October 7, 2014

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

Docket: AMS-NOP-14-0063-0001

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 hereby submits comments to the National Organic Standards Board on the following issues: excluded methods terminology, vaccines from excluded methods (GMO vaccines), assessment of soil conservation practices, contamination issues in compost, inert ingredients, peer review panel, and synthetic methionine in organic poultry feed.

**CFS Supports Extensive Discussion of “Excluded Methods” Terminology**

CFS appreciates the work of the Materials Subcommittee on the Second Discussion Document on Excluded Methods Terminology, and supports the further efforts to clarify and interpret the NOP definition of excluded methods. As an initial matter, CFS agrees with the National Organic Program (NOP) that a guidance document is the most appropriate form for any clarification and interpretations. CFS believes that the current definition of excluded methods is strong and should be used as it was intended—as a benchmark against which new and emerging technologies are weighed. The National Organic Standards Board (NOSB) should develop this guidance document with help from the organic community—the responsibility cannot be delegated to NOP. We believe that this is in the best interest of protecting organic integrity, holding organic to the highest production standards, and ensuring consumer confidence in the organic program and label.
The Cartegena Protocol Definition is a Good Place to Start

In past comments, CFS suggested the Cartagena Protocol definition would be a good starting place for the guidance document. CFS still supports the use of the Cartagena Protocol definition as an appropriate jumping off point for guidance, but we do not believe NOSB can use this definition to replace the current definition. Nor is it a perfect model.

The Cartagena Protocol states that “[a] living modified organism is defined as any living organism that has a combination of genetic material obtained through the use of modern biotechnology, namely: (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in conventional breeding and selection.”

The definition splits modern biotechnology in two parts. CFS believes that Part (i) is a good definition of genetic engineering (GE). All known methods, both old and new, that involve in vitro nucleic acid techniques can be defined as genetic engineering, whether or not they result in recombinant DNA. For example, manipulated nucleic acids could be genes from other species that are altered and recombined with regulatory sequences from different species to form recombinant nucleic acids, and then are inserted into targeted organisms to make new proteins—the most common type of genetic engineering in currently commercialized crops. Or they could be genes from the same species similarly engineered and reinserted, as in cisgenics. The definition would also cover the use of synthetic nucleic acids designed to silence genes when inserted into organisms, or when injected into organisms to transiently change gene expression. Such nucleic acids are not necessarily “recombinant” in that they do not always involve the mixing of fragments of genetic material from different sources, but they are designed and manipulated by scientists in a lab, outside of the context of organisms (in vitro), so involve “in vitro nucleic acid techniques.” Importantly, none of the traditional breeding methods involve in vitro nucleic acid techniques.

Part (ii) of the Cartagena Protocol, in contrast, illustrates the complexity involved in developing clear definitions of genetic engineering. Part (ii) has to do with transgressing species boundaries via cell culture techniques. There are inconsistencies, however, in how “fusion of cells beyond the taxonomic family” is considered among various current, working definitions of GE. As such, it is a good example of the need for further discussion of excluded methods.

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In plants, cell walls must be removed in order for fusion to occur; such “naked” cells are called protoplasts. Protoplast fusion is a modern technique that is done in culture in a lab, outside of the context of the organism. It can be used to transfer genetically engineered nucleic acids into a cell, and thus to facilitate genetic engineering. However, it is usually used to transfer unaltered chromosomes carrying disease resistance genes, male sterility genes, and other desired traits from one organism to another without manipulating the nucleic acids in vitro. Fusion of cells is most often used when transfer of the traits by crossing is difficult or impossible, either because the parents are not closely enough related to cross easily or at all, or when the traits are found in organelles that don’t transfer in the desired crosses. It has been used widely to facilitate hybrid production in Brassicas by transferring male sterility from one species to another, for example.

Protoplast fusion, therefore, is a laboratory method that usually results in a product (organism with specific gene combinations) that is difficult or impossible to obtain through normal reproductive processes. As it may result in the combination of genetic material from species that cannot naturally mate, cell fusion is one example of a new breeding technique that, whether or not it falls under a specific definition of “genetic engineering,” may nonetheless be objectionable in an organic context. Discussions of excluded methods, while inclusive of GE, must not be limited to a GE versus non-GE dichotomy. Some modern breeding techniques are not “natural” and there may be philosophical reasons to avoid them, such as respecting the integrity of the organism, or not wanting to promote hybrid seeds, but they are on a continuum with other modern breeding techniques, and may or may not pose novel risks. In order to delineate a clear understanding of those techniques that are acceptable in organic production and those that are not, the organic community must agree upon what exactly it is about a method or technique that is objectionable in the organic context. CFS suggests that NOSB pose this question in the next discussion.

**CFS Supports a Process-Based Approach, In Accordance with OFPA**

CFS also agrees that NOSB should continue with a process-based evaluation of the terms and techniques to determine whether they are the result of excluded methods—not just genetic engineering—or techniques that are objectionable to the organic community. NOSB should define and analyze these terms in the guidance document itself. The guidance must encompass numerous examples to define the extent and boundaries of the excluded methods term. It should focus on processes rather than product as intended by the National Organic Rule.

Using a process-based approach is important because many of the new and novel breeding methods, such as gene editing, involve introducing specific, engineered nucleic acids into plants.
in order to cause specific mutations in plant genes, but the engineered nucleic acids are
digested in the plant cells without ever being stably incorporated into plant DNA. They do their
work and then disappear, leaving behind a mutation that could have happened naturally but
did not. If the process of GE is excluded, these plants would be excluded. A product-based
definition would rely on the presence of manipulated materials in the organism at the end of
the process, such as recombinant DNA incorporated into the genome, and thus some organisms
derived from new methods of genetic engineering may be defined as not genetically
engineered.

An example of this key difference is the use of genetic engineering to speed up breeding of
plum trees, as in the FastTrack plum example in the discussion paper. The trees are engineered
with genes from another species to make them flower faster for breeding, and then when a
desired tree is found after crossing, the original fast flowering gene is bred out, so there are no
longer any engineered genes in the trees. In a process-based rule, the resulting trees would be
excluded because they were produced using recombinant DNA methods. In a product-based
rule, they would be allowed because they do not themselves contain recombinant DNA
anymore. Process-based rules are broader and capture more techniques.

Whether or not these techniques should be prohibited in organic production is a question for
the organic community. CFS suggests that NOSB start from a process-based place to capture as
many of the new technologies as possible. This will allow the community to determine whether
or not certain techniques are objectionable. If we follow a product-based rule, many techniques
will never be discussed, techniques that could impact the integrity of the organic label. NOSB
must allow the community to weigh in on how well these new methods actually work and if
there are unintended consequences that are novel and not found with traditional breeding.

*The Discussion Document Is Evidence That More Discussion Is Necessary*

CFS also points out that the discussion document itself contains errors, increasing the need for
thorough discussion and research among members of the organic community. For example, in
the section entitled “Terms not in the prior Discussion” there are factual errors in the
definitions and descriptions. Notably, Marker Assisted Selection is confused with use of
selectable markers:

Marker Assisted Selection (MAS) – a process whereby a marker is used for indirect
selection of a genetic trait. Markers are usually DNA but they can be morphological
(such as seed color) or biochemical (specific enzymes). Very commonly in use is the
antibiotic resistance marker so that any population can be exposed to antibiotics and
the organisms that survive have the marker. This technique may not necessarily be considered genetic engineering in itself, but can be used in conjunction with other transgenic techniques or involve inserting recombinant markers.\(^2\)

In MAS, no genes are added to plants. Instead, unique gene sequences or visible traits naturally occurring next to genes of interest in the plant are identified, and then progeny of crosses are screened for these unique sequences or traits—“markers” of the gene of interest because they lie close to it—without having to grow the plants to maturity in a field and look for the characteristic itself (drought tolerance, for example). Recombinant DNA is used in the testing but is not inserted into the plant at any time in the process. Rather, GE materials are used as they would be in other kinds of genetic testing, to examine a sample from the organism rather than to change the organism.

In contrast, the use of selectable markers in genetic engineering does involve putting those marker genes into the plants. Usually, an antibiotic resistance gene or an herbicide resistance gene is placed close to the gene being engineered into the plant—close to the Bt gene, for example. Any cell that expresses the resistance gene is also likely to contain the Bt gene. So the researcher uses the antibiotic or herbicide to kill the cells that do not have the resistance gene, leaving just the few that do, and those few are also very likely to have Bt. This selectable marker is thus a clear example of genetic engineering, having been added to the plant specifically to help detect the gene of interest, whereas in MAS the markers are already present next to the genes of interest and are merely being detected.

Visible rather than selectable markers are commonly engineered into genetically engineered crops and animals, also, such as proteins that fluoresce, giving cells that have taken up the recombinant DNA a special glow. These also are clearly examples of genetic engineering.

**Terms that the Materials/GMO Subcommittee Should Add to the Discussion**

The subcommittee has requested that the community suggest terms and methods to add to the discussion. Upon review of the discussion document, CFS believes that there are many terms and methods that are not currently listed in Appendix 1 or otherwise mentioned in the discussion document. However, CFS and the organic community need more time to generate a complete list of terms for the Materials/GMO Subcommittee to review. Biotechnology companies have individual “platforms” for engineering, each with distinctions. The information is publicly available, but not easily accessible. It will require a review of individual patents. Therefore, CFS requests additional time to collect this information.

CFS notes that Appendix 1 does not include the terms listed on pages 4 to 5 of the discussion document. These terms are various new biotech methods that NOSB should consider and add to Appendix 1. In addition to those terms, NOSB should review two new methods for editing genes: CRISPR and TALEN. NOSB should review these methods alongside Targeted Genetic Modification because they are all “gene editing” techniques that may have some similar concerns, but are unique enough to be considered separately.

**Conclusion**

In conclusion, CFS believes that NOSB has only begun to scratch the surface of this discussion. Consequently, we believe that additional time is necessary to comment on this issue in the detail it deserves. We strongly recommend NOSB place this issue on the agenda for the spring 2015 meeting and announce its inclusion immediately such that the organic community has sufficient time to provide substantive comment. CFS also strongly recommends that the NOSB take precautionary action and adopt a moratorium on techniques that have yet to be evaluated until clarification is possible.

**NOSB Must Not Defer the GMO Vaccines Issue to NOP**

Center for Food Safety does not support the use of GMO technologies in organic production systems because we believe that the novel and unproven technology is incompatible with organic principles and practices. GMO technology is explicitly identified as an excluded method in the NOP Organic Rule, a position we strongly support without any caveats. The rule defines excluded methods as “[a] variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes.” It is clear that GMO vaccines in livestock are prohibited in organic, unless reviewed individually under the National List based on essentiality, availability of alternatives, and impacts on the environment and human health.

The Technical Review (TR) for GMO vaccines, requested by the NOSB and completed in November 2011, demonstrates that non-GMO vaccines are available for virtually every known disease for which livestock vaccines are used. In April 2012, the Livestock Committee stated

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4 7 C.F.R. § 205.2

clearly that of the approximately 73 registered animal vaccines, only 13 are GMO. Furthermore, only 2 vaccines, those for Bovine and Avian Salmonellosis, are available only as GMO. Therefore, it cannot be argued that GMO vaccines are essential to organic livestock production as non-GMO vaccines are readily and even more commonly available.

The environmental and human health impacts of the use of any GMO vaccines in livestock have not been sufficiently investigated or reviewed. CFS’ own focused literature search of veterinary medicine, animal science, and welfare journals uncovered scant information about the potential risks associated with using GMO vaccines. This is not because such risks do not exist but because of the lack of research performed and published to date. None of the studies reported results of direct animal field or laboratory experiments or slaughter examinations of animals injected with a GMO vaccine to assess the unique threats GMO vaccines may pose. As this dearth of data suggests, more research is sorely needed on GMO vaccines and drugs before any conclusive health, safety, and efficacy claims can be made.

The prohibition of GMO vaccines in organic production should extend to emergency eradication programs. CFS shares the real concern with our organic colleagues and the Livestock Committee about the potential lack of available non-GMO vaccines to combat a severe disease outbreak, in the rare event that some type of “emergency” is declared by either the federal or state government. In April 2012, the Livestock Committee recommended changing the standards such that GMO vaccines would be allowed in a declared emergency, and producers could use GMO vaccines in such case without losing organic status of livestock. In October 2014, the NOSB continues to push for emergency exemption for GMO vaccines, under the presumption that GMO vaccines will be the USDA’s preferred choice in emergency eradication programs.

We understand that when farmers lose livestock to a disease outbreak, they could lose a lot more than animals. The loss could translate into the complete elimination of decades of breeding by successive generations of livestock farmers, who have worked hard to breed their particular stock so that their herds or flocks are suited for the type of production system and region where their farm is located. Nonetheless, allowing producers to use an unlicensed GMO vaccine in organic livestock production will not necessarily protect this important genetic resource that is integral to the livelihood of farmers. Surely, USDA can develop a better solution, based upon sound science, which upholds the principle of organic integrity.

CFS agrees with NOSB that a comprehensive system of classifying available vaccines is needed in order to avoid the risk of producers accidentally or unintentionally using a prohibited technology. CFS appreciates the efforts of the Livestock Committee and Vaccines Working

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6 NOSB, Livestock Committee National List Proposal: Vaccines from Excluded Methods, 3 April 2012.
Group to develop a satisfactory resolution to the problem of distinguishing vaccines made with and without excluded methods, and agree that current information is insufficient for NOSB to fully achieve this goal. The Vaccines Working Group outlined three criteria by which vaccines can be identified as made with or without excluded methods. It is encouraging to know that some terminology and product references already exist to indicate that vaccines have been made with certain genetic technologies that would be considered “excluded methods.” It is clear, though, that some significant barriers to establishing sufficient labeling and/or product codes remain.

In order for any classification structures to be successful and beneficial to producers, NOP and NOSB must first address the issue of establishing a more precise definition of “excluded methods.” CFS has provided comments regarding “excluded methods” and agrees that the issue must be a top priority for NOSB. In addition, the definition used by USDA’s Animal Plant Health Inspection Service (APHIS)’s Center for Veterinary Biologics (CVB) for evaluating vaccines must align with the definition of “excluded methods”, once finalized. Organic producers have more at stake regarding GMO contamination. Consumers seek out organic specifically to avoid GMOs, and all appropriate measures must be taken to ensure producers are able to uphold this expectation. Furthermore, methods of production cannot be considered the confidential property of vaccine manufacturers. Without transparency, any attempts to distinguish vaccines will be greatly constricted and ultimately meaningless.

**Soil Conservation Practices Are Essential to Organic Systems; NRCS Metrics Are Not**

Center for Food Safety promotes policies that encourage best management practices in organic. Organic principles and the NOP Organic Rule require that producers “must maintain or improve the natural resources of the operation, including soil and water quality.” Soil conservation is not just a requirement for achieving organic certification, but also an outcome of organic’s broader requirement for producers to conserve and promote biodiversity. If biodiversity conservation is emphasized, soil and water resources are likely conserved as a result.

As the Compliance, Accreditation, and Certification Subcommittee (CACS) states, the Food Security Act of 1985 (P.L. 99-198), with its Sodbuster, Swampbuster, and Highly Erodible Lands provisions, made conservation plans a prerequisite for participation in USDA programs for producers cultivating sensitive land—highly erodible, wetlands, and grassland. Farmers whose land(s) qualify under any of those three provisions, not just Highly Erodible Lands (HEL), are required to submit conservation plans in order to participate in and benefit from conservation

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7 7 C.F.R. § 205.200.
programs. However, in contrast to conventional producers that are only required to design soil conservation plans for sensitive lands, all organic producers are already required to document their entire system in the Organic System Plan. CFS understands NOP’s desire to ensure organic producers are taking appropriate measures, but questions the applicability of NRCS metrics to organic systems.

Developing specific training and tools for producers and certifiers to further the biodiversity conservation mandate of OFPA is an important opportunity to uphold organic’s emphasis on continual improvement. These tools, however, must take into account the fact that soil building and conservation practices on organic farms occur in the larger, highly variable context of the entire organic system. NRCS metrics are not developed within a systems approach and therefore not necessarily relevant to organic systems. As organic is a holistic approach to agriculture, measures to ensure appropriate soil conservation must evaluate the entire picture rather than narrow metrics.

In the interest of meaningful dialogue, CFS also feels that it is important to reiterate that NOP must not incentivize the conversion of lands with high conservation value (HCV) to production acreage. HCV lands are habitats that have been classified as important due to their intrinsic environmental, biodiversity, or landscape values. It is imperative that producers are encouraged to continue managing these lands under conservation plans. Producers hoping to transition land to organic may recognize that pesticide-free HCV lands meet the NOP requirement that lands be free of pesticides for at least 3 years and can therefore transition the land to organic quickly. The NOP has an obligation to guarantee that producers have incentive to conserve not convert sensitive and/or HCV lands.

**CFS Supports NOSB’s Intention to Address Contamination of Compost**

CFS supports NOSB’s intention to propose a process for addressing the contamination of compost inputs on organic farms. Healthy compost, as well as the healthy soil it generates, is fundamental to organic production. However, organic farms are often contaminated with synthetic substances that arrive through compost materials; such contamination threatens to undermine the integrity of organic farming. Prompt action by NOSB is therefore necessary to address this significant issue.

*Compost’s integrity is fundamental to organic agriculture*

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8 See NOSB Crops Subcommittee, *Protecting Against Contamination in Farm Inputs* 1 (Aug. 19, 2014) (stating that this discussion document has the aim of “ultimately proposing a process for addressing contamination of inputs that may be brought onto the farm”).
Compost is vital to the success of organic farming, because it offers numerous benefits to farmers and the environment and also, down the road, to the consumer. In compost, organic material is broken down into a community of beneficial organisms, from bacteria and fungi to earthworms. This entire community is essential to plant health, improving crop yields and the nutritional content of foods.

Because composted soil hosts a diverse array of beneficial insects, bacteria, and other organisms, it ensures that plants receive the full spectrum of nutrients they need to thrive. For example, the bacteria in compost can make nutrients—including macronutrients such as nitrogen, phosphorus, and potassium, and micronutrients like manganese, copper, iron, and zinc—more available to plants by holding those nutrients tightly enough to keep them from washing out but loosely enough that plants can take them up. In other words, compost brings life into soil, which supports healthy plant growth. By fostering healthy soil, compost also increases yields.

In addition, compost and composting directly benefit the environment. Soils treated with compost retain significantly more moisture and also resist compaction, which in turn reduces erosion and the amount of water organic farmers need to give to their crops. Compost also encourages healthier plant root systems, which decrease runoff. Further, research has shown that, on average, soil treated with compost produces plants with fewer pests, reducing the need for pest control. Composting reduces the vegetable matter in landfills, minimizing pollution—such as methane, an ozone depletion gas that is twenty one times more potent than carbon dioxide—that landfills create.

**Presumption of limited synthetics under OFPA**

In its report on OFPA, the Senate confirmed that “[m]ost consumers believe that absolutely no synthetic substances are used in organic production.” According to that report, this expectation is the “basic tenet of OFPA.” Consistent with Congress’s intent, the NOP allows synthetics only under certain very limited circumstances, including where synthetics arrive in organic production as a result of “unavoidable residual environmental contamination.” OFPA regulations otherwise specifically prohibit the use of compost that contains synthetic substances that are not on the National List of Approved and Prohibited Substances.

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10 Id.
11 7 U.S.C. § 6511(c).
12 7 C.F.R. § 205.203(e)(1) (producers “must not use,” among other things, “[a]ny fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production”).

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However, as the Crops Subcommittee recognized in its discussion document, and contrary to congressional intent, many synthetics that are deliberately excluded from the National List are appearing in organic production by way of routine inputs like compost. Absent guidance on such contamination and a mandate of strict avoidance, the NOP is tolerating a known practice that directly contradicts the language and purpose of OFPA and erodes the integrity of organic production.

**Contamination of compost is avoidable**

CFS supports the Crops Subcommittee’s conclusion in its discussion document that contamination of compost is “separate but related” to “unavoidable residual environmental contamination” (UREC). Importantly, the routine contamination of compost covered in that discussion document is not “unavoidable.”

As background, under OFPA, a food may not bear the national organic seal if it contains detectable levels of contaminants that are “greater than [UREC].” OFPA regulations clarify that UREC occurs where “[b]ackground levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.” As Congress explained, “[o]n occasion, organic farmers, although following the strict standards in this bill, may produce products with minimum residues due to inadvertent environmental contamination such as drift from a neighboring farm.”

Pursuant to OFPA’s regulations, contamination with a synthetic is unavoidable only where that synthetic persists in the environment and an organic producer cannot avoid contact. Indeed, the very definition of “unavoidable,” which is “not able to be prevented or avoided,” establishes this. The word “unavoidable” therefore indicates that contamination can be avoided unless it is absolutely inescapable and unpreventable.

Unlike truly unavoidable contamination, such as exposure to DDT or spray from a neighboring farm, contamination of organic compost with synthetic substances is avoidable. As the Crops Subcommitte...
Subcommittee’s discussion document correctly describes, synthetics arrive in compost primarily through use of materials that are themselves contaminated. For example, synthetics are introduced where organic compost is derived from municipal collections of grass clippings that have been treated with herbicides, or from manure from animals that consumed antibiotics or synthetic chemicals in their food.

To avoid such contamination, it is important for NOSB to address root causes that put organic production systems at risk of applying compost contaminated with synthetic substances. CFS strongly opposes any policy or regulation that would place undue burden on organic growers who face substantial financial risk from the presence of detectable levels of prohibited substances. The responsibility rests at the source of the compost or materials. NOSB should recommend that manufacturers intending to sell finished compost products or feedstock materials to organic producers should implement testing to identify the presence and level of contaminants. NOSB should offer guidance to manufacturers of organic compost for ensuring integrity of their product. As with all other aspects of the organic supply chain, segregating conventional source materials from organic should be required throughout the composting process.

**Addressing contamination of compost is vitally important**

Eliminating the contamination of organic compost with synthetics is vital to ensuring the integrity of organic production. As discussed, compost is the foundation for foods’ nutrient levels and the reduced environmental footprint of organic production. Contamination at the compost level therefore substantially undermines organics.

Contamination via compost materials is frequent and significant. That is, as the Crops Subcommittee recognized,

> Compost and mulch materials are probably the most common vehicle for contaminants above unavoidable residual environmental contamination levels to arrive on organic farms. Heavy metals, pesticides, and antibiotics are among the contaminants that arrive in organic materials used for compost and mulch.\(^{19}\)

Given the foundational importance of compost, as well as compost’s currently substantial contribution to introducing synthetics into organic production, NOP oversight of this issue is long overdue and now desperately needed.

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\(^{19}\) NOSB Crops Subcommittee, *Protecting Against Contamination in Farm Inputs*, at 2.
Research needed

CFS recognizes the complexity of identifying and preventing contamination of organic compost. As the Crops Subcommittee found, many outstanding questions remain unanswered regarding testing options, information about the prevalence and types of contamination, and how such contamination may be avoided. We strongly agree with the Crops Subcommittee that research is needed on this urgent issue.

CFS Supports Beyond Pesticides’ Recommendation for NOSB Action on “Inerts”

Center for Food Safety is concerned that the NOSB has once again opted to avoid moving forward with necessary action on “inert” ingredients. “Inert” ingredients in pesticide products are neither chemically nor biologically inert, and are included specifically to augment the capacity of pesticide products. While active ingredients in pesticides have been carefully scrutinized against the requirements of the Organic Foods Production Act (OFPA) by NOSB and the public, “inert” chemicals have not received equivalent evaluation.

As mandated by OFPA, NOSB has thoroughly reviewed all active ingredients added to the National List of approved synthetics for organic production for potential hazards to human health and the environment. NOSB must hold “inert” ingredients to these same assessment standards. In certain cases, pesticide products consist primarily of “inert” ingredients, suggesting that some of the most hazardous pesticidal components are chemicals that NOSB has not evaluated under the legally-required criteria. Substances such as alkylphenol ethoxylates (APEs), for example, have breakdown products which have been linked to endocrine disruption. These “inerts” would likely not meet OFPA’s evaluation criteria for inclusion on the National List—e.g., effects on human health or potential for detrimental chemical interactions—if sufficiently reviewed.

In addition, in 2006 the Environmental Protection Agency (EPA) amended regulations for all “inert” ingredients used in pesticide formulations allowed on food crops. The change requires that each “inert” must have either a residue tolerance level or a formal exemption from an established tolerance level. This reclassification also resulted in EPA eliminating its list categories for “inerts”, which grouped “inerts” according to their level of toxicological concern. List 3 “inerts” had unknown toxicity and List 4 “inerts” were considered to have “minimal risk.” Removing the list system and requiring that all “inert” ingredients have an assigned

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residue tolerance level subsequently rendered the existing NOP regulations out of date. Recognizing this, NOSB recommended in 2010 that NOP establish a collaborative task force (the “Inerts Working Group”) to examine the issue and propose a strategy for re-evaluating listed inerts. At subsequent meetings in October 2010 and May 2012, NOSB recommended renewing exemptions for the former List 4 and List 3 “inerts” only until October 21, 2017 and pending a formal review of “inerts individually and as a class of materials.”

However, the current NOSB agenda includes only an update on “inerts” instead of concrete steps to move forward with the action plan. Despite “List 4 inerts” appearing on the sunset review work plan for the Crops and Livestock Subcommittees, NOSB has made no progress since 2012. NOSB cannot continue to stall with regards to “inert” ingredients in pesticide formulations. The Board must begin its review of each “inert” listed and establish solid expiration dates. Since “inert” ingredients may pose greater hazard than other materials allowed in organic production, their review merits a higher priority than NOSB has allotted to the issue.

Center for Food Safety supports the timeline established by Beyond Pesticides (BP) calling for NOSB to set firm expiration dates between June 27, 2018 and June 27, 2022 for all inerts known to be used in organic production. The exception to this timeframe is the expiration date of June 27, 2017 recommended by BP for three groups of “inerts” that warrant more immediate action—alkylphenol ethoxylates (APEs), Ehtylenediaminetetracetic acid (EDTA) and its salts, and former List 3 inerts.

Current exemptions for these “inerts” must expire by the recommended June 27, 2017 date for important environmental and practical reasons. APEs and the alkyl phenol break-down products are endocrine disrupters and EPA is currently investigating alternative surfactants that are not endocrine-disrupting chemicals. Lack of information and review of EDTA and its salts is inhibiting NOSBs ability to adequately review ferric phosphate, a current National List material of which EDTA is an important “inert” component. The former “List 3 inerts” were approved only in passive pheromone disrupters and the law did not intend for USDA to allow these “inerts” in organic production. This group of chemicals, therefore, has a questionable status in organic and requires immediate review.

While these three groups require immediate attention, allowing the indefinite extension of the listing for any “inert” ingredients would be a violation of organic regulations. All other substances identified by the Inerts Working Group as inerts used in organic production, must be annotated with expiration dates between June 27, 2018 and June 27, 2022, as per the timeline recommended by Beyond Pesticides.
NOP Must Establish a Peer Review Panel Without Further Delay

The Federal Register notice published on May 23, 2014 reminded CFS that NOP has still not appointed a Peer Review Panel (PRP), despite OFPA’s statutory mandate and the NOP’s regulatory duties. Nor has CFS received a formal reply to our 2002 rulemaking petition. USDA cannot continue to ignore its mandatory duty to ensure that a PRP reviews all applications for accreditation.22

A PRP is a critical oversight mechanism designed to ensure that NOP’s accreditation procedures are followed and to assist NOP in improving the quality of its accreditation audits. OFPA creates a mandatory duty for the Secretary to review a report of the PRP when deciding whether or not to approve certifiers. OFPA states: “In determining whether to approve an application for accreditation submitted under 7 U.S.C. section 6514, the Secretary shall consider a report concerning such applicant that shall be prepared by a peer review panel.”23 NOP’s regulations underscore this duty, stating that the Administrator “shall” establish a PRP, “composed of not less than 3 members who shall annually evaluate the [NOP’s] adherence to the accreditation procedures...”24

In 2002, shortly after NOP established its accreditation program, CFS petitioned USDA, urging the agency to establish a PRP.25 CFS and its co-petitioners filed the petition in response to growing public concern about whether NOP was properly performing its role as accredditor of organic certifying agencies. In 2009, NOSB unanimously approved further guidance on the PRP issue. NOSB recommended that NOSB’s executive committee appoint a Peer Review Task Force to review the NOP Accreditation program utilizing the Office of Inspector General and American National Standards Institute reports and the NOSB’s 2005 Recommendations as a starting point.26 CFS commented in 2009, expressing hope that “the circulation of [the 2009] guidance is

21 Unified Agenda of Federal Regulatory and Deregulatory Actions 0581-AD28, National Organic Program, Peer Review Panel (NOP-12-0018), Unified Agenda current as of Spring 2014. Available at: https://www.federalregister.gov/regulations/0581-AD28/national-organic-program-peer-review-panel-nop-12-0018-

24 7 C.F.R. § 205.209.
indicative of USDA’s commitment to quickly establish the long overdue [PRP] and accreditation system."\(^{27}\)

To date, USDA has not answered CFS’s petition, instituted NOSB’s recommendations, or otherwise developed a plan to establish a PRP. The only indication that NOP is once again considering what to do with the PRP was the Spring 2014 federal register notice—which provides little insight into NOP’s next steps. The notice merely shows NOP’s intention to open up section 205.209 to remove the requirement that PRP be established pursuant to the Federal Advisory Committee Act (FACA). After twelve years, this is an unsatisfactory next step, ultimately delaying, once again, the establishment of a PRP. CFS urges USDA to establish a PRP immediately.

**Why is Synthetic Methionine Noticeably Absent from the NOSB Agenda?**

The United States Department of Agriculture (USDA) added synthetic methionine to the National List (NL) in 2001. As with all synthetics added to the NL, the intent was for USDA to temporarily allow its use until researchers and industry could identify alternative, non-synthetic sources of methionine for poultry diets. Unfortunately, this temporary exception has lasted for 13 years. NOSB’s failure to establish a firm termination date has given the organic poultry industry no incentive to seek alternatives, as many feed and poultry producers have personally verified with Center for Food Safety (CFS) representatives. It also contravenes the National Organic Program’s (NOP’s) emphasis on continuous improvement, which is expected by the wider organic community and, as such, integral to the ongoing success of organic.

CFS has repeatedly called for synthetic methionine to sunset from the NL and for USDA to direct government research dollars towards the development of viable organic alternatives. Yet, the absence of the issue from this meeting’s agenda, as promised by the NOSB at its last meeting in April, sends a message of disregard for Congress’s intent that USDA eliminate synthetics from the NL.

At the NOSB meeting in April, several NOSB members justified their reluctance to take action to eliminate synthetic methionine from the NL because they claimed its elimination would have serious impacts on animal welfare.\(^{28}\) Nate Lewis of the Organic Trade Association stated that “the step-down of allowed methionine in organic feed has resulted in an increase in animal welfare issues, like feather-pulling and cannibalism.”\(^{29}\) Mel Gaiman of Heritage Poultry

\(^{27}\) CFS, Comments to the National Organic Standards Board, 4 May 2009.

\(^{28}\) NOSB, spring 2014 meeting transcripts, 29 April – 2 May, 2014.

\(^{29}\) Id, at 136.
Management stated directly that “[t]he need for synthetic methionine in high levels for peak growth and demands for poultry, lower levels than adequate create welfare issues.”\textsuperscript{30} John Brunquell, President of Egg Innovations, stated clearly that “methionine is an animal welfare issue.”\textsuperscript{31} They expressed concerns that its prohibition would directly contribute to feather pecking and cannibalism in particular. As these comments underscore, however, there is little scientific evidence to support this claim.

On the contrary, crowded and unhealthy poultry living conditions and curtailments of access to the outdoors to scratch, peck, and engage in natural behaviors—commonplace on organic poultry farms—is mostly what leads to aggressive behavior. If synthetic methionine is indefinitely allowed on the NL it will undermine the integrity of organic poultry and the USDA Organic label, both from the perspective of those who regularly consume organic poultry products and of poultry producers who believe the lack of available organic feed without synthetic MET degrades both the integrity of their products and consumer confidence in organic. In this vein, the NOSB is doing a disservice to the industry by not creating the pressure needed to stimulate the production of poultry feed free of synthetic methionine.

\textit{Synthetic methionine is not necessary for animal health and welfare}

While there is no disputing the fact that methionine (MET) is an essential amino acid that poultry need in their diet in order to thrive, CFS challenges industry claims that only synthetic methionine provides adequate nutrition and serves to prevent cannibalism within a flock. Cannibalistic behavior and feather pecking are functions of a production system that involves incredible stress and agitation. The use of synthetic nutrients props up these inhumane operations. They use chemicals to aid animals in adapting to stressful environments rather than adapting systems to meet the needs of the animals. This practice is inconsistent with OFPA, the organic regulations, and consumer expectations of organic. Ensuring flocks are not reared in intensive, unnatural, and stressful conditions, as is required of all organic systems and as detailed in Center for Food Safety’s Report: \textit{USDA Stalls Regulations to Improve Organic Poultry Living Conditions},\textsuperscript{32} is by far the best way to combat cannibalistic behavior.

Since MET is one of only two Sulfur Amino Acids (SAA), the industry has claimed that birds fed insufficient levels of MET will crave sulfur and feel compelled to eat the feathers of other birds

\textsuperscript{30} Id at 166.
\textsuperscript{31} Id at 204.
in order to satisfy this craving. However, little field research actually exists to support this link. Instead, 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.

For example, one study from the University of Kassel in Germany found that natural scratching and pecking activity was strongly increased, and feather pecking subsequently reduced, with adequate lighting conditions. Poorly designed production systems also do not allow birds to express their natural foraging behavior, leading to excessive feather pecking. 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. Feed that can be consumed rapidly and satiate birds quickly can “stimulate feather pecking because of insufficiently exercised pecking behavior.”

Supporters of synthetic methionine have argued that feather pecking persists and even increases in outdoor, free-range operations, citing it as evidence that housing is not the issue. However, research has consistently demonstrated that feather pecking in free-range systems is a result of poorly designed outdoor areas that increase fear or stress among the flock. 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. 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,

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37 Rodenburg, B, 2011.
38 Sundrum et al, 2005.
increased use of outdoor areas and reduced fear among the flock.\(^{40}\) 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.\(^{41}\)

In addition, 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.\(^{42}\) This further demonstrates that system design plays the strongest role in feather pecking and animal welfare, and challenges industry claims that feather-pecking will persist and increase in free-range operations. 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.”\(^{43}\)

**Industry reliance on growth performance and cost-efficiency is contrary to organic principles and consumer expectations**

The use of and reliance on synthetic methionine in poultry feed is primarily a function of the industry’s emphasis on growth performance above all else. 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.”\(^{44}\) Synthetic methionine allows producers greater control over precise nutrient levels in order to guarantee cost-efficient but unnatural growth rates. Significant research has demonstrated that in the absence of synthetic-methionine feeds, the overall health of birds is not jeopardized.\(^{45}\) Instead, particular performance measures—such as growth or egg production—may be slightly reduced. A meta-analysis by the Department of Animal Nutrition and Animal Health at the University of Kassel demonstrated that if slower-growing breeds are used rather than conventional breeds,


\(^{41}\) Bestman & Wagenaar, 2003.


\(^{44}\) Sundrum et al, 2005, at 56.

overall protein requirements for broilers are clearly reduced.46 Using slower-growing breeds, of course, means a longer period between hatching and slaughter.

Conversations CFS had in 2014 with organic poultry feed manufacturers further substantiate these findings and the role synthetic methionine plays in organic poultry diets. Manufacturers often claimed that without synthetic methionine the birds certainly would not die, they would simply convert feed to meat and eggs less efficiently, and producers would have to be content with a broiler taking 12-15 weeks to grow to market weight rather than 6 weeks.47 Some manufacturers also acknowledged that housing practices would need to change in the absence of synthetic methionine and that allowing birds to be outside in nature reduces or eliminates the need.48 This suggests that the use of synthetic methionine is also a function of housing chickens indoors. One manufacturer interviewed stated clearly that the phase-out of synthetic methionine would impact the industry in terms of performance and housing practices only.49

One feed manufacturer expressed confidence that if all grasslands in the United States were managed properly, enough chicken could be produced on pasture without synthetic methionine. The biggest stumbling block, according to this manufacturer, is that America has a cheap food policy.50 In addition, more jobs would be created to manage pastured flocks. The number of birds a poultry producer can sustainably raise on pasture depends greatly on a variety of factors—including breed, type of land, and whether they are layers or broilers—and estimates range from 50 up to 500 hens per acre.51 According to the USDA National Agriculture Statistics Service (NASS), peak inventory of organic broiler and layer chickens in 2011 was roughly eleven million. To be pastured, those birds would thus require 220,000 acres of grassland using conservative estimates.52 The amount grassland pasture and range in the United States was 587 million acres in 2002,53 meaning that producing the same volume of organic chickens as in 2011 on grassland would require 0.0004% of US grasslands.

46 Sundrum et al, 2005.
49 Id.
52 220,000 acres at 50 birds per acre would accommodate 11 million birds.
Recent studies of organic poultry diets have found that differences in performance measures are not as pronounced as industry claims and CFS’ conversations with feed manufacturers suggest otherwise as well. A comparative study by researchers at the UK Organic Research Centre of 4 different poultry diets, only one of which included synthetic methionine, found that birds fed the 100% organic diets did not have significant differences in weight or mortality compared to those fed synthetic diets. In fact, the poultry fed 100% organic diets had higher egg output of laying hens compared to those fed a synthetic diet. The study concluded that organic diets required higher overall feed intake and, combined with higher ingredients costs, 100% organic diets would mean increased feed costs for farmers. This study illustrates the fact that the primary deterrent to prohibiting synthetic methionine is the associated costs rather than concern for animal welfare. Growing organically is intended to be an alternative to the destructive, unnatural practices associated with conventional production systems, recognizing that organic producers and consumers will both absorb some additional costs to support organic’s numerous environmental and nutritional benefits.

OFPA is a process-based law that requires management practices that promote natural systems and emphasize quality. The use of synthetic methionine runs contrary and enables organic producers to cut corners and production costs in a manner similar to conventional. In fact, a European Commission study, concluded that banning non-organic feedstuffs as supplementary protein sources will effectively limit the intensification of the industry and redirect poultry production “from a quantity related to a quality oriented production process and to provide a clear distinction between organic and conventional production.”

**Viable organic alternatives are available and require industry and government support**

The organic poultry industry has also defended the use of synthetic methionine with claims that no viable alternatives are currently available. This position ignores chickens’ naturally omnivorous diet. Chickens access methionine from animal proteins, such as foraged insects and worms, and some organic poultry farmers have also supplemented poultry diets with dairy (whey) and other food animal by-products, such as sour milk, bone meal, and blood meal. While a 100% vegetarian diet is not suitable for chickens, certain plant proteins can be included in rations to provide an appropriate, balanced diet. In order to promote continuous improvement, NOSB and NOP must promote all efforts to research the efficacy and availability of alternative and natural sources of methionine. In past comments, CFS has provided its preliminary findings from analyzing existing research in hopes that NOSB, NOP, and the poultry

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55 *Id.*
56 Sundrum et al, 2005, at 78.
industry will take the baton and provide support for innovative ways to break the synthetic methionine addiction.\textsuperscript{57}

The most promising area of research to alternative sources of essential amino acids for poultry rearing focuses on insect species as a sustainable protein source. For example, fly maggots from black soldier flies and houseflies—insects that are particularly high in methionine—can be reared on poultry manure and then provided as a feed ingredient. Organic agriculture is a systems approach and this type of integrated system, where a critical portion of feed is living on and helping to compost waste from that system, supports that approach.

A number of recent studies have focused on the efficacy of insect larvae, or magmeal, as animal feed. In 2013, the UN Food and Agriculture Organization (FAO) released a comprehensive report on the role of insects in food security, including their potential as feed for pigs, fish, and chickens. The FAO report cited numerous studies that demonstrated 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.\textsuperscript{58} A university researcher 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.\textsuperscript{59} A 2012 study found that two species of mealworm larvae were particularly high in essential amino acids, including methionine, and had a close to ideal protein ratio.\textsuperscript{60}

Insect magmeal production has increased in recent years due to increasing demand from aquaculture producers to provide insect proteins to cultivated species of fish. 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. This trend suggests that the commercial availability of

\textsuperscript{57} Center for Food Safety, Comments to the NOSB Docket: AMS-NOP-14-0006, 8 April 2014; Center for Food Safety, Comments to the NOSB Docket: AMS-NOP-13-0049, 1 October 2013; Center for Food Safety, Comments to the National Organic Standards Board Docket No: AMS-NOP-12-0040-0001, 24 September 2012.


\textsuperscript{59} Villet, M.H. no date. Biorecycling with Flies.

\textsuperscript{60} Veldkamp, T. et al. Insects as a sustainable feed ingredient in pig and poultry diets – a feasibility study. Wageningen UR Livestock Research. October 2012; Fanatico, A. Organic Poultry Production: Providing Adequate Methionine, USDA National Sustainable Agriculture Information Service, 2010; Baker, D.H. & Y. Han. “Ideal Amino Acid Profile for Chicks During the First Three Weeks Posthatching.” Poultry Science, 73(9), 1994: 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%).
insect proteins is increasing, and the poultry feed industry has an opportunity to promote further development of insect proteins to meet its methionine needs. In the United States this is slow to happen. The only way to stimulate market innovation and demand is to set a concrete expiration date for synthetic methionine, as the NOSB committed to at its meeting this past April.

Research has also demonstrated that natural methionine supplements provide a viable alternative to synthetic methionine. In India, broilers reared on 15 grams/kilogram (g/kg) of herbal methionine had greater total body weight and greater weight gain than birds raised on 10 g/kg synthetic methionine and 10 g/kg herbal methionine. Even with this similar weight gain, abdominal fat and liver lipid was decreased among birds fed the 15 g herbal methionine diet. In addition, mortality rates of the bird were similar for all diets. 61

A 2014 study at the Maharashtra Animal & Fishery Sciences University in India compared three different diets fed to groups of the same broiler breed: a diet with no supplemental amino acids, a diet with supplemental synthetic amino acids, and a diet with supplemental herbal amino acids. 62 The study found that the herbal amino acid diet produced birds with significantly higher live body weight, a more economical feed conversion ratio, and a higher carcass yield than the synthetic-based diet. 63 Another study comparing herbal and synthetic supplemented diets found that, based upon growth performance results, the herbal formulation 64 could “replace DL-methionine very effectively in the diet of commercial broiler birds when used at the rate of 10 g/kg diet.” 65

Another alternative to synthetic methionine with increasingly positive scientific support is algae. The German company Phytolutions, for example, manufactures a microalga-based animal feed supplement for poultry (as well as cows, pigs, and household pets) called Phytomix that contains high levels of methionine. 66 Research has shown that vitamin-mineral premixes

62 Thakur, A., et al., “Comparative efficacy of herbal and synthetic amino acids for growth performance and hepatoprotective action in broiler chickens.” International Journal of Biomedical And Advance Research, 5(1), 2014: 14-18. (The herbal supplement consisted of high protein herbs Cicer arientinum (Chickpea), Phaseolus mungo (Black gram), Mucuna pruriens (Velvet bean), Trigonella foenum graecum (Fenugreek), Nigella sativa (Black caraway), and Citrullus colocynthis (Colocynth/Bitter cucumber)).
63 Thakur, et al. 2014.
64 Herbal mixture comprised of Allium sativum (garlic), Allium cepa (onion), Phaseolus mungo (Black gram), and Mucuna pruriens (Velvet bean).
66 Phytolutions company website. Available at: http://www.phytolutions.com/node/141. 4.5 mg/kg (dry weight) of methionine.
are normally not required when *Spirulina* has been included in the feed. In addition, chickens receiving diets supplemented with *Spirulina* had better health.\(^6^7\) A review of scientific literature by the UK Organic Research Centre found that *Spirulina* was relatively high in methionine and suitable for all classes of poultry.\(^6^8\)

**Additional Research and NOSB Action is Required**

These are just a few of the innovative ideas that exist to eliminate the use of synthetic methionine in poultry feed. These feed sources will not develop into full-blown, commercial solutions without the cooperation of NOSB, NOP, and the poultry industry. CFS urges the NOSB to stop dragging its feet on this issue and move forward with a solid termination date for synthetic methionine in organic poultry. As this testimony has demonstrated, claims that its prohibition would negatively impact the health and welfare of chickens are wholly unfounded. The continued allowance of synthetic methionine undermines the integrity of organic.

Thank you for your consideration of our comments.

Respectfully submitted by:

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