CENTER FOR FOOD SAFETY

April 7, 2015

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

Docket: AMS-NOP-15-0002

Center for Food Safety Comments to the NOSB

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 five hundred thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

As a public interest organization intent on upholding the integrity of the Organic Foods Production Act (OFPA), CFS herby submits comments to the National Organic Standards Board on the following issues: synthetic methionine proposal, aquaculture regulatory history, copper, nanotechnology, excluded methods, chlorine, and GE contamination prevention.

Petition to Amend Synthetic Methionine Represents Business as Usual

CFS urges the NOSB to vote against the Livestock Subcommittee's proposal to support the petition from the Methionine Task Force (MTF) because it represents a step backwards for the organic poultry industry. The recommended increase in synthetic DL-Methionine (DL-MET) use for broilers, from 2 pounds per ton to 2.5 pounds per ton, combined with the failure to mandate a reduction in DL-MET use, contravenes previous NOSB decisions and public sentiment on the issue As underscored in the minority opinion, the petitioners have provided no scientific justification for their recommended increase. Moreover, the Subcommittee's recommendation fails to assert pressure on the organic poultry industry to take responsibility for the methionine phase-out by conducting feeding trials that contribute to the development of proven alternatives. Instead, this business-as-usual petition represents a thinly veiled

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attempt by large producers to stall implementation of necessary improvements in organic poultry production.

We urge the NOSB to vote against the MTF petition and allow DL-MET to sunset in October 2017, as scheduled. Viable alternatives to synthetic methionine currently exist, such as high methionine corn, whey powder, insect magmeal, and others. The main factor that limits their widespread adoption by organic poultry producers is the lack of available commercial supplies. A demonstrated demand for poultry feed containing non-synthetic, natural methionine is sorely needed to show feed producers that up-scaling their production would be welcomed by the organic industry. This demand would be strongly demonstrated by an NOSB decision to sunset synthetic methionine at its currently scheduled sunset date in two and a half years.

CFS and others have consistently challenged industry's claims that DL-MET is needed to protect animal health and welfare. Instead, poor welfare conditions are directly related to management practices that replicate aspects of the conventional poultry industry. Improper housing, crowded and stressful living conditions, lack of adequate outdoor access, and demand for faster growth all contribute to increased feather pecking and cannibalism that industry falsely attributes to reduced DL-MET. Research suggests that the primary purpose of DL-MET is to ensure that growth and development are not compromised in spite of these unhealthy conditions, not protecting animal welfare.

Petition Takes the Organic Poultry Industry a Step Backwards

In 2001, NOSB evaluated a TAP analysis of DL-MET against OFPA criteria for synthetics allowed on the National List (NL). While the Board determined that use of DL-MET supplements in feed were compatible with organic poultry production, it also expressed a strong preference for supplementing it with non-synthetic sources of methionine (MET).

NOSB and stakeholders agreed that the organic feed sector should continue to research and develop sufficient supplies of allowable organic and natural sources. Since that time, however, both NOSB and industry have devoted little research or resources to supporting viable natural alternatives to DL-MET and the temporary allowance of DL-MET on the NL has languished for over a decade.

In 2012, NOSB took a step in a positive direction by instituting a policy for phasing-out industry reliance on the synthetic input in an effort to "balance various interests." This included:

- (i) providing for the basic maintenance requirements of organic poultry;[1]
- (ii) satisfying consumer preference to reduce the use of synthetic MET in organic poultry production;[2] and
- (iii) motivating the organic poultry industry to continue the pursuit of commercially sufficient sources of allowable natural sources of MET."[3]

The new petition to express MET supplementation rates as averages over the life of the flock addresses none of the interests listed above. Expressing rates as averages is not necessary for maintaining basic bird health. It does not mark a reduction in synthetic MET use or provide adequate motivation for the poultry industry to pursue alternatives. The Subcommittee defends industry's insistence that expressing rates as lifetime averages still allows them to only *marginally* meet the birds' basic needs, and that this is what provides industry with a "tremendous" incentive to continue to pursue alternative sources,[4] yet provides no evidence to support this claim.

Production Interests Overshadow Expected Organic Poultry Industry Improvements

According to the petition, averaging MET limits allows producers to "address MET demands during different life stages, particularly when laying chicks first come into production." But what this really means in practice is that the averaging strategy allows producers to leverage the benefits of MET as a growth enhancer. It has little to do with caring for the basic health and well-being of birds. According to Dr. Walter Goldstein of the Mandaamin Institute, "Feeding synthetic methionine diets promotes animal productivity mainly by stimulating the production of a natural growth hormone (IGF-1) and a growth hormone receptor."[5] He argues that the hormonal effects of DL-MET are comparable to rBGH in dairy cows[6] and, therefore industry's reliance on the synthetic input is driven by economics and not, as industry representatives have suggested, concern for animal health and well-being.

Dr. Goldstein also notes that, "feeding synthetic methionine to stimulate production of growth hormones to push production is distant from organic, systems-based philosophy, and consumer

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[1] NOSB Livestock Subcommittee. (2015). *Synthetic Methionine (MET) in Organic Poultry Feed Proposal*. Revised January 31. p. 193.
[2] *Id*.
[3] *Id*.
[4] *Id*. p. 198.
[5] Letter from Dr. Walter Goldstein, the Mandaamin Institute, to the USDA National Organic Program. November 26, 2014. p 2.
[6] *Id*.

perception and expectations."[7] He argues that, "[a]s knowledge about methionine's role in IGF-1 production becomes public, it seems difficult to believe that synthetic methionine can continue to be used without backlash for the organic movement in general."[8]

MTF Claims that Suitable Alternatives are Unavailable is Unfounded
According to NOSB Livestock Subcommittee proposal, the MTF has invested significant time and money seeking viable alternatives for their industry in an effort to meet consumer expectations, but has been unable to find suitable alternatives to date. However, no elaboration or documentation of this investment of time or sources of information has been provided by MTF or NOSB. The organic community would benefit from seeing information about which alternatives were investigated by MTF, which providers were contacted, and what data were gathered

The Subcommittee proposal also incorrectly states that numerous projects around the world are evaluating herbal and insect based sources, but the need for FDA approval means these sources are years away from being available. That is not true. Insect based sources such as Enviroflight's soldier fly meal are already being sold, and FDA is in the process of certifying these products as "Generally Recognized As Safe" or GRAS. The remaining questions that need to be resolved are whether producers would be required to feed the insects 100% organic feed and whether they would need to become certified organic. CFS encourages NOSB to begin addressing these questions immediately.

The Subcommittee states that, based on "feedback from industry," the flexibility in adjusting diets to the particular demands of life stages will likely result in overall lower MET usage[9] without providing any data to support this claim. Such data gaps include:

- No feeding schedules to show how the methionine will be used over the life of the bird to demonstrate what the averages would look like in terms of total MET use.

- No estimates of total feed consumption per bird at each stage of production or the number of different stages of rations would be developed or how much DL-MET would be provided at each stage.

[7] *Id.* p 2.
[8] *Id.* p 8.
[9] NOSB Livestock Subcommittee. (2015).

For the sake of transparency, the MTF and the Subcommittee should supply some examples showing how the rations would be balanced over the lifetime of the birds demonstrating reductions in overall DL-MET would result.[10]

The Livestock Subcommittee's proposal argues that due to concern about the use of animal byproducts in feeds, organic consumers expect an all vegetarian diet for poultry. This demand for vegetarian-based production systems is cited as justification for the continued need for DL-MET,[11] the implication being that suitable vegetarian sources of MET are unavailable. The Subcommittee's logic is problematic and flawed in the following ways:

- Organic consumers are most concerned about organic poultry having regular and encouraged access to the outdoors and to not be overcrowded in barns. These management practices are what truly protect animal welfare.

- Organic consumers also expect that organic poultry are fed 100% organic diets free of synthetic inputs. To them that is what in large part makes organic, organic.

- Consumers also expect organic animals to be fed naturally suitable diets. Since chickens are omnivores, an organic diet must provide both plant-based and animal-based nutrients. Many plant-based sources of MET, such as organic potato protein, organic sesame meal, and organic expelled sunflower meal are all readily available. Animal-based sources of MET include insect meals (discussed later) and organic dairy byproducts, such as organic skim milk powder and organic whey powder. These products likely do not raise the same concern for consumers as slaughter byproducts, such as blood and bone meal. Research on developing acceptable levels of organic feed-based methionine in an organic poultry ration could begin immediately.

- These complex consumer expectations of organic are not addressed in the Subcommittee's considerations of the DL-MET petition.

[10] For example, assuming a growing (days 22-38) ration with 0.06% MET and a finishing (days 38-54) ration of 0.03% MET would allow the starter ration (days 1-21) to be as high as 0.55% (11 pounds per ton). This assumes a feed intake as recommended by the NRC and life stage divisions for fast-growing broilers as cited in an example in Fanatico, A. (2010). *Organic Poultry Production: Providing Adequate Methionine*. Butte, MT: National Center for Appropriate Technology (NCAT). p. 14.
[11] NOSB Livestock Subcommittee. (2015).

Industry Claims of Cannibalism with Reduced DL-MET not Supported by Science

Primary industry claim justifying continued use of DL-MET: *Producers and certifiers are seeing an increase in feather pecking which can lead to cannibalism, agitation, nervousness, and other behavioral issues, and claim this is a direct function of reduced MET, and preventable with DL-MET.*

- Cannibalistic behavior and severe feather pecking are functions of a production system that involves incredible stress and agitation. Substantial research attributes increased feather pecking behavior to other aspects of industrialized, poultry production systems, such as overcrowded living conditions, unnatural lighting, and the myriad stressors and abrupt transitions experienced by the birds.[12]

- A European Commission study found that "the animal welfare problems in broiler husbandry can be explained principally as side effects of a one-sided selection for growth and feed utilization…intensive broiler fattening with its high growth rates is not compatible with a satisfactory level of health."[13]

- A study from the University of Kassel in Germany found that adequate lighting conditions strongly increased natural scratching and pecking activity, and subsequently reduced feather pecking.[14]

- Poorly designed production systems also do not allow birds to express their natural foraging behavior, leading to excessive feather pecking.[15]

- Research from Wageningen University in the Netherlands demonstrated that the manner in which the birds access their feed is important for the expression of their natural foraging behaviors—pecking and scratching at the ground to obtain grubs, earthworms, and greens.[16]

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[12] Sundrum, A. et al. (2005). *Possibilities and limitations of protein supply in organic poultry and pig production*. University of Kassel: Organic Research Group. August.

[13] Sundrum, et al. (2005). p. 56.

[14] Sundrum, et al. (2005), citing Martin, G. (1991).

[15] Rodenburg, B. (2011). "Preventing feather pecking in laying hens," *World Poultry*, 29 March, 2011. Available at: http://www.worldpoultry.net/Layers/Housing/2011/3/Preventing-feather-pecking-in-laying-hens-WP008683W/; Trudelle-Schwarz, R. (no date). "Cannibalism: Chicken Little Meets Hannibal Lector?" *Stories of Applied Animal Behavior*. Launchberg, K., & L. Shipley, (eds). University of Idaho and Washington State University. Available at: http://www.webpages.uidaho.edu/range556/appl_behave/projects/chicken_cannibalism.html.

[16] Rodenburg. (2011).

- Feed that can be consumed rapidly and satiate birds quickly can "stimulate feather pecking because of insufficiently exercised pecking behavior."[17]

- Compassion in World Farming, a leading organization in promoting the welfare of animals produced for food, outlined strategies for controlling feather pecking and cannibalism in free-range operations. Among CIWF's recommended measures is appropriate feed, but no mention is made of methionine levels. Feed should simply be "high in insoluble fibre and should be provided in a form that is time-consuming to eat and/or additional roughage should be permanently available."[18]

It's All About Organic Systems Management

The primary arguments from industry assume that the current industrial models of poultry production will continue to prevail in organic systems as they have to date. The defense of DL-MET is rooted in the realization that its removal from organic production will likely require some reorganization toward more systems-oriented management strategies.

- Keeping laying hens for more than one production cycle may reduce reliance on DL-MET.[19]

- Allowing for longer growth periods for broilers and/or using slower growing breeds can reduce dietary MET requirements.[20]

- Providing adequate outdoor areas and designs that encourage birds to graze outdoors can add supplemental MET, reducing requirements of formulated feeds. Studies have shown that DL-MET results in higher production only where birds are not actively grazing.[21]

- Insects and worms are mentioned in the Subcommittee's proposal as a naturally available source of MET when chickens have outdoor access and are able to forage.

- The increased ammonia levels in poultry litter that may result from higher protein feeds can be managed by the storage time of litter in the pen, treatment of wastes and litter, and litter changing intervals all have a determining effect on nitrogen

[17] Sundrum, et al. (2005).
[18] Pickett, H. (2009). *Controlling Feather Pecking & Cannibalism in laying Hens Without Beak Trimming*. Petersfield, UK: Compassion in World Farming. October.
[19] Goldstein. (2014), p 8.
[20] Sundrum, et al. (2005).
[21] Mortiz, J. et al. (2005). "Synthetic Methionine and Feed Restriction Effects on Performance and Meat Quality of Organically Reared Broiler Chickens," *J. Appl. Poult. Res., 14*: pp. 521-535.

> emission potential.[22] According to Dr. Goldstein, industry's claims of hazardous ammonia levels is an economic argument, as applying appropriate bedding that absorbs nitrogenous excrement is a possible management tool, but expensive and results in more manure to haul away and manage appropriately.[23]

Feather pecking and cannibalism, which the industry has falsely attributed to low MET levels, can also be mitigated by appropriate system design.

- According to researchers at the University of Warwick, free-range systems in which flocks make greater use of the outdoor area have reduced risk of feather pecking.[24]
- Researchers at the Louis Bolk Institute in the Netherlands and at University of Bristol in the UK similarly found that designing outdoor spaces with sufficient natural or artificial cover, such as trees or hedges, increased use of outdoor areas and reduced fear among the flock.[25]
- The Dutch study also determined that cohabitation of roosters with hens in free-range operations significantly reduced fear and stress, and thus feather pecking, among laying hens.[26]
- Researchers in the UK demonstrated that having fewer differences between the environments in which chickens are reared and the laying environment reduces the risk of injurious pecking.[27]

Commercial availability of natural MET sources achievable in the short-term NOP and industry support

The Subcommittee lists natural feed sources with a high percentage of MET, including blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal, but does not mention insect meal.

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[22] Sundrum, et al. (2005), p 65, citing Dohler et al. (2002) and Groenauer et al. (2002).
[23] Goldstein. (2014).
[24] Pötzch, C. et al. (2001). "A cross-sectional study of the prevalence of vent pecking in laying hens in alternative systems and its associations with feather pecking, management and disease," *Applied Animal Behavior Science, 74*: pp. 259-272; Nicol, C.J. et al. (2003). "Matched concurrent case-control study of risk factors for feather pecking in hens on free-range commercial farms in the UK," *British Poultry Science, 44*: pp. 515-523.
[25] Bestman, M.W.P. & J.P. Wagenaar. (2003). "Farm level factors associated with feather pecking in organic laying hens," *Livestock Production Science, 80*: pp. 133-140; Nicol et al. (2003).
[26] Bestman & Wagenaar. (2003).
[27] Van de Weerd, H.A. & A. Elson (2006). "Rearing factors that influence the propensity for injurious feather pecking in laying hens." *World's Poultry Science Journal*, *62*: pp. 654-664.

The most promising other area of research into alternative sources of essential amino acids for poultry rearing focuses on insect species as a sustainable protein source:

- Fly maggots from black soldier flies and houseflies—insects that are particularly high in methionine—can be reared on poultry manure or food waste and then provided as a ground-up feed ingredient.

- In 2013, the UN Food and Agriculture Organization (FAO) released a comprehensive report on the role of insects as feed for pigs, fish, and chickens. The report cited numerous studies demonstrating how a variety of insect species including black soldier flies, silkworm, grasshoppers, crickets, cockroach, and termite provide a protein-rich alternative to fish, soy, or meat meal in poultry diets.[28]

- A researcher at Rhodes University in South Africa has investigated the prospects of commercial magmeal production, using agricultural or municipal waste as a food source for fly larvae. One kilogram of fly eggs can turn into 300 kg of protein in about 72 hours with sufficient food.[29]

- A comprehensive analysis of 42 studies by researchers at Wageningan University in the Netherlands in 2012 determined that two species of mealworm larvae were particularly high in essential amino acids, including methionine, and had a close to ideal protein ratio.[30]

Insect magmeal production has increased in recent years due to a rise in demand from aquaculture producers to feed insect proteins to cultivated fish species. With demonstrated need and support from USDA, this could become commercially available in the short term.

- Companies around the world such as EnviroFlight, Ynsect, AgriProtein, Protix, and Enterra have emerged to meet this demand, developing innovative ways to utilize agricultural wastes and produce sufficient quantities of insect larvae.

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[28] Van Huis, A. et al. (2013). "Insects as animal feed," in *Edible insects: future prospects for food and feed security*. United Nations Food and Agriculture Organization. Full report available at: http://www.fao.org/docrep/018/i3253e/i3253e00.pdf.
[29] Villet, M.H. (no date). *Biorecycling with Flies*.
[30] Veldkamp, T. et al. (2012). *Insects as a sustainable feed ingredient in pig and poultry diets – a feasibility study*. Wageningen UR Livestock Research. October; Fanatico, A. (2010); Baker, D.H. & Y. Han. (1994). "Ideal Amino Acid Profile for Chicks During the First Three Weeks Posthatching." *Poultry Science, 73(9)*: pp. 1441-1447. doi: 10.3382/ps.0731441 (Poultry scientists have found that rather than exact levels of individual amino acids the ratio of those acids to one another is more important for poultry health. An ideal ratio for poultry health has been determined such that the ratio of methionine + cysteine to lysine should be around 70%).

- This trend suggests that the commercial availability of insect proteins is increasing, and the poultry feed industry has an opportunity to promote further development of insect proteins to meet its methionine needs.

Livestock Committee's Aquaculture Legacy Document Needs to Expand Its "Institutional Memory" of Organic Aquaculture Debate

Center for Food Safety appreciates the desire of the NOSB to document the history of organic aquaculture regulatory development as a way to preserve institutional knowledge for future Boards. Based upon Center for Food Safety's experience in participating in that process from the onset, we would like to take this opportunity to suggest some additions to the document, from the public and NGO perspective.

Conventional Aquaculture Industry Driving Regulations

Throughout the course of discussions on organic aquaculture at the NOSB, CFS has observed that the groups tasked with making recommendations on organic aquaculture were dominated by individuals from the conventional aquaculture-related industry. This resulted in the consistent minimization in working group reports of critical issues of concern raised by the public in oral testimony at NOSB meetings and written submissions to the NOSB docket. And, it resulted in the submission of final NOSB recommendations to the NOP that the large majority (99%) of the organic community do not support, as documented in the Livestock Committee's attachment: "Organic Aquaculture Standards Development: A Public Comment History."[31] (also see: "Setting the Record Straight" in this document).

As the institutional memory document states, in September 2000 the NOSB appointed 6 Board members to an Aquatic Animals Task Force (AATF) to assess the feasibility of certifying aquaculture and wild capture operations. This first working group consulted with the organic community, including academics, fisherpersons, and environmentalists, but also received strong input from the conventional aquaculture-related industry.[32] The AATF's final report

[31] Livestock Subcommittee. (2015). p. 222, footnote 10.

[32] Individuals that participated in discussions of aquaculture standards included: Dan Butterfield (Butterfield Catfish Farm), George Lockwood (Industry consultant; World Aquaculture Society), Chris Duffy (Greatbay Aquaculture), Richard Nelson (California Aquaculture Association), Gary Fornshell (Aquaculture Extension Coordinator, University of Idaho), John Hargreaves (LSU Aquaculture Research Station), Robin Downey (Pacific Coast Shellfish Growers Association), Deborah Brister (SeaGrant).

determined that standards for organic aquaculture were feasible, but not for wild capture or mollusk production.

With just a few non-industry members involved, the Task Force still represents the most balanced group in the development of aquaculture standards. The recommendations in the final report were favorable to the development of certified organic aquaculture, but approached the issues of wild caught fishmeal and fish oil and open ocean pens with reservation and restrictions. In particular, they recommended restricting fish feed rations of nonorganic wild-caught fishmeal and fish oil to 5 percent, recognizing that this would result in significantly "restrict[ing] the species of aquatic animals that could be raised organically."[33] The AATF also asserted that its decision to prohibit the certification of wild harvest fish would make wild-caught fishmeal and fish oils unavailable to organic aquaculture producers.

But, since the conventional aquaculture industry provided the driving force behind the development of organic aquaculture regulations, they intervened to block the implementation of the workgroup's measured approach to organic aquaculture. AATF's recommendations were tabled and eventually overturned by the conventional aquaculture industry, because, it did not want any of their options to be curtailed.

Several years later, the issue was again picked up by the conventional aquaculture-industry and two working groups were formed to tackle the organic aquaculture issue —the Aquaculture Working Group (AWG) and the National Organic Aquaculture Working Group (NOAWG). Both of the groups' final reports differed substantially from the AATF's, focusing on molding standards to fit existing industrial systems of production and insisting on the need for open-ocean pens and feeds containing high levels of wild-caught fishmeal and oil in feed rations.

The AWG was formed based on a recommendation from NOSB at its October 2004 meeting, NOP published a Federal Register notice in January 2005 calling for volunteers to form a second aquatic animals task force to develop proposed organic production, handling, and labeling standards for aquatic animals. This Task Force was originally to consist of the Aquaculture Working Group (AWG) and the Wild Caught Working Group, but the latter was never formed due to lack of interest.

- The notice requested working group candidates representing fisheries, aquaculture producers, handlers or processors of aquatic animals, aquatic animal health and nutrition specialists, marine conservationists, consumer representatives, academics,

[33] NOSB Aquatic Animals Task Force. (2001). *Recommendations on Operations that Produce Aquatic Animals*, May 30. p. 7.

and accredited organic certification agents.[34] When the AWG was formed in May 2005, it consisted almost entirely of conventional aquaculture-related industry members with the exception of Rebecca Goldburg, then with the Environmental Defense Fund (EDF).

- Other members included Sebastian Belle (Maine Aquaculture Association), Robert Bullis (Advanced Bionutrition Corporation), Ralph Elston (AquaTechnics Inc), Ronald Hardy (Aquaculture Research Center, University of Idaho), John Hargreaves, George Lockwood, Robert Mayo (Carolina Classics Catfish), Christopher Nelson (Bon Secour Fisheries), Bart Reid (Permian Sea Shrimp Co.), Albert Tacon (Aquatic Farms Ltd), and Kwamena Quagrainie (Aquaculture Marketing, University of Arkansas).

- This imbalance is best expressed by NOSB member Joe Smillie's comment to Rebecca Goldburg at the November 2007 meeting: "Just like to thank you, Becky, for working on the AWG, it was really great. I know you are sort of alone there [laughter]…"[35]

Prior to the formation of the AWG, the USDA's Cooperative State Research, Education, and Extension Service recruited individuals to join a National Organic Aquaculture Working Group (NOAWG). Formed in December 2003, NOAWG released a White Paper in May 2005 "intended to serve as a primary reference and discussion document for organic aquaculture in the United States."[36]

- While the historical memory document characterizes the NOAWG as another "private sector ad hoc group of approximately 85 individuals interested in advancing organic aquaculture in the United States,"[37] leadership in this working group again consisted predominantly of conventional aquaculture-related industry members.

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[34] Federal Register vol. 70, no. 14. (January 24, 2005). At 3357.

[35] USDA. (2007). *Transcript from the November 28, 2007 meeting of the National Organic Standards Board*, Arlington, VA. p. 108.

[36] Lockwood, G., R. Nelson & G. Jenson (eds.). (2005). *National Organic Aquaculture Working Group White Paper: Proposed National Organic Standards for Farmed-Aquatic Animals and Plants (Aquaculture) with Supporting Documentation and Information.* p. iii.

[37] National Organic Standards Board Livestock Subcommittee. (2015). "Aquaculture Materials Review Update Report." February. p. 220; see also USDA National Organic Program. (2006). *Interim Final Report of the Aquaculture Working Group*. Winter. Available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5062436. p. 3.

- Nine people are listed on the NOAWG as the writing and review team, 6 of whom were also members of the AWG: Sebastian Belle, Ralph Elston, John Hargreaves, Ron Hardy, Robert Mayo, and Albert Tacon.

- The remaining three members were: Gary Fornshell, James Kotcon (Plant Pathology, West Virginia University), and Fred Conte (Aquaculture Specialist, UC-Davis). No public interest organizations, environmentalists, farmers or consumers were represented in any of the workgroups, with the exception of EDF.

- The White Paper was prepared and edited by George Lockwood, Richard Nelson, and Gary Jensen (Aquaculture Program leader at the National Institute of Food and Agriculture; Interagency Working Group on Aquaculture).

The inclusion of these membership lists in the institutional memory document provides essential information about the strong influence of the conventional aquaculture industry in producing reports and recommendations to the NOSB on key issues affecting aquaculture standards development. They further demonstrate the absence of the full spectrum of stakeholders in the aquaculture workgroups and in the drafting of key documents that drove the development of NOSB recommendations and that formed the basis of impending organic aquaculture regulations. This represents a significant departure from how Congress and the public envisioned the function of the multi-stakeholder NOSB under OFPA and how it would make recommendations to the NOP and USDA Secretary.

Industry influence was also acknowledged by the NOAWG in its 2005 White Paper where it states:

> Since the final recommendations of the NOSB AATF (October 2001) departed significantly from the ad-hoc NOSB Aquaculture Working Group majority recommendations, the industry requested that the NOP not proceed further towards the establish of organic standards for aquaculture at that time. To do otherwise would have placed some major species of potential organic certification (salmon, trout, catfish, shrimp, striped bass, sturgeon, and shellfish) into doubt.[38]

Critical Areas of Disagreement Between Workgroups and the Public

The aquaculture standards proposed by the industry-led working groups included the use of wild caught fish as feeds and open ocean facilities. As the Livestock Committee's timeline notes,

[38] Lockwood, G., et al. (2005).

in 2007 these were identified as “issues of concern” by NOSB and separated into independent recommendations. Both issues were strongly opposed by a majority of the organic community and this stakeholder input is an important part of the standards history.

- At that time, the environmental challenges posed by wild-caught fish feeds and open-ocean net pens were determined to be too significant to be allowed in organic by an overwhelming majority of the US public. Yet, despite this significant area of public debate, it is barely mentioned in the Livestock Committee’s document.

- Instead, the only reference to public opposition at the November 2007 in the institutional memory document is where it states: “The meeting was marked with the NOP’s first activist demonstration where protesters opposing net pens and feeding forage fish to salmon paraded through the meeting wearing fish hats.”

- There is no attempt in the document to explain why members of the public felt compelled to conduct such an unprecedented protest.

- CFS joined that protest. And, for the record, the reason for the protest was because the public felt that its concerns were not being heard by either the aquaculture workgroups or the NOSB. They observed that individuals with vested economic interests in aquaculture and the development of organic aquaculture standards neglected to substantively address the large majority of public concerns raised in their reports.

Public Concerns about Organic Aquaculture have Remained Largely Ignored

Workgroup reports provide only part of the historical record. The remainder of that record includes 15+ years of substantial public participation in the organic aquaculture debate. This information can be found in regulations.gov (for 2007 to present) and the transcripts of public testimony (from 2001 to present).

While the so called “repetitive areas of concern” by the public are noted in the document, the narrative fails to address how and/or if those concerns were ever resolved or to what extent. The “institutional memory” document includes a footnoted link buried at the bottom of page 222 that is labeled simply, “Information compiled from public records.”[39] Those fortunate enough to click on the link will find that it opens to an additional document prepared by NOSB member Colehour Bondera.

[39] Livestock Subcommittee. (2015). p. 222.

As briefly touched upon in the "Organic Aquaculture Standards Development: A Public Comment History", an overwhelming 54,254 public comments (over 99 percent) directly expressed concern that the ecological damage caused by fish farms is too substantial to be organic. Among the commonly raised reasons for this concern was that wastes from fish farms cannot be sufficiently recycled and escapes cannot be fully prevented. Additionally, 49,561 comments (over 99 percent) felt that the likelihood of ocean-based contaminants in wild-caught fishmeal and oil makes it unsuitable for organic feeds. Over half of all comments felt that the unsustainability of sourcing feeds from wild fisheries also makes it unsuitable for organic.

These and other significant contributions from the public on critical issues of concern with respect to the organic aquaculture standards were given minimal space and consideration in the Subcommittee's "institutional memory," by relegating them to a link in a footnote.

Setting the Public Record Straight

It is interesting to note that there is no mention in the institutional memory document of the number of people who submitted comments or provided oral testimony that *favor* ocean-based aquaculture or *favor* allowing feed and oil from wild fish. After examining the available public record and public testimony, CFS can attest to the fact that less than 1 percent of total comments favored these issues. As this data point suggests, since the industry was running the workgroups and writing the reports there was no need for them to participate in the public process. This is reinforced by the buried public comment history analysis, which illustrates that over the past decade only a few dozen oral and written comments consistently weighed-in supporting open ocean pens and wild-caught fishmeal and oils.[40]

In contrast, the public has regularly and repeatedly stated at every NOSB meeting at which organic aquaculture has been on the agenda, that open ocean fish farms and the use of wild-caught fish for oil and meal in feed do not meet the requirements of organic certification. Over 54,000 public commenters have expressed this position in their comments that are part of the public record.

Public comments have also consistently expressed opposition to organic certification for the farming of migratory fish species, such as salmon. The inability of certain aquatic animals to express their natural behavior in confinement, particularly those that instinctually swim

[40] Bondera, C. (2015). *Organic Aquaculture Standards Development: A Public Comment History*. January.

hundreds, if not thousands, of miles between fresh and salt water to spawn and die in their birth river, makes their farming incompatible with the NOSB's own Organic Principles.[41]

It is important to note that public input on organic aquaculture standards has not only been oppositional. **Since 2006, a substantial number of commenters have consistently voiced support for greater research into the potential of land-based, inland, closed-loop, recirculating systems to raise certain fish species as certified organic.**

- Fifty-three fisheries-based, farmer, environmental, and consumer organizations, with millions of supporters nationwide, have signed a position statement agreeing that such systems are the ones that have the potential to meet the OFPA criteria.[42] To that end, they advocate that the NOP tests such systems first, since it lacks experience with certifying non-terrestrial based systems to be certified organic. They argue that evaluations of such systems must be conducted with sufficient transparency and public scrutiny to ensure that the highest level of scientific and policy-making expertise be brought to bear on the development of this novel, organic, industrial sector before it is fully commercialized.

Conclusion
A historical memory document is only useful if it includes all histories and players involved. Otherwise, it is likely to be viewed as revisionist and suspect by those whose benefit it aims to serve. Failing to adequately explain the role and substance of public participation in an institutional memory report undermines the twin pillars of OFPA and the organic policy making process – public participation and transparency. Without including both, organic policy-making and the role of the multi-stakeholder NOSB come into question and so does the value of the organic label and USDA seal on organic fish as well as other certified organic products.

Copper Products: Fixed Coppers and Copper Sulfate

Center for Food Safety appreciates the fact that copper has been used for centuries in agriculture and livestock rearing, and that it still remains an important tool for organic farmers to prevent nutrient deficiencies in soil and to control common plant diseases. Universally found in nature, copper and is a micronutrient essential for plant growth. At the same time, we

[41] National Organic Standards Board. (2001). "NOSB Principles of Organic Production and Handling," *NOSB Policy and Procedures Manual*, October 17. pp. 30-31. Available at: www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3013893.
[42] Organic Aquaculture Position Statement, available on Center for Food Safety's website at: www.centerforfoodsafety.org/files/aquaculture-position-statement_10116.pdf.

cannot lose sight of the fact that copper products are toxic and the breakdown product, elemental copper, is persistent. Excessive use of copper products poses a risk to non-target plants and animals. Copper can be toxic to wildlife, including birds and mammals,[43] aquatic life,[44] to the workers who apply them[45] and to those who ingest, breathe or come into contact with copper.[46] When copper builds-up to toxic levels in soils, it can be detrimental to earthworms and other beneficial soil organisms [47] and suppress nitrogen fixation rates by Rhizobium.[48]

Due to the toxicity of accumulated copper in soil and its aquatic toxicity, it is imperative that NOSB support organic farmers in reducing its use and recommend that USDA allocate funds to assist in the development of alternative management practices. In this vein, we support the recommendation to relist copper with the caveat that a robust research strategy must be recommended by the NOSB to the NOP and that urgent funding is sought to ensure that the research is carried out.

Limited copper use is necessary in the short-term

Copper products can be less toxic than other types of disease control materials, when used properly. And, at this moment in time, they may be the only material available to organic growers to combat some serious crop diseases, such as late blight in tomatoes and potatoes, which can cause complete crop failure.

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[43] Edwards, D. (2006). *Reregistration Eligibility Decision (RED) for Coppers*. U.S. Environmental Protection Agency, EPA 738-R-06-020. July: pp. 48-52.

[44] Boyd, C.E. & L. Massaut. (1999). "Risks associated with the use of chemicals in pond aquaculture," *Aquacultural Engineering, 20*: pp. 113-132; Baldwin, D.H., J. Sandahl, J.S. Labenia & N.L. Scholz. (2003). "Sublethal Effects of Copper on Coho Salmon: Impact on Nonoverlapping Receptor Pathways in the Peripheral Olfactory Nervous System," *Environmental Toxicology and Chemistry*, *22(10)*: pp. 2266–2274. Also see literature review in: Kiaune, L. & Singhasemanon. N. (2011). "Pesticidal Copper (I) Oxide: Environmental Fate and Aquatic Toxicity," in: D.M. Whitacre (ed.), *Reviews of Environmental Contamination and Toxicology, 213*: pp. 1-26.

[45] "Direct hazards to applicators are the major concern." Organic Materials Review Institute. (2001).*Copper Sulfate.* September 21. p. 5, line 243.

[46] Edwards, D. (2006). *Reregistration Eligibility Decision (RED) for Coppers*. U.S. Environmental Protection Agency, EPA 738-R-06-020. July.

[47] Spurgeon, D.J., S.P. Hopkin, & D.T. Jones. (1992). "Effects of Cadmium, Copper, Lead and Zinc on Growth, Reproduction and Survival of the Earthworm *Eisenia fetida* (SAVIGNY): Assessing the Environmental Impact of Point-Source Metal Contamination in Terrestrial Ecosystems," *Environmental Pollution, 84*: pp. 123-130; Brandt, K.K., et al. (2006). "Decreased abundance and diversity of culturable *Pseudomonoas* spp. Populations with increasing copper exposure in the sugar beet rhizosphere," *Federation of European Microbiological Societies, 56*: pp. 281-291; Van-Zweitan, L., G. Merrington, & M. Van-Zweiten. (2004). "Review of impacts on soil biota caused by copper residues from fungicide application," *SuperSoil 2004: 3rd Australian New Zealand Soils Conference,* 5-9 December 2004. University of Sydney, Australia.

[48] Obbard, J.P. & K.C. Jones. (2001) "Measurement of symbiotic nitrogen-fixation in leguminous host-plants 1320 grown in heavy metal-contaminated soils amended with sewage sludge." *Environmental Pollution*, *111*: pp. 311-320.

Since copper is an elemental product and cannot decompose, it can accumulate in the soil over time. That is why growers must limit the amounts they apply. Organic certifiers require routine monitoring of copper levels in the soils of those who use copper for disease control in order to identify early evidence of build-up and to prevent toxic accumulation. These important controls help to minimize human and environmental impacts.

In the long-run, and in the spirit of continuous improvement that remains at the core of OFPA, alternatives must be found to avoid the long-lasting adverse effects caused from the application of copper for disease control. Given the need for the NOSB to evaluate and balance these concerns, CFS is mindful of the fact that at this time alternatives are not yet available to address the many combinations of diseases and affected crops for which copper may be the only control available.

Worker health and safety must be a priority

Despite the NOSB's recommendation in 2011 that the NOP provide guidance for worker health and safety at organic operations where copper products are applied, this has not happened. The recommendation specifically states that:

> The Committee will work with the National Organic Program to advance guidance that ensures that organic operations are strictly meeting, and to the extent possible, exceeding the standards established by the product label in meeting principles of sustainability and a sustainable work environment for all those who work in organic production.

We, therefore, urge the NOSB to remind the NOP of the need to produce guidance on this important issue of worker protection. In addition, we urge the NOSB to include language for protecting workers in its relisting of copper.

Proposed next steps

Transparency and continuous improvement are the twin pillars that support the success of organic as a production system, label, and market. Every five years the Sunset process provides the NOSB an opportunity to conduct a comprehensive review of materials that carefully examines their toxicity to humans and the environment, and to evaluate their essentiality and the existence of available alternatives. It also affords the organic community a chance to share their experience, observations, and research, and to make recommendations to the NOSB to inform their deliberations and decisions. As the next step in this Sunset process, we urge the NOSB, in conjunction with its technical reviewers, to document the combinations of crops and diseases for which organic farmers currently find copper to be a necessary part of their disease control systems. The outcome of that research should then provide a solid basis for discussion about alternative disease control strategies that do not rely on the use of copper products.

We also recommend that the Board survey the most recent published literature on the health and environmental effects of copper to assess particularly vulnerable communities and ecosystems that must be protected from exposure. In the absence of this information, it is impossible for the NOSB to make sound recommendations based upon the OFPA criteria of protecting human and environmental health.

We urge the NOSB to review this information, once compiled, and to use these findings to craft more detailed annotations for copper sulfate and fixed coppers that include a limited list of acceptable uses.

This research will have the added effect of aiding growers in identifying viable alternatives that can meet their needs and in developing plans to reduce or phase-out copper products in their operations. It will also help interested researchers in tailoring their research projects to better meet the needs of the organic farming community.

NOSB should clarify language in the annotations for copper products that supports farmers in using copper products in a manner that does not create a toxic build-up of copper in their soil. Identifying the products available that will control targeted pests with the least amount of elemental copper is essential. Margaret McGrath at Cornell, for example, has investigated different copper fungicides and analyzed the percentage of metallic copper contained.[49] These range from 1.8 percent to 75 percent. Research on alternative copper product formulations has been conducted in the EU as well.

Research Needs

Widespread solicitation of agriculture scientists and extension agents with the appropriate expertise must be sought to conduct necessary copper-related farm research. To that end, we agree with the National Organic Coalition's comments that that the NOSB and NOP must inform OREI administrators of the urgent need to fund research on this topic and for USDA to circulate requests for proposal (RFP) that include the following research components as well as other salient issues that arise during its Sunset investigations:

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[49] McGrath, M. (2013). *Copper Fungicides for Organic Disease Management in Vegetables*. Cornell Vegetable Program, Cornell Cooperative Extension. Available at: http://cvp.cce.cornell.edu/submission.php?id=151&crumb=crops|crops|squash_-_summer|crop*31.

- A comprehensive systems management-based approach to organic disease and lessening the need for copper use on a crop-by-crop basis.

- Breeding plants that are resistant to the types of diseases for which copper is used – induced resistance.

- Developing alternative formulations of pesticides and fungicides, such as smaller particles (not engineered nano products) of copper that that facilitate coverage and thereby reduce the amount of copper that needs to be applied.

- Assessing existing cultural practices such as crop rotations, sanitation practices, and the timing of irrigation relative to the climatic conditions in which the copper is being used to make crops less prone to disease.

- Evaluating nutrition and soil fertility management approaches to mitigate the impacts of plant diseases on organic crops such as the use of plant extracts, beneficial microbes, and a host of other emerging tools and materials.

- Determining more efficient methods for spreading copper on leaf or flower.

- Identifying the copper products that contain the least amount of elemental copper [see Margaret McGrath's work noted above], and investigating ways to reduce the amount of elemental copper in all products.

Conclusion

We have repeatedly seen that those substances on the NL upon which farmers heavily rely but which pose certain health and/or environmental risks often have received little funding to research preferable alternatives, including cultural practices. So, when the sunset dates approach, needed information which would allow farmers to change course and improve their production systems with less-toxic and non-synthetic alternatives has simply not been available. Copper is a case in point. It is incumbent upon the NOP and USDA to target organic research to meet the needs of farmers and take to heart the intent of OFPA to continuously improve organic production systems. That way everyone benefits—people, the planet, and organic markets.

Nanotechnology and Materials Must be Completely Prohibited in Organic

While we appreciate the NOP's recognition of the importance of preventing the intrusion of nanomaterials into organic, the policy statement issued by the NOP (24 March 2015) does not constitute a straightforward prohibition, as CFS and much of the wider organic community had expected. Instead, it leaves the door open for engineered nanomaterials to be included in organic foods, for instance, through the National List petition process. CFS's position has always been that a prohibition of nanotechnology and nanomaterials, such as those required for genetic engineering, irradiation, and sewage sludge, must be permanently adopted in order to prevent their use in organic in perpetuity.[50]

In addition, CFS was disheartened to read the NOP's statement in its March memo that it "does not consider nanotechnology to be intrinsically benign or harmful." If that is the case, then why did the NOP go to all of the trouble of writing a memo to prohibit it in organic in the first place? We disagree with this claim of intrinsic neutrality of nano technologies and materials because there is an abundance of data to the contrary. In fact, research has shown harm in animal and cell culture studies from nanomaterials small enough to enter human cells (250 nm)[51] and even enter human cell nuclei.[52] In that vein, we have repeatedly presented evidence to the NOSB demonstrating our concerns and underscoring why the technology is incompatible with organic, on numerous occasions.

Below is a condensed account of some of our major human health concerns[53]:

> Due to their size, nanoparticles can cross biological membranes, cells, tissues, and organs more readily than large particles.[54] When inhaled, they can go from the lungs into the blood system.[55] There is growing evidence

[50] Center for Food Safety, (2000). "Comments on National Organic Standards Board (NOSB) Materials Committee Classifying Engineered Nanotech Materials as "Synthetic" and Prohibiting Nanotechnologies and Materials in Organic," Docket No. AMS-TM-09-0014.
[51] Wick, P., et al. (2010) "Barrier Capacity of Human Placenta for Nanosized Materials," *Environ Health Perspect 118*:432-436. Available at: http://dx.doi.org/10.1289/ehp.0901200 [online 12 November 2009]; Panté N., M. Kann. (2002). "Nuclear pore complex is able to transport macromolecules with diameters of about 39 nm." *Mol. Biol. Cell*, *13*:425–434.
[52] Ahlinder, L. et al. (2013). "Large Uptake of Titania and Iron Oxide Nanoparticles in the Nucleus of Lung Epithelial Cells as Measured by Raman Imaging and Multivariate Classification." *Biophysical Journal 105(2)*: 310–319. Accessed 6 Apr. 2015; Dam D.H.M., J.H. Lee, & T.W. Odom. (2012). "Direct observation of nanoparticle-cancer cell nucleus interactions," *ACS Nano*, *6*:3318–3326.
[53] NanoAction. (2007). *Principles for the Oversight of Nanotechnologies and Materials*; See also, Holsapple, M.P. et al. (2005). "Research Strategies for Safety Evaluation of Nanomaterials. Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs," *Toxicological Sciences, 88(1)*: 12-17.
[54] Holsapple, et al. (2005).
[55] *Id.*

> that some nanomaterials may penetrate intact skin,[56] especially in the presences of surfactants or massaging or flexing of skin and gain access to systemic circulation.[57] When ingested, nanomaterials may pass through the gut wall and into the blood circulation.[58] Once in the blood stream, nanomaterials can circulate throughout the body and can lodge in organs and tissues including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system.[59] Once inside cells, they may interfere with normal cellular function, cause oxidative damage and even cell death.[60]

Given these hazards associated with nano technologies and materials, their allowance in organic should be permanently prohibited and excluded like genetic engineering, irradiation and sewage sludge and included under Section 205.105 (1) (h) of the Organic Rule. We urge the NOSB to take up this matter again at the next Board meeting and recommend this permanent prohibition to the NOP and USDA.

Nano Materials in Packaging Already Prohibited in OFPA

The use of nano substances in primary food packaging and in food contact substances represents a major and growing source of concern for organic consumers. Packaging is a predominant product category where food-related nanotechnologies and contact substances are being deployed to extend a product's shelf-life, particularly through the use of antimicrobials like nano-silver. This type of nano packaging is designed as a delivery system whereby the nanoparticles embedded in the packaging act as a preservative, anti-microbial or anti-fungal, among other things. As such, we believe that the authority already exists within the organic rule to prohibit nano antimicrobials in packaging under section 205.272 (b) (1). The rule specifically states that packaging materials and storage containers or bins that contain a synthetic fungicide, preservative or fumigant are prohibited for use in the handling of any organically produced agricultural product and ingredient. We therefore urge the NOSB to seek clarification with the NOP that nanomaterials in packing are prohibited and that they are included in 203.272 (b)(1) of the Organic Rule.

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[56] Monteiro-Riviere, N. et al. (2006) "Penetration of Intact Skin by Quantum Dots with Diverse Physicochemical Properties," *Toxicological Sciences, 91*: pp. 159-165; Rouse, J.G. et al. (2007) "Effects of Mechanical Flexion on Penetration of Fullerene Substituted Amino Acid-Derivatized Peptide Nanoparticles through Skin." 7(1) *Nano Letters, 7(1)*: pp. 155-160.

[57] Toll R. et al. (2004). "Penetration Profile of Microspheres in Follicular Targeting of Terminal Hair Follicles," *Journal of Investigative Dermatology, 123*: pp. 168-176.

[58] Florence, A.T. & N. Hussain. (2001). "Transcytosis of nanoparticle and dendrimer delivery systems: evolving vistas," *Adv Drug Deliv Rev, 50*: S69-S89.

[59] Oberdörster, G. et al. (2005). "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy," *Particle and Fibre Toxicology, 2*

[60] Borm PJ & W Kreyling. (2004). "Toxicological hazards of inhaled nanoparticles—potential implications for drug delivery," *J. Nanosci Nantechnol, 4(5)*: 521-531.

NOSB "Excluded Methods" Terminology: Discussion of New Breeding Technologies

After reviewing a wide variety of new breeding technologies that could be encompassed in OFPA's existing Excluded Methods definition, it is CFS's considered opinion that they are included in the current definition. Since we have concluded that the definition works well as written, we urge the NOSB and NOP to not open up the regulations or try to alter the definition in any way. We view the list of methods named in the Excluded Methods definition as illustrative, not comprehensive. Therefore, it is not necessary to list every new breeding technology when the overall description encompasses a broad swath of significant, new and emerging technologies adequately. If there are ambiguities or concerns, these can be met by issuing guidance.

What is at Stake

The National Organic Standards Board (NOSB) is considering the definition of "excluded methods" in the wake of a proliferation of new breeding technologies for crops, almost all of which are types of genetic engineering. Many of these technologies may also be used in animal production. Two important questions under discussion[61] are: What are the new technologies that NOSB wishes to exclude from organic methods as "genetic engineering"? Is the current process-based definition of "excluded methods" up to the task of keeping organic agriculture free of genetic engineering in light of these new technologies, and if not, what changes should be made?

CFS has commented on NOSB discussion documents regarding terminology and new breeding technologies previously. Here we extend our comments to more fully address the terms and methods that NOSB should consider, and how these are addressed by the current "excluded methods" definition.

NOSB definition of "excluded methods" is broad and covers most new breeding technologies

For reference, the current process-based definition of "excluded methods" is as follows:

> Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a

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[61] National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.

foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

Under this definition, methods other than traditional breeding that "genetically modify organisms or influence their growth and development" are excluded whether or not *in vitro* nucleic acid techniques are involved, as long as the methods "are not possible under natural conditions." Methods that use engineered DNA, RNA, proteins, or other molecules or procedures to change organisms during any part of the breeding process are thus excluded from organic production.

Lists of terms and methods related to new breeding technologies that are not currently used in the definition of excluded methods

It is important to identify what new technologies are being developed and used in crop breeding in order to determine if the "excluded methods" definition is broad enough to keep organic production free of genetically engineered organisms. Thus a list of terms and methods related to new breeding technologies that are not specifically used in the current definition has been included in previous NOSB discussion documents, with the intent of discussing whether the terms need to be explicitly incorporated in future definitions, and if so, in what way.

Terminology is not standardized for the new breeding technologies. Different authors devise their own terms and abbreviations for the same or very similar methods; and companies often provide trademarked names for processes based on more general methods. This complicates efforts to understand the landscape of new breeding technologies, and to define them for these purposes.

Some terms related to new technologies were listed in previous NOSB discussion documents. Others are being suggested here by CFS for discussion by NOSB, either because the new terms are used in relevant literature and are synonymous with previously NOSB-flagged technologies, or because the terms refer to technologies missed before. After the list, we organize the terms, provide key references, and discuss the relationships of these methods to previous genetic engineering methods and NOSB's definitions.

Red = terms in the 1st discussion document, and not in the current list of examples in the definition of excluded methods (from Appendix 1, August 22, 2014 discussion document)

- Silencing

- Embryo Rescue
- Microinjection
- Biolistic device
- Somaclonal variation
- Transposons
- Transduction

Blue = additional terms in the 2nd discussion document, and not in the current list of examples in the definition of excluded methods (from "2. Terms not in prior Discussion," pp. 4 – 5 of pdf, August 22, 2014 discussion document)

- Doubled Haploid Technology
- Targeted genetic modification (TaqMo)
- FasTrack
- Synthetic Biology
- Cisgenics
- Intragenesis
- Plastid transformation
- Gene silencing via RNAi and DNA methylation
- RTDS (Rapid Trait Development System)
- Site directed mutatgenesis via oligonuclueotides, zinc finger nuclease (ZFN)
- Agro-infiltration
- Reverse Breeding
- Embryo transfer of animals
- Marker Assisted Selection (MAS)

Black = terms CFS suggests adding for discussion, not in previous discussion documents, elaborated in the next section

- TILLING (Targeting Local Lesions IN Genomes)
- Oligonucleotide directed mutagenesis (ODM)
- DuPont's Seed Production Technology (SPT)
- Genome elimination
- Synthetic chromosomes
- Synthetic gene technologies
- Genome engineering
- Gene editing
- Gene targeting (GT)
- Sequence-specific nucleases (SSNs)
- Meganucleases
- Zinc-finger nucleases (ZFNs)

- Clustered Regularly Interspaced Short Palindromic Repeats and associated protein genes (CRISPR-Cas system)
- Transcription Activator-Like Effector Nucleases (TALENs)
- Fast flowering
- Cisgenesis
- Intragenesis
- RNA-dependent DNA methylation (RdDM)
- Gene silencing via RNAi pathway
- RNAi-based pesticides
- Grafting of GE rootstock with non-GE scion
- Cloned animals produced through somatic nuclear transfer and their offspring

Organizing the terms and methods to facilitate analysis of new breeding technologies for NOSB "excluded methods"

The terms listed above for new breeding technologies are grouped by the tasks the methods accomplish, such as speeding up conventional breeding or making changes to existing genes within organisms. They are also grouped by the types of changes made to the genetic material of the engineered organism.

New technologies that are excluded methods under the current definition

1. There is a class of new technologies that specifically targets gene sequences within organisms in order to cause mutations. Existing genes are altered by using engineered *in vitro* nucleic acids or proteins to cause breaks in specific locations on chromosomes that are then repaired in ways that cause the desired changes. In addition to changing existing genes, the methods can be used to add new gene sequences at specific locations. Some of these methods deliver engineered *in vitro* nucleic acids into organisms to make the changes without those nucleic acids becoming a permanent part of the organism. In other cases the nucleic acids required to make the changes are engineered into the organism as permanent transgenes. In addition, proteins (SSNs) made from the engineered nucleic acids can be introduced into cells instead of nucleic acids to cause the changes (Voytas and Gao 2014). In all of these variations, the end result is an engineered change in the organism's genetic material and, thus, they are excluded methods.

This category of technologies has different names:

- Targeted genetic modification (TaqMo) (Kuzma and Kokotovich 2011, Kokotovich and Kuzma 2014)
- Synthetic gene technologies (Then 2015)
- Genome engineering (Voytas and Gao 2014)

- Gene editing (Puchta and Fauser 2013)
- Gene targeting (GT) (Puchta and Fauser 2013, Endo et al. 2015)

Within the technologies in this category, methods differ by the types of enzymes used to cause the breaks in the genes, and what each method requires for the break to occur in a specific location:

- Sequence-specific nucleases (SSNs) (Voytas and Gao 2014):
- Meganucleases (Gao et al. 2011, as cited in FSANZ 2013)
- Site directed mutagenesis via oligonucleotides, zinc finger nuclease (ZFN), zinc-finger nucleases (ZFNs) (Dow, APHIS 2012)
- Clustered regularly interspaced short palindromic repeats and associated protein genes (CRISPR-Cas system) (NYTs 3/20/2015)
- Transcription activator-like effector nucleases (TALENs) (Sprink et al. 2014).

The technologies below use engineered nucleic acids to induce sets of specific mutations in organisms for breeding programs:

- Oligonucleotide directed mutagenesis (ODM) (Lusser et al. 2011)
- Cibus Rapid Trait Development System (RTDS) (Beetham et al. 2012 patent)

2. Recent elucidation of the way that organisms turn down or off (silence) expression of their own or invading virus genes using specific small RNA molecules – the RNA interference (RNAi) process – has resulted in an explosion of RNAi methods to engineer organisms with different characteristics. Some techniques use RNA-producing transgenes to silence genes within an organism or even in organisms that eat the engineered organism. Other methods involve injecting or otherwise delivering RNA molecules directly into organisms to silence their genes. Silencing is referred to differently by various researchers, reflected in the list below. Also, RNAs are being engineered for delivery as dusts or sprays to kill pests and pathogens directly. All silencing techniques result in changes in gene expression and are excluded from organic production by the current definition:

- Silencing
    - Gene silencing via RNAi and DNA methylation
    - RNA-dependent DNA methylation (RdDM) (Lusser et al. 2011)
    - Gene silencing via RNAi pathway (Casacuberta et al. 2015, Baier et al. 2014, Lubasik and Zielenkiewicz 2014, Hirschi 2012, Heinemann et al. 2013, Lundgren and Duan 2013, Wagner et al. 2015)
    - RNAi-based pesticides (Palli 2014, Zhu 2013)

3. Some of the new techniques are designed to make plant breeding faster andnot to directly change the genetic material of the final product. In the following methods, genetic engineering is used in the process initially but the intent is to leave no trace of that engineering behind after its purpose has been served (e.g. Dirks et al. 2009, p. 841). Because genes are modified using engineering techniques during some part of the process, these are all excluded methods. Also, for some of these methods there are unintended effects of the initial engineering that in fact do leave behind traces in the final varieties that could have unwanted consequences.

These methods use genetic engineering to produce the equivalent of inbred lines within one or two generations,[62] thus speeding hybrid breeding programs:

- Doubled Haploid Technology:
  - Reverse Breeding (Dirks et al. 2009)
  - Genome elimination (Comai 2014)

These methods speed up the time to flowering in woody plants by introducing a transgene for rapid flowering from another species, so that crosses can be made sooner, with the goal of breeding out the "fast flowering" gene later:

- FasTrack (Waltz 2012)
- Fast flowering (Flachowsky et al. 2011)

These methods facilitate hybrid seed production by using GE "maintainer lines" to perpetuate male-sterile parents, where the GE trait is bred out of the final variety:

- DuPont's Seed Production Technology (SPT) (Waltz 2012)

4. This aspect of genetic engineering involves introducing genes from the same or closely related species into an organism and below are the terms specifically used to describe those processes:

- Cisgenics or cisgenesis, if the introduced genes including regulatory sequences are from the same or closely related species and are arranged in the normal orientation
- Intragenics or Intragenesis, if the introduced genes are from the same or related species but are engineered to have novel sequence arrangements or to have

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[62] There are several ways to make doubled haploids, and some do not involve genetic engineering at any stage of the process (review: Bhojwani and Dantu in Davey and Anthony 2010, pp. 61 – 78).

different regulatory sequences associated with them (Prins and Kok 2010, Lusser et al. 2011)

All cisgenic and intragenic techniques involve introducing engineered genes and thus changes to the genetic material of recipient organisms and, therefore they are excluded methods according to the current definition.

5. The definition of "Synthetic Biology" is much broader than the definition used by the Materials/ GMO Subcommittee in the discussion document. The term "synthetic biology" is used by the developers of many of the new breeding technologies discussed above. Nonetheless, it is mainly encompasses genetically engineering, using techniques that allow larger amounts of genetic material to be engineered at one time. Common to many explanations of synthetic biology is the application of engineering principles to the fundamental components of biology.

SynBerc, the University of California/Department of Energy synthetic biology research consortium, defines synthetic biology as: *a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems…, as well as the re-design of existing, natural biological systems for useful purposes*.

Recent advances in bioengineering have enabled scientists to make new sequences of DNA from scratch. By combining these advances with the principles of modern engineering, scientists can now use computers and laboratory chemicals to design organisms that do new things such as produce biofuels, create complex flavor/fragrances like saffron, or excrete the precursors of medical drugs, like artemisin. Many of these products are already in the market and more are coming soon.

- Synthetic Biology is a set of excluded methods that include:
  - Synthetic chromosomes (Shenoy and Sarma 2010, pp. 12-13; Gaeta et al. 2012)

6. There are a variety of methods for genetically engineering parts of cells, such as organelles, and these also are excluded methods under the current definition:

- Plastid transformation (Maliga 2004, as cited in NOSB discussion 2014)

7. Some techniques for producing novel biochemicals in organisms involve transient expression of genes or RNAs. For example, genes on vectors can be injected or infiltrated into leaves of

plants where the engineered genes are expressed for the life of the leaf, making vaccines or other high-value products. The current definition of excluded methods is broad enough to cover a transient change in gene expression such as this, where *in vitro* nucleic acids are introduced to modify plant characteristics for a limited time:

- Agro-infiltration (Chen et al. 2014, FSANZ 2013)

8. Some applications of genetic engineering involve creating transgenic rootstocks that confer resistance to pathogens, or some other property. Certain molecules including some products of engineered genes can cross the graft union from the GE rootstock into the non-GE scion. Since the combination of stock and scion comprises the "organism," the whole plant, not just the genetically engineered portion, is prohibited by the current definition:

- Grafting GE rootstock/ non-GE scion (Shenoy and Sarma 2012)

9. Certain methods involve isolation and growth of parts of organisms under conditions that would not occur naturally and are not part of traditional breeding, and thus are prohibited by the current excluded methods definition. Protoplast fusion in plants is one of those methods, where cells are isolated, their walls are removed, and the resulting protoplasts are fused in order to mix their contents (organelles, chromosomes, etc.) to make "hybrids." This method might be used to mix genetic material of species that could not normally mate. In practice, most protoplast fusions are done between species that are fairly closely related and theoretically could be crossed, although with some difficulty.

- Protoplast fusion [63](Goodman et al. 1987, Grosser et al., in Davey and Anthony 2010, pp. 175 – 198, Eeckhaut et al. 2013)

10. Embryo transfer in animals should also be considered an excluded method under the current definition in that it is a method that "influence[s] their growth and development by means that are not possible under natural conditions". Natural reproduction is a basic principle of organic production. The EU, Canadian, IFOAM, KRAV (Swedish), SA (Soil Association-UK), and Bio-Gro (NZ) organic standards all prohibit embryo transfer and prohibit or limit induced ovulation and birth.

- Embryo Transfer in animals

[63] Protoplast fusion was discussed in the National Organic Standards Board GMO ad hoc Subcommittee Discussion Document Excluded Methods Terminology, February 6, 2013. It is a controversial excluded method because of its use in some breeding applications used by organic growers. An NOP Policy Memo 13-1 was issued to clarify.

11. Cloned animals produced through somatic nuclear transfer and their offspring should also be considered an excluded breeding method under the current definition of excluded methods. The organic standards in Canada, the EU, UK (Soil Association), IFOAM, New Zealand (Bio-Gro and Demeter), and Sweden (KRAV) all ban the certification of clones and their offspring as organic. The US NOP has declared that clones are not organic, but has yet to issue a regulation on clone offspring.[64]

- Cloned animals produced through somatic nuclear transfer and their offspring

Conclusion
In these comments, CFS has assessed new breeding technologies being used to engineer microbes, plants and animals and finds that the NOP current definition of excluded methods covers nearly all of the new breeding technologies being developed in laboratories around the world. Given the fact that emerging technologies come and go, only some of which make it to the market each year, CFS does not think it would be prudent to list every single technique as an example in the regulations. The existing list of methods in the Excluded Methods definition is meant to be illustrative and not exhaustive and, therefore, CFS urges the NOSB and NOP keep it that way. We recommend that the NOP issue guidance to clarify any ambiguities or confusions as they arise.

Chlorine

Center for Food Safety understands that chlorine is an effective sanitizer to control microbial pathogens on produce, equipment and surfaces, and wastewater. However, there is a growing unease that we share about the need to eliminate chlorine from organic disinfection processes because of "concerns about its efficacy on the produce and about the environmental and health risks associated with the formation of carcinogenic halogenated disinfection by-products."[65] For this reason, CFS recommends that the NOSB pursue a two-fold strategy to achieve an overall reduction in the use of chlorine in organic systems: promote alternative sanitizing practices and methods that eliminate the need for chlorine disinfectants, and provide clarification for producers regarding when sanitizing is necessary and when cleaning is sufficient.

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[64] See Miles McEvoy, Policy Memorandum, Jan. 31, 2011 available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088956
[65] Gil, M.I. et al. (2009). "Fresh-cut product sanitation and wash water disinfection: Problems and solutions," *International Journal of Food Microbiology, 134*: 37-45.

CFS Supports the Following National Organic Coalition Recommendations
"The use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the wash water.

To be consistent, the use of other approved disinfectant products in wash tank water systems should also be reviewed as to the possibility of absorption, at what concentration, and any negative health effects. This would include paracetic acid.

Based partly on the efforts of EPA's Design for the Environment results, prioritize research on a variety of cleaning and disinfection materials for use in organic food processing, especially those that would be readily available, at a reasonable price and effective in a variety of situations."

GE Contamination Prevention Strategy Guidance for Excluded Methods

We support the call for shared responsibility for preventing GE contamination of organic agriculture, also expressed in comments by National Organic Coalition the Organic Seed Alliance and others. While it is obvious that "the organic part of this shared responsibility is practiced extensively already," what is also obvious is that the USDA has not taken the necessary steps to protect this important industry, which is the fastest growing sector of agriculture in the U.S.

In response to the questions and points raised in the Prevention Strategy Guidance for Excluded Methods Discussion Document, we would like to make the following recommendations:

- The NOSB take advantage of its role as advisor to the USDA to communicate to the Secretary that mandatory regulations are urgently needed to ensure GE patent owners and growers share the responsibility of preventing contamination events. This includes instituting mandated, field-based, prevention practices and a mechanism to compensate organic operations when prevention measures fail. Such compensation must include social harms, economic harms and restitution costs.

- The NOSB should respond to USDA's announcement that it is withdrawing its 2008 proposal to update GE regulations with a strong statement of support for developing a new and stronger proposal that better reflects the agency's authority, new science about GE environmental and health related harms, and that need to protect famers from GE contamination.

- While CFS agrees that testing and monitoring for unwanted GE traits in seed sourced for organic production is a good idea, we are concerned about unintended consequences, particularly reducing the availability of organic seed.

- It is too soon to establish a threshold in either non-organic or organic seed. USDA must first incentivize more investment in public breeding and sourcing of organic seed. In addition, more information is needed to minimize unintended and undesirable consequences such as the concentration of ownership of seeds by a few large suppliers and increased genetic uniformity because fewer varieties are available for "at-risk crops" for both untreated, non-organic and organic seed, among others things.

- The subcommittee must explore how/if the USDA's AC21 initiative currently underway can provide comprehensive data on the state of contamination of organic, including in seed, and to ascertain what how it plans to address this urgent issue of concern to organic growers.

The organic sector continues to shoulder an unfair burden with respect to GE contamination prevention and the unwanted presence of GE material in seed. Perhaps the greatest challenge faced by organic farmers with respect to the threshold discussion is the absence of any recourse for seed companies (and any organic operation) once they find themselves in the situation where contamination is routinely a problem. At that point, it would be difficult to reliably and consistently meet a threshold, even despite their best prevention efforts. Moreover, when contamination is found, there is no recourse available to farmers – no way to collect compensation for testing costs, prevention measures (e.g., opportunity costs of buffers), losses incurred from not being able to sell that seed, or costs associated with cleaning up seed lines.

In the absence of a secure safety net to cover contamination incidents, the financial burden and risk for seed suppliers will only increase with a threshold in place. This cost will undoubtedly be passed on to farmers in the form of higher seed costs and/or fewer varieties. It would also most likely discourage further investments in seed development that is appropriate for organic agriculture, due escalating costs of production.

In the final analysis, USDA-mandated GE contamination prevention measures are essential to the continuing success of organic agriculture, and to preserving biological diversity and food security. Anything short of pulling in the reins on GE agriculture is a disservice to the fair farming principles that the USDA is entrusted by the nation to uphold.

Respectfully submitted by,

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