sheds light on the stakes of Board members

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with a potential economic gain so their vote can be viewed and judged in that light by other Board members and the public.

**Non-profit Organizations Act in the Public Interest for the Public Good**

When considering COI with respect to non-profit organizations or NGOs (non-governmental organizations) in particular, it is important to differentiate them from profit-making entities. NGOs historically have been viewed as providing public benefits that are an essential aspect of civil society. They take over a full range of public burdens that that government is simply incapable or unwilling to shoulder. In return for their specific activities undertaken for the public benefit, NGOs receive a tax exempt status. See I.R.C. § 501(c)(3). This is one of the clearest and obvious ways that NGOs can be differentiated from for-profit entities:

> [t]hrough these [NGO] organizations, citizens can resolve societal problems and enhance the quality of life for all, without channeling all problem-solving efforts through government...The exemption for charitable organizations is, then a derivative of the concept that they perform functions which, in the absence of organizations, government would have to perform. Therefore, government is willing to forgo the tax revenues it would otherwise receive in return for the public services rendered by charitable organizations.\(^70\)

Members of the boards of public interest groups have a fiduciary duty to consider the public interests groups’ missions in their decision-making.\(^71\) Thus, the inherent structure of public-interest organizations and the purpose behind their tax-exempt status require that NOSB board members of such groups represent the public interest, and minimize the risk that the members act on behalf of individual or private interests.\(^72\)

In fact, as early as 1924, the Supreme Court discussed the government’s rationalization for exempting certain organizations from taxes: “[e]vidently the exemption is made in recognition of the benefits which the public derives from corporate activities of the class named, and it intended to aid them when not conducted for private gain.”\(^73\) Therefore, even if an NGO receives funding from an individual or company, the donation is to fund work done on behalf of the organization for the public good and not for individual gain or for the profit-making of its shareholders. This distinction is an important one and the reason why COI considerations must be viewed differently for NGO representatives than for representatives of for-profit entities.

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\(^{70}\) Rationales for Tax Exemptions, Part One. Section 1.2. Pages 8-9.

\(^{71}\) Armenian Assembly of Am., Inc. v. Cafesjian, 772 F. Supp. 2d 20, 103 (D.D.C. 2011).

\(^{72}\) See Trinidad v. Sagrada Orden de Predicadores de la Provincia del Santísimo Rosario de Filipinas, 263 U.S. 578, 581 (1924) (stating that public interests groups’ tax-exempt status rests on “the recognition of the benefit which the public derives from the corporate activities” of such groups)

NOP Policy Memo Dismisses the Importance of COI Disclosures

We absolutely see no reason why, at this point in time, the NOP finds it necessary to hide conflict of interest disclosures and discussions behind its closed doors. Keeping such discussions in the public eye ensures that no deals are cut or irregularities occur. When decision-making authority is solely granted to the NOP, neither the NOSB nor the public are privy to the basis upon which such decisions are made. This is certainly not what CFS envisioned would be the final COI Policy.

Contrary to statements made in the NOP Memo, CFS believes that “interests” are not inherently acceptable or unacceptable. What concerns us most is when secondary interests conflict with the execution of the primary interests. In this case, the primary interest of the NOSB is decision making in support of OFPA implementation. It is not merely the “appearance” of conflicts that are important, but also the “actual” conflicts. Because all stakeholders have “interests,” deliberations about which interests and conflicts cross the line into affecting good decision-making must be left to the Board itself. Given the evidence that NOSB members have been incredibly forthcoming in their discussions throughout the years, we see no reason to justify the need for changing the process at this point in time.

As a respected NGO with 350,000 supporters nationwide, CFS finds the NGO COI example in the NOP Memo particularly problematic. It is indicative of a wholesale lack of understanding by the NOP of the multiplicity of contributions that NGOs make to civil society and how NGOs fulfill their stated mission with tax exempt contributions from the public at large. We find the following example inaccurate, as discussed below this excerpt from the NOP Memo:

Two months before a Board meeting, this same non-profit organization receives a large ($5,000+) donation from a special interest group that has expressed a strong position on a topic being considered at the upcoming NOSB meeting. This would likely be considered a conflict of interest, as a reasonable person is likely to assume that such a large donation from a specific group could reasonably be seen as a gift given to shape a Board member’s decision.74

We completely disagree with this assessment. On the contrary, people, foundations and other NGO supporters generally give donations to support the causes and issues about which they care most and have a strong opinion. In the example above, there is nothing at all suspect about the fact that “a special interest group that has expressed a strong position on the topic being considered” gave a donation to an organization that supports their point of view. That is the case even if the Director of that organization is a Board member. What would be suspect is if an NGO had inexplicably changed its position on record close to a Board meeting, and it was later determined that the “special interest group” asked for the change in return for their contribution. In either instance, it would be highly irregular if

the small sum of $5,000 persuaded a reputable NGO to change its stance on an issue. And, if an NGO did that, it would not be highly reputable for long.

Reject the PDS Proposal and Support Public Discussion and Disclosure of COI

We believe that the goal of the NOSB’s COI policy should be to facilitate the open, transparent, and equitable functioning of the Board as a whole by distinguishing those instances of genuine financial gain from instances where it would be inappropriate for a certain individual to cast a vote.

We urge the NOSB to reject the NOP COI Guidelines currently being imposed upon the Board. They have not been aired in public or had the benefit of stakeholder input, which is the convention routinely followed under OFPA. CFS recommends that the Board return to considering Option A. We further urge the NOSB to work with the NOP in drafting a mutually satisfactory discussion document for public input at its April 29-May 1, 2014 meeting.

Confidential Business Information

CFS wholeheartedly supports the recommendation of the Materials Subcommittee to eliminate the provision for confidential business information from the Materials Petition. As aptly put by the Subcommittee, “the importance of transparency of the petition process, the right of the public to fully know the materials included in or on certified organic process, and the potential for an untenable administrative burden of management CBI” is reason enough to not allow CBI claims in petitions to add a substance to the NL.

Thank you for your consideration of our remarks.

Respectfully submitted by:

Lisa J. Bunin, Ph.D.
Organic Policy Director

Paige M. Tomaselli
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Sarah M. Stevens
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Appendix A

Streptomycin Petition Text*

As an organic consumer, I believe that spraying antibiotics on organic apple and pear trees goes against the principles of organic. While the organic rules prohibit the use of antibiotics to treat livestock and poultry and to incorporate it into their feed, the exception for apples and pears is unacceptable and has gone on far too long.

Streptomycin and tetracycline are the only antibiotics that have ever been allowed in organic systems. Just as organic consumers have vehemently opposed the use of tetracycline, we want the use of streptomycin to stop as well.

Most concerning to me is the public health threat posed by the continued use of streptomycin. Once resistant genes are present in any bacteria, the pool of resistance increases and spreads. The most resilient bacteria survive and reproduce and that's how resistance grows. This increasingly diminishes the ability of antibiotics to treat human and animal infections. It is imperative that the NOSB act now to prohibit all antibiotics in organic.

I urge the NOSB to stick to the agreed upon end date of October 14, 2014 for streptomycin use in organic apple and pear production, and I strongly oppose an extension of any kind.

(Signed by 30,498 CFS Members)

*This petition was also submitted via regulations.gov to the public docket.
Appendix B

Organic Aquaculture Petition Text*

I am writing to urge the NOSB to deny any and all petitions for synthetic materials in organic aquaculture unless and until regulations to guide the development of organic fish farms are in place.

The Organic Foods Production Act requires that a rigorous review is conducted of all synthetic materials petitioned to be used in organic systems to ensure that they do not harm human or environmental health. Yet, without defining the system within which these substances will be used, it is impossible to adequately review their impacts.

I oppose allowing organic aquaculture in open ocean-based facilities because escapes into the wild are inevitable. In addition, farmed fish can carry diseases and parasites that would disrupt the ocean ecology in the vicinity of the aquaculture facility. By the same token, I do not support feeding farmed fish meal and fish oil from wild fish because toxins in the ocean cannot be avoided. The allowance of migratory fish, such as salmon, in aquaculture facilities must also be prohibited because such confined conditions would severely inhibit their natural behavior to migrate and spawn in inland waters. NOSB cannot simply ignore these concerns and begin the review of synthetic materials for a system of organic aquaculture that does not yet exist.

I urge the NOSB to wait until regulations have been finalized by the NOP to guide the development of organic aquaculture. These fundamental public concerns about the types and locations of organic fish farms and what fish are allowed to be farmed organically must be addressed before the NOSB votes to approve or deny any petitions for the use of synthetic materials.

(Signed by 14,882 CFS Members)

*This petition was also submitted via regulations.gov to the public docket.