National Organic Standards Board Meeting
Galt House Hotel, Grand Ballroom C, Louisville, KY October 28-30, 2014

National Organic Standards Board
Materials Subcommittee
Proposal: Research Priorities for 2014

August 26, 2014

Introduction

A Recommendation for a Framework to set Research Priorities was approved at the National Organic Standards Board (NOSB) meeting in May 2012. Part of that recommendation was that the priorities from the previous year of NOSB deliberations would be presented at each fall meeting. Therefore, we have collected suggested research topics from the NOSB Subcommittees and from suggestions within the public comments and present the top research priorities for approval this fall.

Each fall, after a recommendation is finalized by the NOSB, the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

Background

The reasons for encouraging research into organic production systems are well discussed in the previous two Materials Subcommittee papers from fall 2011 and spring 2012.

The recommendation that was passed recommends that potential topics be prioritized. The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but will be evaluated by the Materials Subcommittee in selecting the top research needs.
Criteria for research topics are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Research Priorities in 2012 and 2013

In 2012, the NOSB adopted research priorities and identified topics for future review. In 2013, the Materials Subcommittee proposed research priorities and identified topics for future review, but they were not adopted by the NOSB until spring of 2014 because the fall 2013 meeting was cancelled due to a government shut down. All of these topics, listed here, are still priorities.

Research Priorities for 2012[1]

Whole Farm Systems Research
Evaluation of Copper Sulfate for Rice
Evaluation of Antibiotics (Tetracycline and Streptomycin) alternatives
Evaluation of Genetically Modified Vaccines (GMO)
Organic Aquaculture
Methionine Alternative
Carrageenan

Priorities for 2013[2]

Whole Farm Systems
Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight
Evaluation of Genetically Modified Vaccines (GMO)
Methionine Alternative
Organic Aquaculture
Aquatic Biodiversity
Herd Health
Pastured Poultry and Salmonella
Commercial Availability Assessments
Consumer Demand
Fate of Genetically Engineered Plant Material in Compost
Reduction of Genetically Modified Content of Breeding Lines

Proposal: NOSB Research Priorities 2014

For 2014, the Subcommittee has added the topics below as priorities for research. In addition, the Subcommittee continues to support all research priorities identified in 2012 and 2013.

Handling Subcommittee

Alternatives to Bisphenol A (BPA)

The Handling Subcommittee plans to take up the issue of whether to prohibit BPA in packaging material used for organic foods in light of mounting evidence that it may be harmful. There needs to be an increase in research about suitable alternatives for the linings of cans used for various organic products such as tomatoes, beans and soups.

[1] **2012 Other Topics for Future Review**

Parasitism
Mastitis
Herd Health
Plant Extract to organically control methane producing bacteria in livestock

[2] **2013 Topics for Future Review**

Chlorine Alternatives
Sulfuric Acid Alternatives
Parasitism
Mastitis
Pneumonia

This issue meets the following criteria in the NOSB research priorities framework:

- Persistent and Chronic
- Challenging
- Lacking in Primary Research

Crops Subcommittee

Plant Disease Management

There is a need for research into plant disease management practices and alternative materials, particularly for the humid areas of the country, that decrease reliance on copper or other substances that might have a negative impact on the soil and health of workers. Pathogens include, but are not limited to: *Alternaria, Erwinia, Pseudomonas, Xanthomonas, Cercospora, Colletotrichum, Cladosporium, powdery mildew, downy mildew, Phytophthora, Pythium, Mycosphaerella, Phomopsis, Taphrina, Elsinoe, Gnomonia, Fusicladium, Nectria, Phyllosticta, Diplocarpon, Albugo, Guignardia, Botrytis, Exobasidium, Entomosporium, Exobasidium, Pestalotia, Phoma, Cristulariella, and Monilinia fruticosa.*

Citrus greening, caused by the bacterium *Candidatus Liberibacter*, and spread by a disease infected Asian citrus psyllid, is an emerging problem. Promising avenues of research include disease-resistant varieties, predators and parasites and how they interact with approved materials, nutrition (calcium, boron, and nitrogen have been identified), and botanical oils.

In particular, both biological control of plant diseases and bio-pesticides should be a research priority to support organic growers. A large body of research has shown that plant diseases caused by bacteria and fungi can often be prevented by the application of a non-pathogenic microorganism before infection occurs. Although much basic research has been done to identify microbial biological control agents, there is still a need for commercial development, field testing, and adoption by growers. Biological controls have been researched for late blight of potato and tomato (*Phytophthora infestans*), several diseases caused by *Botrytis cinerea*, and powdery mildew (several species), controlled by mites, fungi, bacteria.

Although many biological controls and bio-pesticides have been effective in research plots, they have often not succeeded commercially because they can't compete with inexpensive synthetic chemicals used by non-organic farmers. Biological materials are often more expensive than conventional pesticides, and they need be applied before disease is apparent. In the past, there was little market for biological controls, because the organic acreage was limited. Now that organic acreage has increased, the market for alternative plant disease controls has also increased, which can spur commercialization of natural methods of disease control. The availability of biological controls for plant diseases can also make it more feasible for conventional farmers to transition to organic, thus benefitting organic consumers.

This topic meets all the criteria in the NOSB research priorities framework.

Soil Building Practices

Humates seem to fill a need for practices and materials that accelerate the development of organic matter in the soil, especially in the transition to organic practices. Are there other such practices and materials? Building soil health with nonsynthetic practices is integral to organic management practices.

This meets all the criteria for research support.

Mitigation Measures for Residues in Compost

Residues of pesticides in compost material are a problem that requires research, according to OMRI. Because of the importance of compost to organic management systems, research is needed on types of mitigation measure that are efficacious, identification of problematic feedstock (e.g. cotton-based materials and yard waste), types of corrective action, and if thresholds for allowable residues are established, testing guidelines are required.

This meets all the criteria for research support.

Organic No Till

Organic no-till practices are a subset of whole farm systems. Unlike chemical-based no-till systems, organic no-till builds biodiversity and increases soil health. And, compared to tilled organic systems, organic no-till preserves and builds more soil organic matter, conserves more soil moisture, reduces soil erosion and requires less fuel and labor. Some of the questions raised for whole farm systems in general relate to organic no-till practices: How does biodiversity contribute to pest and disease resistance? What is the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests? In addition, research into organic no-till should address practices that lead to effective weed control with minimum interference with the crop.

This issue meets the following criteria in the NOSB research priorities framework:

- Persistent and Chronic
- Challenging
- Lacking in Primary Research

Materials/GMO Subcommittee: Seed Purity from GMO Research Needs

How contaminated with GMOs is at-risk seed?

There is a lack of data on how much crop contamination is occurring from seeds as a vector compared to drift or handling practices.

This issue meets the following criteria in the NOSB research priorities framework:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.

Research on integrity of breeding lines and foundation seed and ways to mitigate small amounts of genetic presence in breeding lines.

A concurrent question is: Are public germplasm collections that house at-risk crops contaminated?

Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be researched.

This issue meets the following criteria in the NOSB research priorities framework:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.

Risk Reduction from Off-Target Exposure to Non-Permitted Materials

What we have found to be true is that organic farmers can gather a great deal of vital information about how to reduce the impact of contamination from the development of a sound organic system plan (OSP) and through the knowledge shared by their USDA organic certification agent.

However, even if the best OSP plan is intact, organic farms may still be at risk from the impact of contamination from agricultural farms utilizing GMOs and their pesticide treatment.

Successful coexistence suggests that organic farms can exist without harm, consistent with consumer and farmer choice to avoid or minimize contamination. Avoidance or minimization may be achieved through users of GMOs and pesticides adopting practices that prevent non-permitted materials in OSPs from causing involuntary exposure by moving off their target site.

Research efforts are needed on behalf of organic stakeholders, NGOs, USDA (Natural Resources Conservation Service, National Institute of Food and Agriculture, Risk Management Agency, etc), Land-Grant Institutions, and in coordination with partner agencies, such as the U.S. Environmental Protection, state Departments of Agriculture, and others, on alternative strategies that can 1) develop and examine management practices that enhance public and farmer awareness of at-risk organic farms, 2) identify effective practices and standards that will prevent non-target impacts of materials used on farms not certified organic, and 3) best methodologies to provide information and training.

Critical and timely questions include: Are there strategies in place or that could be put in place that can provide information, training, to enhance public awareness of at-risk organic farms? Which methodologies are successful in ensuring risk reduction from materials not permitted under organic standards?

This issue meets the following criteria in the NOSB research priorities framework:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.

- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.

Livestock Subcommittee

Mastitis

Mastitis, which has been listed for two years as a topic for further review, is the second priority of the Livestock Subcommittee. Mastitis is a disease that results in inflammation of the mammary gland. It is generally associated with dairy animals. It can be caused by bacteria, physical injury, etc. Mastitis is one of the most common and expensive diseases of dairy cattle. It can result in reduced milk production, discarded milk, treatment, and veterinary expenses. An urgent need exist for looking at ways to reduce mastitis in dairy herds. The research needs include the areas of herbal treatment of mastitis and management practices, and consider the efficacy of organic treatments used by, recommended to, and available to organic producers.

This issue meets the following criteria:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Lacking in primary research on mastitis prevention. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Parasitism

Parasitism of livestock, which has been listed for two years as a topic for further review, is the third priority of the Livestock Subcommittee. The control of internal and external parasites is important to animal welfare, growth, reproduction, and production. In organic production, the control of parasites is critical. The use of antibiotics is prohibited. A limited number of substances are available to control parasites. Antibiotics are not allowed in organic livestock production for growth, reproduction, and production. Antibiotics can be used on sick animals. However, these animals cannot be sold as organic. A critical need exist to explore ways to find materials for the control of internal and external parasites in organic livestock operations. Research is needed that considers the efficacy of organic treatments used by, recommended to, and available to organic producers.

This issue meets the following criteria:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Lacking in primary research on parasite prevention. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

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Pneumonia

Pneumonia was a topic for further review in 2013, and is the fifth priority of the Livestock Subcommittee. Pneumonia denotes a swelling of the lungs. Pneumonia is rare when animal populations and densities are low. In the winter, animals are housed or gather more closely together, increasing the concentration of pathogens in their environment. Confinement and higher animal densities result in increased air temperatures, humidity, and condensation, which are beneficial conditions for pathogen survival and transmission. Pneumonia in a herd or flock means animals are not performing up to their maximum potential, production costs are higher, labor is increased, and food product quality is compromised. Responsible animal caretakers know it is their duty and responsibility to address animal welfare concerns and ensure a safe and healthy environment for their animals. Research is needed that considers the efficacy of organic treatments used by, recommended to, and available to organic producers.

This issue meets all of the research criteria.

Herd Health

Herd health was a topic for further review in 2012 and a priority issue in 2013. It is the sixth priority (tied with aquaculture) of the Livestock Subcommittee. The assessment of preventative organic practices to improve organic livestock health are critical and of high importance. These include general animal health as it relates to diseases prevention, uterine infections in peri-parturient animals, growth, and identification of vaccine types, nutrition, and production systems. It thus encompasses some of the more specific issues and is also related to the 2012 and 2013 priority of whole farm systems research.

This issue meets all of the research criteria.

Plant Extracts

Use of plant extracts to organically control methane producing bacteria in livestock was a topic for further review in 2012 and is the Livestock Subcommittee's ninth priority. Plant extracts that could be environmentally and economically beneficial to organically control methane producing bacteria in the animal could lead to practices that reduce methane. Reduced methane results in more energy going to the animal from a given amount of feed. This reduces total feed required to meet nutritional needs and particularly helps grazing animals which have high protein availability.

This topic meets the following research criteria:

- Challenging
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Call for Researchers

We hope that this information will be useful for researchers in many fields to defend and solicit funds for research that benefits organic production and handling. There is an ongoing need for organic research on a wide range of issues. There is a wealth of data and research on topics of interest to the organic community. However, there is a paucity of research on our current issues conducted in an organic environment. Therefore, we invite the public to comment on these topics, to circulate this widely, and to recommend

that funders also prioritize these topics. Please submit comments on funders who might want to remain informed of research opportunities in organics.

Committee Vote

Motion to adopt the proposal on NOSB Research Priorities for 2014.

Motion by: Jay Feldman
Seconded by: Zea Sonnabend
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Second Subcommittee Vote

Motion to amend the NOSB Research Priorities for 2014 by adding the section "Risk Reduction from Off-Target Exposure to Non-Permitted Materials."

Motion by: Jennifer Taylor
Seconded by: Jay Feldman
Yes: 5 No: 1 Absent: 1 Abstain: 0 Recuse: 0

Approved by C. Reuben Walker, Subcommittee Chair, to transmit to NOSB August 27, 2014

National Organic Standards Board
Materials/GMO Subcommittee
Second Discussion Document on Excluded Methods Terminology

August 22, 2014

Introduction and Scope

A year ago the project was started to grapple with the definition of "excluded methods" in the USDA organic regulations. This is the definition that appears in the rule (7 CFR 205.2; Terms Defined):

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

The definition was based on the best efforts of the NOSB in 1995 and has provided adequate guidance to prohibit the use of the most obvious genetically engineered crops such as herbicide-resistant corn and soybeans and Bt cotton, as well as prohibit processing inputs such as genetically engineered yeasts and enzymes. However, this definition contains terms that are unclear, outdated and incomplete in light of new methods of recombinant DNA technology that have emerged since the definition was first adopted in 1995.

In 2011 and 2012 a number of confusing issues came before the NOSB and to the NOP which made it necessary to revisit the definition. These include genetically engineered vaccines for livestock, the use of cell fusion within plant families to create male sterility in brassica hybrids, whether or not GMOs could be used in biodegradable bioplastic mulches, and the question of whether mutated algae might therefore be genetically engineered. The current definition is inadequate to clarify these issues.

In 2013, NOSB first Discussion Document on excluded methods,[1] each of the terms in the above definition was discussed further, terms involved in traditional breeding, such as mutagenesis and conjugation, were defined and discussed, and new terms that may be considered to be genetic engineering were brought up. No conclusions were suggested except that there is a need to do more work on the subject. The discussion questions posed asked commenters to suggest principles on which to base GE distinctions, to offer opinions on what terms were and were not excluded methods, and to bring forward new terms that may need consideration. A list of the terms brought up is in Appendix 1.

The NOSB received about 16 substantive public comments on the first discussion document, and also many general comments about keeping GMOs out of organic agriculture. The intention of this Second Discussion Document is to summarize the substantive public comments received on the previous one and to propose some further questions to move forward the issue of strengthening the Excluded Methods Terminology. The goal, as this effort continues, is to have concrete determinations for the National Organic Program, Accredited Certifiers, and organic producers to use in keeping GMOs out of organic food and farms.

[1] NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5102656

This Discussion Document builds onto where the other one left off. The sections below titled "Relevance to Rulemaking", "Comments on Definition(s), Principles, and Criteria", "Process or Product" and "European Approaches" are all summaries of information that was submitted through public comments. The subsequent "Discussion" section includes the NOSB subcommittee analysis of the issues brought up. Finally, the questions at the end aim at collecting more input from the public on how to proceed.

Note: The Subcommittee recognizes that the usual public comment time period is not long enough to fully circulate, digest, discuss and respond to these issues. We strongly urge the NOP to create the ability for longer comment periods as was adopted by the NOSB in its Public Communications Recommendation on April 10, 2013.

Relevance to Rulemaking

In our first Discussion Document we did not state whether the subcommittee was proposing a change in the regulation or to address this subject through guidance.

Several commenters pointed out the language from the Senate report that accompanied OFPA, which was quoted in the first proposed rule. (62 Fed. Reg. 65850, 65875)

> While the OFPA mandates that the Secretary develop organic standards, it is silent on the issue of genetically engineered organisms (GEOs) and their products. However, the accompanying Senate report language states that ''as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production. The committee is concerned that production materials keep pace with our evolving knowledge of production systems.[2]''

This reference from the Senate report was quoted in the first proposed rule somewhat out of context. It appears to have been used by the congress as justification for a registration program for organic materials that was subsequently removed from the conference report. However, it implies the same need for flexibility as quoted below from the rule's preamble.

From the preamble to the current rule (65 Fed. Reg. 13512, 13521):

> We recognize that the phrases, ''natural conditions or processes'' and ''not considered compatible with organic production,'' may be subject to interpretation.
> ....
> we recognize that industry and consumer expectations regarding the products of these techniques in organic production systems may evolve. We believe that, taken together, these phrases allow for a degree of flexibility to ensure that our regulations continue to accurately reflect industry practices and consumer preferences. In cases where questions may arise regarding a specific technique, we anticipate that such questions would be resolved by the Administrator based on recommendations from the NOSB.

[2] U.S. Senate. 1990. Food, Agriculture, Conservation and Trade Act of 1990 - Report to Accompany S2830. Rpt 101-357, 101st Congress, 2nd Session. Government Printing Office, Washington, DC.

The Materials/GMO subcommittee has discussed this issue and believes that NOP Guidance is the most appropriate form for any clarifications and interpretations to be made regarding excluded methods, for the very reasons mentioned by the Senate and the NOP.

Comments on Definition(s), Principles, and Criteria

This section is in two parts. Part 1 summarizes the public comment regarding principles and criteria to consider in clarifying or revising the excluded methods definition further. Part 2 consists of the additional terms brought up by commenters with some of their definitions provided. Appendix 1 contains the terms that were defined and discussed in the first Discussion Document.

1. Other definitions related to Excluded Methods to draw from –

A. The Cartagena Protocol definitions (CFS public comment):

"Living modified organism"

> "[a] living modified organism is defined as any living organism that has a combination of genetic material obtained through the use of modern biotechnology.

"Modern Biotechnology" (also adopted by Codex Alimentarius):

> (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."[3]

"While this language is more specific, the underlying theme of the definition is the same However, the distinctions presented by the Cartagena protocol definition could also be used to inform a newly created guidance document.[4]"

B. Proposed new definition of Excluded Methods (Dag Falck public comment):

> Methods that change the genetic material of an organism through recombining DNA[5] through laboratory methods and in ways that are not dependent on the use of conjugating, sexual or asexual reproduction methods, including transgenic (intraspecific or intergeneric), or cisgenic (intrageneric) transfers of genes. Methods not included in the definition are: other natural, classical, or modern breeding techniques that depend on movement of genes only through a conjugative, sexual or asexual reproduction method with parent gene material from within the same taxonomic family[6].

C. Ethical Criteria (FiBL public comment):

> 1. The genome is respected as an indivisible entity and technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins).
> 2. The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e.g. digestion of the cell wall, destruction of the cell nucleus through cytoplast fusions).
> 3. The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from

[3] Convention on Biological Diversity. 2013. The Cartagena Protocol on Biosafety. Available at: http://bch.cbd.int/protocol.
[4] Center for Food Safety 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070
[5] http://en.wikipedia.org/wiki/Recombinant_DNA.
[6] Dag Falck, Nature's Path 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

(e.g. Terminator technology).[7]

D. Operational criteria (Rich Theuer public comment):

It is very helpful that you set forth these operational criteria for implementing the phrase "without the use of excluded methods:"

1. Keeping genetically modified organisms out of organic livestock feed, crops, and food; and
2. Preventing the introduction of novel proteins into soil and water ecosystems.

This is the kind of guidance that certifiers, producers, and handlers can execute.[8]

2. Terms not in the prior Discussion[9]

The descriptions provided here are our best attempt to summarize very technical issues. More information can be found in the cited sources. While some of these techniques may seem to obviously be consistent with the existing excluded methods definition, others are not, and some may or may not be depending on specifics. These are presented only as examples to give readers the context and descriptions of some terms that will be evaluated in our future work.

- Doubled Haploid Technology – A breeding technique used to create homozygous inbred lines in one generation instead of the many required by traditional methods. Used widely in wheat, canola and corn, it involves the following steps: emasculation, pollination, 2,4-D treatment, embryo culture, and colchicine treatment. It often involves crosses between wheat and corn.
- Targeted genetic modification (TagMo) – a collective term for the zinc finger nuclease techniques that create DNA double-stranded breaks at specific genomic locations that can then be used to alter the target gene. The genetic modification would not necessarily involve transfer of nucleic acids from another species, nor would it be easy to detect in a final product. It is unclear how these would be regulated in the U.S.
- "FasTrack" – a breeding scheme that has so far been used in plums where an early-flowering gene from poplar is inserted into a plum tree. When the plum flowers in less than a year, it is crossed with non-transgenic varieties carrying desirable traits. Markers are used to identify the right traits and, at the end of the breeding program, only those are selected that do not have the transgene.
- Synthetic Biology – practitioners generate new DNA sequences the way computer programmers write code, creating new life-forms. Called by one of its founders "genetic engineering on steroids[10]". So far it has been used to generate a yeast that produces a malaria drug and to make synthetic vanilla.
- Cisgenics – A genetic modification of a recipient organism with a gene (cisgene) from a crossable (sexually compatible) organism. This is not always interpreted as a prohibited technique because such crossing may be able to occur in nature.
- Intragenesis – genetic modification of a recipient organism that involves the insertion of a reorganized, full or partial coding region of a gene, often with a promoter and/or terminator from another gene of the same or crossable species.

[7] FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

[8] Richard Theuer 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

[9] Among many sources used for definitions are the following: Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888; Podevin N, Devos Y, Davies HV, Nielsen (2012) Transgenic or not? No simple answer! EMBO reports 13: 1057 – 1061; Waltz E (2012) Tiptoeing around transgenics. Nature biotechnology 30: 215–217; Wikipedia for each term.

[10] Phillpot, Tom 2014. Now your Food Has Fake DNA in It. Mother Jones http://www.motherjones.com/environment/2014/08/food-fake-dna-synbio-vanilla-ice-cream

- Plastid transformation – Plastids are semi-autonomous organelles within higher plants with a small, highly polyploid genome. Technology has been developed for genetic modification of this genome independent of nuclear DNA. Currently used commercially in tobacco, and widely researched.[11]
- Gene silencing via RNAi and DNA methylation – Interfering with the regulation of gene expression through inserting methyl groups onto RNA and DNA that then supress the expression of the gene. Can occur in nature, but is used as a recombinant technique in cancer research and plant breeding.
- RTDS (Rapid Trait Development System) – the next generation precision gene editing technology developed by Cibus company. Similar to the oligonucleotide targeted DNA modification (below) it does not leave behind transgenic material, only uses it to create a change in a precise area of a gene.
- Site directed mutagenesis via oligonucleotides, zinc finger nuclease (ZFN) – an introduction of recombinant DNA through transient molecules that are identified by zinc-finger nucleases, with or without a repair template. The techniques resemble transgenesis but the end products are similar to, and indistinguishable from, conventionally bred plants.
- Agro-infiltration – Similar to the zinc finger nuclease technique above, but using an *Agrobacterium* to inject several foreign DNA molecules into the plant cell.
- Reverse breeding – A process that uses several other techniques such as RNAi to suppress meiotic recombination, tissue culture, and then double haploidization to create parental lines that are homozygous to use in breeding F1 hybrids.
- Embryo transfer of animals – a technique used in animal breeding. It involves inducing superovulation of donor with gonadotropins, artificial insemination, recovery of embryos, isolation and storage of embryos, transfer of embryos back into animals, and then pregnancy.
- 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.

Process or Product?

Public commenters offered several papers from Europe that discussed the difference between a processed-based standard for GMOs and a product-based standard. This is relevant to the current discussion because the Federal Rule for organic is based on a process-based approach to all of organic production, yet there are some areas where the process is intertwined with the product or a quantitative tool can be used to assess the validity of a process approach. See discussion section for more.

"The US oversight system was built mostly around the idea that GM plants should be regulated on the basis of characteristics of the end-product and not on the process that is used to create them."[12]

"The first challenge is to make sure that regulatory frameworks remain fit for purpose. However, frameworks that use process-based definitions as a trigger for regulatory oversight might not be functional over time (Sidebar B). Several authors have argued that new biotechnology-based plant breeding techniques might not fit into, or might rapidly outgrow, the established defi- nitions for GMPs *[COGEM*

[11] Maliga, P. 2004. Plastid transformation in higher plants. Annu Rev Plant Biol. 2004;55:289-313. http://www.ncbi.nlm.nih.gov/pubmed/15377222

[12] Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888

2006 (9), Morris SH 2008 (10) as cited in original] or other narrowly defined product definitions [*Kuzma, J.2011 (8), Ledford, H. 2011 (11), Waltz, E. 2012 (12) as cited in original]*. NPPs *(new plant products*) blur the sharp distinction between GMP and non-GMP, and introduce a new continuum between genetic engineering and conventional breeding. Process-based legislation will require not only updates to the lists of new biotechnological plant breeding techniques but also debate on their classification as GMP or non-GMP. However, such flexibility is rarely evident in regulatory frameworks.[13]

> ***"Sidebar B*** | Process-based compared with product-based regulatory frameworks[14]
> Process-based regulatory frameworks
>
> Argentina, Brazil, the EU and many other countries have put new process-based regulatory systems in place to regulate the use of genetically modified organisms (GMOs), as the techniques used for their production were thought to raise specific safety concerns. In these jurisdictions, a GMO is mainly characterized by the transformation techniques used in its production. The definitions of GMOs used by these countries are often partly or fully based on those put forward by international organizations such as the United Nations Food and Agricultural Organization (FAO) and international treaties such as the Cartagena protocol.
>
> Product-based regulatory frameworks
>
> Canada and the USA opted to regulate all plants or products with new traits developed either through genetic engineering or any other plant breeding techniques under the same, yet existing, regulatory system [26,27]. The transformation techniques were not considered inherently risky. Therefore, the focus of product-based regulatory systems is on the risks of products and new traits or attributes introduced into a plant, rather than the method of production."

European Approaches to Classifying Genetic Manipulation Methods

The EU has made the distinction between "traditional" breeding methods and conventional (transgenic) breeding.[15]

FiBL submitted a comment that included a chart that describes methods with a yes/no column for compatibility with organic standards for both plants and animals. The NOSB could work on something similar and the methods that receive consensus can be incorporated into guidance. A subset of this chart is presented here as an example:[16]

Method	Excluded (by FiBL)	Why
Embryo rescue	No / YES in animals	Plants: Embryo is maintained on artificial media, but no genetic changes occur. Animals: Embryo transfer on organic farms is rejected, therefore also embryo rescue
Microinjection	YES	Invasive technique that violates integrity of a cell
Biolistic device	YES	Invasive technique that violates integrity of a cell

[13] Podevin N, et. al. (2012) Transgenic or not? No simple answer! EMBO reports 13: 1057 – 1061
[14] *ibid.*
[15] (Directive 2001/18/EC. and an EU background paper 'Current plant breeding techniques', DOC.XI/464/92.
- Clemens van de Wiel, Jan Schaart, Rients Niks & Richard Visser, "Traditional plant breeding methods", 2010 - http://edepot.wur.nl/141713)
[16] FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

Somaclonal variation	YES, if artificially introduced	Somaclonal variation results from mutation and is identified during in vitro culture, but might not necessarily be introduced by the tissue culture...
Transposons	Yes if artificially introduced	Transposons are a regulatory element influencing gene silencing and mutation rate. Transposons can be artificially introduced by genetic engineering, see genetic engineering
Transduction	No	Is a natural phenomenon

This type of evaluation in Europe has led to an independent effort to define and certify "Organic Varieties" and even Organic Animal Breeding.[17] In this idea (which has not yet been written into any regulations), only approved non-GMO plant breeding methods would be used to create what could be certified as an Organic Variety or Organically Bred Animal. In this country, a parallel idea has been floated that organically grown seeds be held to different criteria regarding GMOs than conventional seeds, even those not called GMO.[18] If such ideas were adopted, then a set of organic plant breeding standards could be developed, or at least organically produced varieties may be distinguished from other varieties, such as not being able to have used cell fusion for Cytoplasmic Male Sterility (CMS) or double haploid technologies.

Discussion

Definition(s), Principles, and Criteria

The subcommittee likes the definitions regarding biotechnology from the Cartagena Protocol for several reasons. First, it is more specific than the current definition regarding recombinant DNA and direct injections or fusion between families. Second, it is well accepted internationally and therefore provides the NOP with good justification for adopting into guidance. Third, it provides a better framework than the existing definition to further elaborate the various technologies that would be allowed as well as those which would be prohibited. This will be discussed further below.

The definition proposed by Mr. Falck in B above also attempts to make it clearer, but is not as widely accepted or known.

The criteria and principles in comments C and D above are valid points that the subcommittee appreciates the input on. The points raised in D as operational are accepted as part of our goals for how to interpret the principles and definition adopted, but they would be the subsequent step after the broader issues of definition and principles. Perhaps other operational criteria would be helpful as well. Operational criteria for determining acceptability of crop inputs derived from GMO feedstocks and/or fermenting organisms (potentially including corn gluten meal, corn steep liquor, and biodegradable mulch, for example), disinfectants like alcohols, and processing aids would be appropriate in guidance to certifiers and materials review organizations and/or in the materials listings. The subcommittee will be looking at this point in developing future work plans.

We are posing further discussion questions on some of the criteria raised in the FiBL comment (point C above) to see if these criteria are useful and realistic.

[17] Neff, A.S. & Augsten, F. 2009. Assessing Reproductive and Breeding Techniques in Organic Agriculture using Cattle Breeding as an Example. FiBL Discussion Paper. Submitted with FiBL public comment to docket AMS-NOP-12-0070

[18] Still, Andrew, 2013. Adaptive Seed Catalog and Seed Ambassadors Blog. http://www.seedambassadors.org/

Process or Product?

Since the whole underpinning of the U.S. organic regulations is a process-based system, it would make sense that this concept carry over to defining excluded methods. This is indeed the basis of the current definition. However, this is not currently how U.S. government agencies regulate GMOs, as noted above, or handle other issues such as pesticide residues or water quality standards.

While some commenters seemed to feel that there might be advantages to a product-based definition, such a structural revision is beyond the sope of this current effort. Therefore, the rest of this discussion will assume continuing a process-based approach.

European Classification Concepts applied in the U.S.

It would seem to make sense to try to distinguish between traditional and transgenic breeding techniques for both plants and animals. The FiBL suggestion of doing this through a chart has some strong benefits, including:

- the chart could be developed over time, with the terms everyone agrees to adopted first and then the more controversial ones hammered out over time.
- such a chart can follow logically from the Cartagena Protocol definition to indicate recombinant DNA, direct injection, cell fusion outside of families and other guidance provided by that definition that is somewhat lacking in the current definition.
- A chart such as this would be easier for the NOP to maintain as instruction or guidance and would not be as lengthy as a list of crop varieties and inputs. Additionally, it does not have to be updated as frequently.
- It maintains a transparency to all stakeholders that is now somewhat lacking in how GMOs are regulated.
- It gives ACAs clear instruction on how to evaluate seeds, vaccines, microorganisms and other potential GMOs.

At this juncture, before we even start to create a table of excluded methods terms, we invite input from the public on whether or not this is a worthwhile effort and any ideas for how to implement such an idea.

Unresolved Issues

Exploring this issue has brought to the attention of the subcommittee that engineered genetic manipulation of plant breeding materials has already occurred in many of the crop varieties that are currently being used in organic farming. A partial list:

- Disease resistant tomatoes (embryo rescue to introduce resistance genes)
- wheat and barley (double haploid technology using wheat and corn crosses along with embryo rescue and colchicine gene doubling)
- hybrid corn parent lines (double haploid to get homozygosity in 1 generation)
- Seedless tangerines and mandarins (mutations through irradiation)
- Brassica hybrids (cell fusion from radish traits)[19]

Many of these techniques that were used in initial crosses that have now passed down through many generations may not be traceable any longer. There are also many new varieties in development that will strongly challenge any definitions or regulatory scheme. Without a revised definition and some guiding

[19] for detail on this issue, please see: Myers, Jim 2014. in Proceedings from the 7th Organic Seed Growers conference. https://seedalliance.org/index.php?mact=DocumentStore,cntnt01,download_form,0&cntnt01pid=30&cntnt01returnid=139

principles to use for past and future determinations about excluded methods, there may not be effective ways to regulate either past or future techniques and their products.

Discussion Questions
The Materials/GMO ad hoc Subcommittee is seeking response from the organic community on the issues presented in this discussion. A few of the particular questions to address are:

1. Are the definitions presented from the Cartagena Protocol an appropriate basis for guidance to further enable NOP and the NOSB to sort out terminology? (on page 3)

2. Among the criteria suggested, we would like feedback on the ones mentioned below and ask whether there are any other important criteria to use in genetic engineering determinations.

- Technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins).
- The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e.g. digestion of the cell wall, destruction of the cell nucleus through cytoplast fusion).
- The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from (e.g. Terminator technology).

3. Would it be a good approach to continue a process-based evaluation of the terms and techniques, determine whether they are a result of genetic engineering, and then list both the GE and non-GE terms in a chart maintained by the NOP in the public record? If so, please offer suggestions on how this could be implemented. If not, please suggest any alternatives.

4. Are there terms or methods not included in appendix 1 that should be added to the discussion? Briefly explain.

Subcommittee Vote
Motion to adopt the proposed Second Discussion Document on Excluded Methods Terminology

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

Appendix 1

Terms defined and discussed in the first Discussion Document. They are presented in the same order they were in the document.

<u>In current definition of Excluded Methods:</u>

Cell Fusion
- Protoplast Fusion
- Somatic hybridization

Micro-encapsulation
Macro-encapsulation
Recombinant DNA
Gene Deletion
Genetic Engineering
Mutagenesis (mutation breeding)
Conjugation, genetic
Fermentation
Hybridization
- Hybrid
- Nucleic Acid Hybridization

In Vitro Fertilization
Tissue Culture
- Cell Culture
- Primary and Batch Cell Culture

<u>Not in Definition of Excluded Methods</u>

Silencing
Embryo Rescue
Microinjection
Biolistic device
Somaclonal variation
Transposons
Transduction

Approved by C. Reuben Walker, Subcommittee Chair, to transmit to NOSB August 27, 2014

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Glycerin

August 27, 2014

Summary of Proposed Action:

The petitioner has requested removal of Glycerin (CAS Number 56-81-5) from 205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The petitioner believes that the process of microbial fermentation that is used to produce organic glycerin is a superior method for the production of organic glycerin because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). Further, they state "an important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used "only when the product is not commercially available in organic form." Certified organic glycerin is currently available, but there is no "commercial availability" requirement to incentivize processors to use it or certifiers to require it. This is why glycerin should be removed from the National List; in order to encourage organic agricultural production."

There has been a significant amount of confusion regarding the classification of Glycerin as synthetic/non-synthetic because of the various methods by which it can be manufactured. In April 2013, the National Organic Program (NOP) issued draft guidance on classification of materials that should provide some clarification on the status of glycerin produced by these various methods. However, as of this date, this guidance document has not been issued in its final form. Further, the Handling sub-committee recognizes the irony that Glycerin produced from organic source materials using hydrolysis could be classified as both organic and synthetic.

Additionally, public written and oral comments presented for the spring 2014 NOSB meeting indicated that the removal of Glycerin from 205.605(b) could have significant negative impact on natural flavorings used in organic products, due to the fact that Glycerin is often used as a carrier. The comments generally expressed concern regarding the commercial availability of sufficient quantities of organically produced Glycerin to meet the demand for these natural flavorings. With the current listing for Flavors at 205.605(a), the annotation is as follows: "non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative." During the Handling sub-committee discussion, the question came up as to whether current practice is to allow Glycerin – from hydrolysis of fats and oils –, which is currently classified as synthetic, to be used as a carrier in natural flavorings. **Therefore, the Handling Subcommittee seeks feedback on the current practices regarding Glycerin in natural flavors.**

Because of the confusion around classification of Glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced Glycerin, the Handling sub-committee, after significant discussion, is proposing the listing of Glycerin at 205.606, and removal of Glycerin from 205.605(b). Based upon the draft classification of materials document, the form of Glycerin that would qualify for listing at 205.606 would include Glycerin produced by microbial fermentation of carbohydrate substances. It is the Handling sub-committee's intent with this recommendation to provide incentive to increase the amount of organic Glycerin used, while also recognizing the possibility of issues around commercial availability.

Background

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

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantage claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245^{o}C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.
Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495^{o}F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

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

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

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11.
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional *process* used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation "produced by hydrolysis of fats and oils." It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock used at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils.
4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce non-synthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast *Candida krusei* is used commercially to produce certified organic glycerin as well as non-synthetic non-organic glycerin.

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

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

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

Substance Fails Criteria Categories 2, 3, 4 (see attached checklist)

Subcommittee Action & Vote

Classification Motion: Motion to classify Glycerin produced by microbial fermentation as agricultural.
Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Motion to list Glycerin at 205.606
Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Motion to remove Glycerin – produced by hydrolysis of fats and oils - from 205.605(b)
Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB August 27, 2014

NOSB Evaluation Criteria for Substances Added To the National List

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

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

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

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

sources? [§6502(21)]				The products are simpler substances. Since it involves the **addition of water**, this explains why it is called hydrolysis, meaning **splitting by water**. **A-B + H_2O --> A-H + B-OH** **(http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)** For fermentation method, see above.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		The process of hydrolysis is a naturally occurring process, but this material is manufacturing using high heat and pressure. Incidentally, all (food) digestion reactions are examples of hydrolysis, and the involvement of water is often not appreciated. Generally these reactions are controlled by enzymes such as carbohydrases, proteases, lipases, nucleases, more specific examples of which are fairly well known. **(http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)** For fermentation, see above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	X			Petitioner claims to have a fully organic version manufacturing using a fermentation process. See petition, (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924) Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			Glycerin is used in a wide variety of products including food, cosmetics, industrial and medical. It is a strong humectant. In organic food products it is used to improve texture, increase volume and is a major carrier for flavorings and colorings.

8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]				Alcohols could be used a carriers for flavorings. And there are myriad other materials that could have a similar functional use in other formulations (such as softening and mouth feel in ice creams, keeping baked items soft, etc.) but glycerin is unique in that it can serve in all these functions.
9. Are there any alternative substances? [§6518(m)(6)]	X			Glycerin manufactured from petroleum products, glycerin from saponification of fats and oils and fermentation methods.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X	X		Given the wide use of glycerin, it is likely that there are substitutes for particular uses, but it is unlikely that any one material would work in all the applications where glycerin is used.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

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

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

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	Petition is for removal of synthetic glycerin. Petitioner claims there is sufficient quantity of organic glycerin available. Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	See above. Petitioner claims there is sufficient organic glycerin available and the synthetic version is no longer necessary.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?	X			See petition at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?	X			When synthetic glycerin was recommended for inclusion on the National List, there was an insufficient supply or organic glycerin. According to the petitioner, that is no longer the case. Per the TR: There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);	X			
b. Number of suppliers and amount produced;	X			There are currently 21 USDA certified organic operations supplying glycerin for organic

				food or cosmetic products. Specific supplier information (TR Table Line: 674)
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;	X			
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or	X			
e. Other issues which may present a challenge to a consistent supply?	X			

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Whole Algal Flour

August 20, 2014

Summary of Proposed Action:

The Handling Subcommittee has reviewed the petition submitted by Solazyme, Inc. seeking permission to have Whole Algal Flour added to the National List of Approved Materials under §205.606 – Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Whole Algal Flour is manufactured from, a microalgae by fermenting and harvesting cultures of a non-toxigenic strain of *Chlorella protothecoides.* The petitioner noted that algae is also a single-celled organism which could possibly place it on §205.605(a) – Non-agricultural (non-organic) substance (non-synthetic). It's primary proposed use would be as a whole food ingredient used as either a partial replacement for food ingredients that provide dietary fat and/or protein such as cream, milk, eggs/egg yolks, and/or butter or shortening in baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings and soups or as an added ingredient for texture and mouth feel enhancement.

On September 6, 2013 the petition was received by the National Organic Program and forwarded to the NOSB's Handling Sub-committee for petition review and consideration for listing. On January 14, 2014 the Handling Sub-committee received from the petitioner a response to several questions that they had concerning whole algal flour after the review of the original petition had been completed. Both the original petition dated September 6, 2013 and the supplemental dated January 21, 2014 contained a tremendous amount of information that was redacted because it was considered to be Confidential Business Information (CBI). This afforded the Subcommittee no opportunity to make a determination on the material or to complete its responsibility of looking at ancillary substances for the newly petitioned material.

Explanation of Motions: The Handling Subcommittee made the Classification Motion listed below because it could not determine whether the material was synthetic or non-synthetic based on the information provided. The Subcommittee made the Listing Motion shown below because it felt that they could not make a full determination due to the uncertainty created by the redaction of a large amount of Confidential Business Information (CBI). The Subcommittee also discussed the essentiality of this substance, since there are numerous alternatives available for use that are currently allowed, as stated in the petition. The Subcommittee could also not complete its due diligence assessing ancillary substances because of a lack of access to the appropriate information.

Evaluation Criteria (see attached checklist)

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

Substance Fails Criteria Category: 2 (see attached checklist)

Subcommittee Action & Vote

Classification Motion: Move to classify Whole Algal Flour as non-synthetic.
Motion by: Harold Austin
Seconded by: John Foster
Yes: 0 No: 0 Absent: 2 Abstain: 6 Recuse: 0

Listing Motion: Move to list Whole Algal Flour on section 205.606 (of the National List): non-organically produced agriculture products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
Motion by: Harold Austin
Seconded by: John Foster
Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB August 19, 2014

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]				Unable to determine due to CBI.
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i);				We can't determine due to inability to establish what possible ancillary substances there might be in both the main substance and ancillary substances alike due to CBI

	§6518(m)(4), 205.600(b)(3)]			blackout.
7.	Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]			Unknown. Page 6 and 7 of the petition for Whole algal flour states that on June 7, 2013 the FDA issued a No Questions letter (GRN 469) for whole algal flour. The petitioner has self-affirmed WAF to be GRAS, page 4 of the petition. Because there is so much CBI there is no logical way to determine this.
8.	Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]			Unknown

Category 2. Is the Substance Essential for Organic Production? Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			Petitioner claims that it should be classified as a microorganism and is nonagricultural. It may belong on 205.606 non-organically grown agricultural product.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Made by fermentation process in a closed system. Process is CBI.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]				Goes through fermentation and has either potassium hydroxide or sodium hydroxide added to adjust the ph (both are on the national list).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	X			Organic milk, cream, eggs/egg yolks are currently being used and others.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		There currently are alternatives being used.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
9. Are there any alternative substances? [§6518(m)(6)]	X			There are substances currently on the National List of Approved Substances that are being used such as: starch products, some of the gums, hydrocolloids, to name just a few.
10. Is there another practice (in farming or			X	

handling) that would make the substance unnecessary? [§6518(m)(6)]				
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		Ancillary substances are unknown at this time due to the huge amount of CBI within the materials petition. A decision on limitations can't be made because there is no possible way to determine what the ancillary substances in this material are. Also, by the petitioners own statement they add different things based upon the individual customer's needs.

Category 3. Is the substance compatible with organic handling practices? Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]				Unknown
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling [?				We are not able to make that determination with the information provided. Petition contains too much CBI and the potential list of ancillary substances is not able to be determined, even with the supplemental information provided by the petitioner.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]				We are not able to make that determination with the information provided.
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		The primary use is to reduce and replace substances currently being used to help reduce fat content, improve texture and mouth feel in some products.

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			There currently is not an organic form of this substance available on the market for use in organic handling.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?	X			
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	Unknown
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Other issues which may present a challenge to a consistent supply?			X	

Sunset 2015 Review
Meeting 2 - October, 2014
Handling Subcommittee Review
Gellan Gum
August 20, 2014

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Gellan Gum — *Agricultural*

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

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

Technical Report: 2006

Petition(s): Gellan gum (2004)

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

Regulatory Background:

Proposed for addition to National List 6/3/09 (74 FR 26591)

Added to National List 12/13/2010 (75 FR 77521)

Sunset Date: 12/14/2015

Reference: 7 CFR 205.605(a)

Subcommittee Review

Summary:

Gellan gum is a polysaccharide gum produced as a fermentation product of the microbe Sphingomonas elodea. This bacterium produces a gum which is useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, etc.

Gellan gum was petitioned for addition to 205.605(b) in 2004. In 2006, a technical evaluation report was completely for the Handling Committee. The committee recommended the addition to 205.205(b) in April, 2007. However, detailed discussion among the board, the NOP and the petitioner at that meeting led to the conclusion that gellan gum is in fact non-synthetic, and accordingly should be added to 205.605(a). The Handling Committee made an updated recommendation in December 2007, and it was passed by the full NOSB at the April, 2008 meeting.

The 2007 and 2008 discussions weighed heavily the question of whether gellan gum provided sufficiently unique properties other than those afforded by gums already listed on 205.606. Based on the petition, the 2006 TAP review, and testimony from the petitioner and other stakeholder, the board concluded that gellan gum was in fact essential:

The Board considered what constitutes “essential” for organic handling of a finished retail product and how that may be different from that of a material used in crop or livestock production. It was agreed that certain materials might be essential for creating a product that meets consumer expectations of taste or texture. A

number of commenters cited gellan gum would greatly enhance the organic consumer products they make for this reason. One commenter stated that gellan gum has unique functionality that is not offered by similarly produced gums that are currently allowed in organic handling. There were no public comments specifically opposing the listing of gellan gum on 205.605.

An extensive search of relevant medical and food science literature since 2007 shows no significant new data or findings that would impact the evaluation of this substance. We were unable to locate any relevant regulatory changes related to this ingredient among the world's regulatory bodies.

The current listing is for: Gellan Gum – high acyl only

This is significant because low acyl gellan gum has been determined to be synthetic; only high acyl is non-synthetic and should be listed on 605(a).

At the Spring 2014 NOSB meeting, two commenters noted that low-acyl gellan gum should be on 605(b), not (a). We wish to clarify that low acyl gellan gum is synthetic and isn't being considered in this recommendation. The existing listing and the sunset proposal is only for the high acyl gellan gum, which is non-synthetic.

Numerous other commenters confirmed that the material remains essential in the production of non-dairy beverages and other foods.

The 2007 and 2008 discussions also focused on the role of the isopropyl alcohol used to separate the finished gellan gum from the fermentation materials. According to the 2006 TR, the FDA limits the amount of isopropyl alcohol in the finished gellan gum to .075 %. Regardless, the presence of the isopropyl alcohol was acknowledged in the petition, TR and recommendation and factored into the evaluation of the material.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) 7 U.S.C. 6158(m)(6) the alternatives to using the substance in terms of practices or other available materials; (7) its compatibility with a system of sustainable agriculture.

Subcommittee Review

The Handling Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Motion to Remove Gellan gum from §205.605(a)

Motion by: Joe Dickson

Seconded: John Foster

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Sunset 2015 Review
Meeting 2 - October 2014
Handling Subcommittee Review
Tragacanth
August 22, 2014

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Tragacanth Gum — *Agricultural*

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

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

Technical Report: none

Original Petition: Tragacanth Gum (PDF) (2007)

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

Regulatory Background:

Proposed for addition to National List 6/3/09 (74 FR 26591)

Added to National List 12/13/2010 (75 FR 77521)

Sunset Date: 12/14/2015

Reference: 7 CFR 205.606(x)

Subcommittee Review

This substance was originally reviewed by the handling committee and added to 205.606 by the NOSB in May, 2008. The committee noted at the time that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited, and organic tragacanth gum was not known to be in production. The Board Summary from the 2008 recommendation is reprinted here:

> Tragacanth gum, water-extracted is an exudite gum and is harvested and processed in a manner which is identical to other exudite gums already included on §205.606 of the National List. The Board considered whether it is necessary to add another gum to the National List and was persuaded that although Tragacanth gum is derived by an identical process to gum Arabic, it has sufficiently different functionality to justify its inclusion on the National List.
>
> The Board also considered the reasons for this material being commercially unavailable in an organic form and the prospects for such availability in the future. At present this tree is primarily cultivated in Iran and the current embargo which exists on U.S. trade with this country had disrupted the supply of even the conventional form of this material. Turkey has increased its production of conventional Tragacanth gum and also is expanding its organic production. The petitioner is working closely with their Turkish supplier and believes that a supply of this material in an organic will be made available in the next several years. The Board feels that this material meets evaluation criteria in all four categories required for listing on section 205.606 of the National List.

Commercial Availability

While the petition and 2008 recommendation note that Turkey is expanding organic production of

tragacanth gum, a thorough search of internet sources and ingredient supply catalogs provided no suggestion that the ingredient is available in organic form. This aspect is specifically highlighted here in order to elicit comments from any suppliers or other stakeholders who are aware of organic sources of the ingredient. At the Spring 2014 meeting, the NOSB only heard from one certifier verifying that this material is in current use in non-organic form. We invite any other users of this substance to verify its necessity through written or oral comment.

Safety and Regulatory Acceptability
A search of the medical literature shows no new safety or other medical data related tragacanth gum since the original petition and review process. We were unable to locate any relevant regulatory changes related to this ingredient among the world's regulatory bodies.
In summary, this may be a material with few current users and with possibly functional organic alternatives available. If there are users of this material out there with compelling arguments as to its necessity, we encourage them to comment on this material for the fall meeting.

Motion to Remove:
This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) 7 U.S.C. 6158(m)(6) the alternatives to using the substance in terms of practices or other available materials; (7) its compatibility with a system of sustainable agriculture.

Subcommittee Review
The Handling Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Motion to remove Tragacanth Gum from §205.606(x)
Motion by: Joe Dickson
Seconded by: Harold Austin
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Sunset 2015 Review
Meeting 2 - October 2014
Handling Subcommittee Review
Marsala
August 22, 2014

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Marsala *Agricultural*

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

Listing: Fortified cooking wines. (1) Marsala

Technical Report: none

Petition(s): Marsala, (2007)

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

Regulatory Background:

Proposed for addition to National List 6/3/09 (74 FR 26591)

Added to National List 12/13/2010 (75 FR 7751)

Sunset Date: 12/14/2015

Reference: 7 CFR 205.606(g)(1)

Subcommittee Review

Summary:

This is the second posting for the Sunset 2015 review for Fortified Cooking Wine – Marsala, which was added to the National list in 2010; please refer to the questions answered in Category 4.

Marsala was originally petitioned in 2007 for addition to 205.606 because it was considered a unique flavor ingredient that was not commercially available as organic. At present, there appears to be very few if any organic entrees utilizing Marsala as an ingredient. This could be an indication of low consumer product demand. The Handling Subcommittee proposes to remove Marsala from 205.606, and we request that the public provide comment regarding the following: the commercial demand for both conventional and organic Marsala, and the impact that the removal of Marsala from 205.606 would have on your business. During the first comment period, in spring 2014, the original petitioner, did not comment and the Subcommittee could not find current contact information for them.

Motion to Remove:
This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **205.600(b)(6) the substance is essential for the handling of organically produced agricultural products.**

In an informal 2013 survey of a handful of stores and certifiers, no products containing Marsala were

encountered. It appears that there is limited to zero use of Marsala in organic entrees in the US; this might be an indication of low demand or little interest in Marsala as an ingredient in organic entrees. Additionally, no organic or conventional Marsala was found to be available on any of the 30 websites listed on the original 2007 Sherry Petition Organic Fortified Cooking Wine Source List. With low demand, the limited availability of organic Marsala in the U.S. may not be an issue. Without input from the original petitioner, it's difficult to assess the impact of a decision to de-list Marsala.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Motion: Remove Marsala from the National List at 205.606(g)(1)
Motion by: Tracy Favre
Seconded by: Zea Sonnabend
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

NOSB Evaluation Criteria for Substances Added To the National List (Optional Checklist)

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	x			2007 original Petition (pg.1-2)-Marsala is a key flavor ingredient in organic entrees. In 2007, there were no sources of organic fortified cooking wine available in the quantity and form necessary for their products.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?		x		In an informal 2013 survey of a handful of stores and certifiers, no products containing marsala were encountered. It appears that there is limited to zero use of marsala in organic entrees in the US; this might be an indication of low demand or little interest in marsala as an ingredient in organic entrees. Additionally, no organic or conventional marsala was found to be available on any of the 30 websites listed on the original 2007 Sherry Petition Organic Fortified Cooking Wine Source List.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance		x		See question # 2.

	cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4.	Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?		x		See question # 2.
5.	Does the industry information about unavailability include (but is not limited to) the following?:		x		
	a. Regions of production (including factors such as climate and number of regions);				
	b. Number of suppliers and amount produced;		x		
	c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;		x		
	d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		x		
	e. Other issues which may present a challenge to a consistent supply?		x		If there is no demand for marsala, there will be no incentive to produce organic marsala.

Sunset 2015 Review
Meeting 2 - October 2014
Handling Subcommittee Review
Sherry
August 22, 2014

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

Sherry *Agricultural*

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

Listing: Fortified cooking wines. (2) Sherry

Technical Report: none

Original Petition: Sherry (2007)

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

Regulatory Background:

Proposed for addition to National List 6/3/09 (74 FR 26591)

Added to National List 12/13/2010 (75 FR 7751)

Sunset Date: 12/14/2015

Reference: 7 CFR 205.606(g)(2)

Subcommittee Review

Summary:

The original petition cited the flavor profile of cooking Sherry as being unique, and that no organic sources of were available. Cooking Sherry, or Sherry of any kind, is made using standard wine making processes, and is fortified with Brandy, which acts as a preservative and therefore no added sulfites are necessary. There are small-scale organic sources of Brandy available in the U.S., although the quantities available are not certain. Additionally, there are international sources of organic Brandy. The key to the manufacture of Sherry is Flor yeast, which is available from Spain. Generally, there is low demand for Sherry in the United States, with Americans preferring other forms of wine. The United Kingdom and other European countries have higher demand for Sherry.

After discussions with various industry personnel, there seems to be no barrier to manufacture of organic Cooking Sherry, but there is very low demand for it. The original petitioner of the material did not comment during the first comment period in Spring 2014, and contact information was unavailable. One U.S. producer of organic wines did indicate that he has been contacted 2-3 times in the last few years to see if he produced the product, but the requester indicated that his price was too high.

With low demand, the limited availability of organic Sherry in the U.S. may not be an issue. Without input from the original petitioner, it's difficult to assess the impact of a decision to de-list Cooking Sherry.

The Handling Subcommittee requests public feedback regarding the impact that removal of Sherry would have on your operation.

Motion to Remove:
This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: 205.600(b)(6) the substance is essential for the handling of organically produced agricultural products.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Motion: Remove Sherry from the National List at 205.606(g)(2)
Motion by: Tracy Favre
Seconded by: Zea Sonnabend
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

NOSB Evaluation Criteria for Sunset Review (Optional checklist)

Category 1. Adverse impacts on humans or the environment? Fortified Cooking Wine - Sherry

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i);	X			Over consumption of alcoholic beverages does have harmful effects on human health, but cooking sherry is not typically over consumed.

§6518(m)(4), 205.600(b)(3)]				
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]			X	
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Substance: Fortified Cooking Wine - Sherry

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			Made from wine grapes and fortified with brandy, both agricultural products.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		Natural fermentation process and distillation.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Natural fermentation process creates alcohol in the grape juice.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X			Natural fermentation, with the inclusion of Flor yeast creates the unique flavor profile.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]	X			Low demand but there are small scale producers in the U.S.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		According to the petitioner, the flavor profile of Cooking Sherry imparts a unique flavor to the final product but it is not absolutely essential for use.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	
9. Are there any alternative substances? [§6518(m)(6)]	X	X		Other fortified wines could be used but would not have the same flavor profile
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]			X	
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

Category 3. Is the substance compatible with organic handling practices? Substance: Fortified Cooking Wine - Sherry

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Cooking Sherry as currently on the National List is not organic.
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		See above comment
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		See above comment
4. Are the ancillary substances reviewed compatible with organic handling [?			X	No ancillary substances
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	Flavor profile only.
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		Because of the brandy in fortified wine, it has natural preservative properties but that is not the primary use in products.
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]			X	Primary use is to impart a specific flavor profile to foods.

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			Original petition cited the flavor profile of cooking Sherry as being unique to the product, and no organic sources of the material was available.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?		X		Conversations with various industry personnel indicate that there is low demand for sherry in the U.S. except as a cooking wine, therefore there has been no significant incentive for development of an organic source. However, there are no real obstacles to producing an organic version, based upon materials and/or processes.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?		X		There seems to be no barrier to production except for limited demand.

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?	X	X		Initial investigation has indicated that small-scale producers would be able to provide the ingredient, but information regarding the amount required as an ingredient for the products mentioned in the petition is not available. There was no information available regarding foreign sources for the material.
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);		X		A small-scale producer is available in the Pacific Northwest, however there is insufficient information regarding the national demand for the product so it's not clear whether the location of the manufacture of the material is relevant.
b. Number of suppliers and amount produced;	X			Investigation has only shown one small- scale U.S. producer on an as-needed basis but the total amount produced is not available.
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;		X		See comment above.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		See comment above.
e. Other issues which may present a challenge to a consistent supply?	X			Limited production due to limited demand could cause restrictions in availability should demand increase.

Sunset 2016 Review Summary
Meeting 1: October 2014
Request for Public Comment
Handling Substances

September 2014

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling which must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2016. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until spring 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the fall 2014 public meeting. These comments should be provided through www.regulations.gov by October 7, 2014 as explained in the meeting notice published in the Federal Register on September 8, 2014.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

***For Comments That Support Substances Under Review*:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

(1) not harmful to human health or the environment;

(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic handling.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with handling.

For Comments Addressing the Availability of Alternatives:
Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at Section 205.606.
For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through October 7, 2014 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2016 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances
August 27, 2014

SUNSET 2016: HANDLING SUBSTANCES

Egg white lysozyme *Nonsynthetic*

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Egg white lysozyme (CAS # 9001–63–2)

Technical Report: 2011 TR: Enzymes, 2003 TAP: Enzymes, Plant and Fungal

Petition(s): Egg white lysozyme 06/05/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 05/2003 Recommendation to relist 11/05/2009

Regulatory Background: Added to National List 09/11/06, 71 FR 53299

Renewed 08/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB
No additional information is requested

L-Malic acid *Nonsynthetic*

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: L-Malic acid (CAS # 97-67-6)

Technical Report: Malic Acid April 2003. New TR requested in 2014

Petition(s): L-Malic Acid 11/01/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 05/2003 Recommendation to relist 11/05/2009

Regulatory Background:

Added to National List 09/11/06 71 FR 53299

Renewed 08/03/2011 76 FR 46595

Sunset Date: 9/12/16

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB
The Handling subcommittee is interested in comments regarding the essentiality of this substance. We encourage current users of this substance to provide detailed comments describing the situations in which l-malic acid is the only appropriate substance for a given technical application.

Microorganisms *Nonsynthetic*

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Microorganisms - any food grade bacteria, fungi, and other microorganism.

Technical Report: 2014 TR, 2003 TAP

Petition(s): Microorganisms 12/10/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 05/2003

Recommendation to relist 11/05/09

Regulatory Background:

Added to National List with annotation 09/11/06 71 FR 53299

Renewed 08/03/2011 76 FR 46595

Sunset Date 9/12/2016

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the following:

Microorganisms will be first major review of ancillary substances used with the listed substance and the HS is trying to follow the Ancillary Substance Policy adopted by the Board in 2013.

The chart below lists all the ancillary substances by functional class that were identified in the Technical Report as well as those that have been turned in by Accredited Certifiers to make sure they are reviewed. The HS seeks additional public input on any other ancillary substances that may be in use in microorganism products that go into organic food.

Comment is also welcome in favor or against any particular ancillary substances with specific attention paid to alternative choices.

Ancillary Substances by Food Additive Functional Class[1]	
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid
Preservatives	sodium benzoate, potassium sorbate
Stabilizers	maltodextrin

[1] this list does not include ancillary substances that are already on the National List. From the 2014 Technical Report and spec sheets.

Cyroprotectants used to freeze-dry microorganisms	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

Activated charcoal *Synthetic*

Use - As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Activated charcoal (CAS #s 7440 - 44 - 0; 64365 - 11 - 3) - only from vegetative sources; for use only as a filtering aid.

Technical Report: Activated Carbon 8/14/02

Petition(s): Charcoal/Activated Carbon 5/20/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 9/2002

Recommendation to relist 11/05/09

Regulatory Background:

Added to National List with annotation 9/11/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. Is this substance still used as a filtering aid by organic handlers as part of their organic production process? Could either the handlers themselves or certifiers please confirm that this is still being used and thus there still exists a need for its continued listing?
2. Have the stakeholders that have relied upon this substance as part of their handling production process looked at other practices or alternatives as a possible replacement? If so could you give us examples of what other alternatives you have looked at and are they suitable replacements for activated charcoal?
3. Has the use of this substance increased or declined during the current sunset cycle? (This question would apply to Handlers- for your specific operation and for certifiers – for those operations that you certify and inspect on an annual basis).
4. Have the sources changed for where activated charcoal comes from, that might impact the need to continue its listing on the National List or not? (natural source versus synthetic source).

Peracetic acid *Synthetic*

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Peracetic acid/Peroxyacetic acid (CAS # 79 -21- 0). For use as a sanitizer on food contact surfaces.

Technical Report: 11/3/2000 TAP (for processing)

Petition(s): none

Past NOSB Actions: NOSB review and recommendation for addition to the National List 11/15/2000

Recommendation to relist at 205.605(b) 11/5/09

Regulatory Background:

Added to National List with annotation 9/11/06 71 FR 53299

Renewed: 8/03/2011 76 FR 46595

Sunset Date: 9/12/16

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

No additional information is requested

Cyclohexylamine *Synthetic*

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Cyclohexylamine (CAS # 108 - 91 - 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: 02/2001

Petition(s): Cyclohexylamine 11/29/2000

Past NOSB Actions: NOSB review and recommendation for addition to the National List 10/2001

Recommendation to relist: 11/5/09

Regulatory Background:

Added to National List: 09/11/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?

Diethylaminoethanol *Synthetic*

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Diethylaminoethanol (CAS # 100 -37- 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: 2/2001 TAP

Petition(s): Diethylaminoethanol 11/29/00

Past NOSB Actions: NOSB review and recommendation for addition to the National List 5/2002

Recommendation to relist: 11/5/09

Regulatory Background:

Added to National List 09/11/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?

Octadecylamine *Synthetic*

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Octadecylamine (CAS # 124–30–1) for use only as a boiler water additive for packaging sterilization.

Technical Report: 2/2001 TAP

Petition(s): Octadecylamine 11/29/00

Past NOSB Actions: NOSB review and recommendation for addition to the National List 10/2001

Recommendation to renew: 11/5/09

Regulatory Background:

Added to National List: 09/11/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/11/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?

Sodium acid pyrophosphate

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Sodium acid pyrophosphate (CAS # 7758-16-9)

Technical Report: 9/2001 TAP (report is for Sodium Phosphates as a group).

Petition(s): Sodium acid pyrophosphate 10/31/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 5/13/2003

Recommendation to relist 11/5/09

Regulatory Background:

Added to National List 09/12/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the essentiality of this substance. We encourage current users of this substance to provide detailed comments describing the situations in which sodium acid pyrophosphate is the only appropriate leavening agent for a given technical application.

Tetrasodium pyrophosphate (TSPP)

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

Listing: Tetrasodium pyrophosphate (CAS # 7722–88–5) - for use only in meat analog products.

Technical Report: 2014 Limited Scope TR, 2002 TAP

Petition(s): TSPP 12/10/2001

Past NOSB Actions: NOSB review and recommendation for addition to the National List 9/17/2002

Sunset Recommendation to relist: 11/5/09

Regulatory Background:

Added to National List 09/12/06 71 FR 53299

Renewed 8/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the following:
The 2014 Technical Report elaborated on many alternatives to the use of this substance, both alternative vegetarian protein sources and alternative ways of processing this protein. The subcommittee would like public comment that is very specific about situations in which using TSPP would be the only viable choice and the reasons why.

The subcommittee has also raised the concern about the sole function of this input being to restore texture after complex processing and this runs counter to §205.600(4): "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law". Input is sought on this subject.

Preliminary discussion among the Handling subcommittee is leading towards an inclination to remove this substance because of the concerns mentioned above.

National Organic Standards Board
COMPLIANCE, ACCREDITATION, AND CERTIFICATION SUBCOMMITTEE

Assessing Soil Conservation Practices Discussion Document

August 27, 2014

I. INTRODUCTION:

The Organic Foods Production Act of 1990 (OFPA) and the National Organic Program (NOP) standards emphasize the importance of maintaining and improving soil quality in numerous places. Over the years of National Organic Standards Board (NOSB) deliberations and public discourse, we find a clear and consistent commitment to these tenets; in fact, keeping soil in good tilth is both a founding principle and expectation of the entire organic community. Because soil conservation is critical to maintaining soil health, and soil health is critical to the future of farming, the NOP has tasked the NOSB Certification, Accreditation, and Compliance Subcommittee (CACS) with generating a discussion document to assess the state of soil conservation practices on organic farm and livestock operations. It is our intention to bring soil conservation *per se* permanently and deliberately into the public discourse when we talk about soil management and the practices employed on organic farms.

With the help of the certification community and public, we hope to provide clarity about which aspects of soil conservation found within the regulation are working well and which need further attention or warrant guidance as to their implementation. This assessment of practices will then be used to develop specific training and tools to further soil conservation objectives.

II. BACKGROUND:

The NOP is aware of concerns regarding use of appropriate soil conservation practices on organic farms, for instance prevention of soil erosion, tillage, fencing of livestock from streams, application of manure on frozen soil, and overgrazing of pasture. The Board would like to determine if and how grower and livestock operations are complying with the portions of the regulation stating that operators must maintain or improve the natural resources, including soil and water quality. Since the Natural Resources Conservation Services (NRCS) has been critical to improving our soil resources for decades, CACS looked to the NRCS for technical expertise and to assist in aligning as closely as possible organic practices and regulatory guidance with their longstanding valuable work toward a sustainable soil culture.

The following paragraph is taken from the NRCS webpage.

“The NRCS mission is to improve the health of our Nation’s natural resources while sustaining and enhancing the productivity of American agriculture. The NRCS achieves this by providing voluntary assistance through strong partnerships with private landowners, managers, and communities to protect, restore, and enhance the lands and waters upon which people and the environment depend. The NRCS Vision is to create productive working lands in harmony with a healthy

environment. Their conservation process entails the following three steps, including 1) resource inventory and assessment; 2) technical assistance and technology transfer; and 3) conservation and implementation. The 2011 – 2015 NRCS Strategic Plan has three priorities including: 1) getting more conservation on the ground; 2) increasing organizational effectiveness and efficiency; and 3) creating a climate where private lands conservation will thrive."

The intersection between NOP and NRCS goals is evident and the opportunity to share best practices is welcomed.

III. RELEVANT AREAS IN THE RULE:

205.2 Terms Defined:

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

205.200 General

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

205.203(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

205.203(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

205.203(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

205.203(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying: (see numbers 1 – 5).

205.205(d) The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation: (see letters a – d).

205.240(c) A pasture plan must be included in the producer's organic system plan, and be updated annually in accordance with §205.406(a). The producer may resubmit the previous year's pasture plan when no change has occurred in the plan. The pasture plan may consist of a pasture/rangeland plan developed in cooperation with a Federal, State, or local conservation office: *Provided,* that, the submitted plan addresses all of the requirements of §205.240(c)(1) through (8).

IV. DISCUSSION:

As mentioned above, maintaining and improving soil quality is a founding principle of organic production whose roots are deep within the non-governmental standards across the country long before OFPA and the NOP were born. OFPA and the NOP merely but significantly codified these principles into law and regulation. While both emphasize the importance of soil quality and conscientious soil management and the practices that impact and influence both, *soil conservation* has often been given short shrift in recent public discourse, albeit unintentionally. The days of the Dust Bowl and the acute attention to programmatic soil conservation that came with it are far behind us, the legacy of those days' remains, of course, and our responsibility for that legacy remains robust.

The following paragraph is also taken from a NRCS webpage.

"The NRCS draws on a long history of helping people help the land. For more than 75 years, NRCS and its predecessor agencies have worked in close partnerships with farmers and ranchers, local and state governments, and other federal agencies to maintain healthy and productive working landscapes. It is the NRCS role to provide national leadership and technical assistance for the conservation of our natural resources to ensure the continued production of food and fiber."

The passage of the Food Security Act of 1985 (P.L. 99-198), (with its Sodbuster, Swampbuster, and Highly Erodible Lands provisions) made conservation a prerequisite for participation in USDA

programs. In order for organic operators to participate in, and benefit from conservation program investments, they are required to submit conservation plans if they have erosion problems. Because the NOP and the NRCS have common goals, this discussion document presents an ideal opportunity to solicit feedback regarding the similarities and differences in their implementation requirements for soil and water conservation practices. The NOSB values the opportunity to collaborate with partners such as the NRCS.

In closing, our hope is to generate meaningful dialogue within the organic community to identify and evaluate opportunities for improving soil and water practices in organic farming and livestock operations. We offer this platform as a means for thoughtful discourse and responsible discussion to propose solutions where applicable and to strive for continual process improvement. We welcome your answers to the questions below in preparation for the fall, 2014 NOSB meeting.

V. QUESTIONS:

1) How do certifiers assess whether production practices, identified in an organic system plan and/or observed on-site, maintain or improve soil quality? Is visual assessment sufficient?
2) What tools, other than visual inspection, could aid certifiers in evaluating soil management practices, e.g., Revised Universal Soil Loss Equation 2 (RUSLE2) or soil organic matter levels?
3) What benchmarks do certifiers have for issuing noncompliance's related to soil conservation: for instance, visible erosion, overgrazing, and evidence of manure application on frozen ground, manure or compost stored in flooded areas? Are quantitative benchmarks used?
4) What qualifications do certifiers seek among inspectors for evaluating soil management practices on-site?
5) What tools do inspectors use (other than soil testing) to evaluate/measure the adequacy of soil management during on-site inspections? Is one on-site inspection enough to assess erosion if it is done during a single visit?
6) How do certifiers respond if a review/on-site inspection indicates that there is a soil management problem? Do certifiers issue notices of noncompliance or note as a finding to be reassessed at a later time?
7) How do certifiers respond when complaints are filed about a producer's soil management?
8) Some USDA benefits require producers to be in compliance with Highly Erodible Land (HEL) provisions. Are certifiers aware of USDA Natural Resource and Conservation Service (NRCS) classification and HEL provisions? Should certifiers verify whether production acreage is classified as "highly erodible land" (HEL) and ensure appropriate soil management practices for HEL?
9) Are certifiers aware of USDA NRCS's tolerable soil loss standards? Should certifiers verify whether production acreage has been assessed to meet tolerable and sustainable soil loss levels?
10) When NRCS personnel who provide technical assistance on organic operations observe soil management risks and problems should the producer be required to communicate this information to their certifier?

National Organic Standards Board
Livestock Subcommittee
Findings and Recommendation in Response to September 2010 NOP Memorandum
Livestock Vaccines Made With Excluded Methods - Proposal

August 19, 2014

I. Introduction:

Vaccines are critical for the prevention of disease and to prevent needless suffering of livestock. For the vast majority of diseases for which a vaccine may be used there is a vaccine available which is not made with excluded methods. However, most certifiers do not require producers to document that the livestock vaccine used is not made with excluded methods. The National Organic Standards Board (NOSB), working with the National Organic Program (NOP), has spent considerable time over the last several years reviewing how best to address the issue of vaccines made with excluded methods in order to be in compliance with the Organic Food Production Act (OFPA) and the Regulations. The NOSB unanimously passed a resolution requesting that the NOP help obtain a comprehensive list, similar to the coded list of registered vaccines maintained by the Animal Plant Health Inspection Service (APHIS) that could be provided to the NOSB and certifiers, to help guide policy and practice. However, attempts to create such a list have not been successful. One key finding of our work to date is that the definition of "excluded methods" requires revision, and that the use of the term "GMO" (genetically modified organism), while commonly used, nationally and internationally, reflects an oversimplification. This document outlines the central issues related to vaccine use in organic livestock production, and notes that 7 CFR Section 205 allows for petitions for specific vaccines made with excluded methods. We also present the history of NOSB work to clarify apparent inconsistencies in practice, review in brief the complexity of the definition of "excluded methods", reiterate some of the Working Group Interim Report, provide a synthesis of public comment received, comments on international vaccine use, and recommend that the NOP provides Guidance on this subject.

II. Background:

In 2009 the NOSB commented on the use of livestock vaccines. They noted that with no antibiotics used in organic livestock production, the basic measure of prevention through use of vaccines is critical to the health of the animals. They pointed out that all vaccines are produced in federally regulated and licensed facilities and in November 2009 the NOSB recommended that all vaccines be allowed, as practiced at that time, in order to prevent disease and needless suffering of livestock, with the caveat *"that vaccines made by non-excluded methods be used before those made by excluded methods"* (Board Vote: Yes-11; No-2; Abstain - 0; Absent- 2)

In September 2010 the NOP asked the NOSB to formally review GMO vaccines in accordance with the criteria in Section 205.600. The NOSB requested a Technical Report which would address the evaluation criteria as specified in the Act (7 U.S.C 6517 and 6518).

In November 2011 the Technical Report, "Vaccines made from Genetically Modified Organisms", was received by the NOP. This document provided some critical information to the NOSB

The NOSB conducted a review of Vaccines made with excluded methods using the Checklist and criteria as specified at 205.600. The NOSB prepared a Proposal dated April 3, 2012, for public comment and possible vote at the Public Meeting in May 2012. This proposal included the following recommendations:

"This recommendation concerns the class of livestock vaccines derived from excluded methods, commonly called GMO vaccines. There are approximately 73 registered animal vaccines, of which 13 are GMO. Only 2 vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO. At present livestock producers use all vaccines and are not required to determine if they are using non-GMO (conventional) or GMO derived vaccines. GMO vaccines are not legally allowed in organic production. This recommendation proposes a change which will allow GMO vaccines only in a declared emergency and, further, that at such time producers could use GMO vaccines without losing organic status of livestock. The recommendation also proposes changes to the definition of "emergency treatment program". The entire recommendation applies to the class of vaccines derived from excluded methods, but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases."

Recommended Committee Action & Vote,
1. Modify language in 205.238 (6) as follows, change shown in italics.
Administration of vaccines and other veterinary biologics, *provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).*

2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided*,*

(1) *such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and*

(2) such vaccines are approved in accordance with §205.600(a);

3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

4. Change the Definition of "Emergency pest or disease treatment program*"* in section 205.2 with the additions shown in italics.

Emergency pest or disease treatment program: *A mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease, except for a program requiring substances described in section 205.105(e) regarding only vaccines produced with excluded methods, in which case such program is defined as a mandatory treatment program authorized by a declared Federal or State emergency for the purpose of controlling a pest or disease."*

Based upon public comment and the need for additional technical information before voting, the NOSB decided to table the proposal until a future meeting, but passed a resolution.[1] The resolution requested: 1) That NOP identify all vaccines registered with USDA as GMO or non GMO; 2) That Vaccine manufacturers voluntarily and truthfully label vaccines about their absence of GMO content; and 3) That the NOP or other USDA agency publish a real time tracking system to identify GMO and non GMO vaccines.

In response to the NOSB's May 2012 resolution, the NOP convened the Vaccines Made With Excluded Methods (MWEM) Working Group. The working group included two members of the NOSB, NOP staff, and staff from the Center for Veterinary Biologics (CVB), the division in the Animal Plant and Health Inspection Service (APHIS) that approves and regulates vaccines for use in livestock and pets.[2]

[1] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098924

[2] **Working Group Participants:**

In February 5 2013 the Working Group prepared an Interim Report summarizing its work, and this report was sent to the Livestock Subcommittee and subsequently was posted to gather public comment.

In April 2013 an update was provided at the Public Meeting.
(Note that there was no public meeting in fall 2013 owing to government shutdown).

In April 2014 the results of a pilot project analysis conducted by one certifier was presented as part of the Livestock Subcommittee report indicating that none of the vaccines used by livestock producers certified by that certifier were made with excluded methods according to verification received by the certifier from manufacturers. The NOSB requested further comment from certifiers.

In summer 2014 the Accredited Certifiers Association (ACA) conducted a simple survey amongst its certifiers which indicated that because of the considerable complexity of verification there is a lack of consistency nationwide in how certifiers are verifying that vaccines used in organic livestock production are not made with excluded methods.

III Relevant Areas of the Rule:

The USDA organic regulations at 7 CFR part 205 contain several references that are relevant to the discussion on the use of vaccines in organic livestock production.

The first reference, under the "Livestock healthcare practice standard", requires that "the producer must establish and maintain preventive healthcare practices, including… administration of vaccines and other biologics" (205.238(a)(6)).

The second reference on the National List of Allowed and Prohibited Substances allows the use of livestock vaccines, which are synthetics as follows: 205.603(a)(4) as follows: "Biologics – vaccines" (205.603(a)(4)) (without annotation).

The third reference at 205.672 deals with emergency pest or disease treatment which is defined in 205.2 as a "mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease." The OFPA Statute (7 USC 6506(b)(2)) refers to exemptions for organic "farms subject to a Federal or State emergency pest or disease treatment program." This suggests that Congress did not intend to include locally declared programs. In the past, vaccines MWEM have been required as part of disease eradication programs. It is unclear as to the effects of these eradication programs on organic livestock producers.

The fourth reference is:

> Section 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

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(* indicates working group facilitator)

> "To be sold or labeled as "100 percent organic", "organic," or "made with organic (specified ingredients or food groups)", the product must be produced or handled without the use of:…
>
> (e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with 205.600 (a)."

Section 205.600 (a) "Evaluation criteria for allowed and prohibited substances, methods and ingredients" specifies:

> "The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:
>
> 205.600(a) Synthetic and nonsynthetic substances considered for inclusion on, or deletion from, the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518)".

Thus, under this section (205.105(e)), the use of excluded methods is prohibited in organic production.

To date the NOSB has not recommended any vaccines made with excluded methods be added to the National List.

Excluded methods are defined under the USDA organic regulations (205.2):

> "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions and processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing positions of genes when achieved by recombinant DNA technology). Such methods do not include traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. "

The methods that are excluded and, thus, prohibited, are those 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.

IV Discussion:

The preamble to the final rule (65 FR 80554) in 2000 discussed the NOP's response to comments about use of vaccines MWEM in organic livestock production. Some commenters wanted all vaccines MWEM to be completely prohibited from organic livestock production while others wanted all vaccines to be temporarily allowed until more information could be assembled in the future to determine if any of the vaccines MWEM were necessary for production. At the time, NOP chose to structure the provision so that vaccines MWEM could only be used by organic production if they are affirmatively included on the National List after review by the NOSB. But, with no information or guidance about how to identify vaccines MWEM, many organic livestock producers, with approval from their certifiers, have chosen vaccines based upon disease prevention and not based on whether they are made with excluded methods.

To rectify this divergence between regulatory language and industry practice, the NOSB, in 2009, recommended a change to section 205.105(e) to allow the use of vaccines made with excluded methods if vaccines made without excluded methods were not commercially available. That recommendation stated

that such a change would not require individual review of vaccines made with excluded methods. The NOP has not implemented this change into the USDA organic regulations. Therefore, the current exception at section 205.105(e) to allow vaccines made with excluded methods only applies to those that are reviewed according to 205.600.

In September 2010, the NOP requested that the NOSB review vaccines made with excluded methods (i.e. GMO vaccines or genetically engineered vaccines) in accordance with section 205.600.

The Livestock Subcommittee requested a Technical Review of GMO Vaccines which used the criteria found at 7 U.S.C. 6517 and 6518. The Livestock subcommittee drafted a proposal and submitted it to the full Board. The NOSB discussed the proposal pertaining to the use of vaccines MWEM at its May 2012 public meeting. The NOSB received considerable public comment on this issue leading up to and at this public meeting. Comment was split with members of the general public advocating for a prohibition on vaccines MWEM and certifiers and producers asking for more detailed information about current vaccine use and clarification about which vaccines were MWEM. Due to the need for additional technical information before voting, the NOSB decided to table the proposal until a future meeting, but passed a resolution that included a request for more information from USDA.

In response to the NOSB's May 2012 resolution, the NOP convened the Vaccines Made with Excluded Methods Working Group.

The Working Group first collected information regarding the use of vaccines, government programs that may require the use of vaccines, technical information about how vaccines are made and how vaccines are regulated. In response to requests from the NOP, CVB and Veterinary Services (VS) from APHIS elaborated on regulations that could require livestock producers to use vaccines. The working group's understanding is that the Secretary of Agriculture has the authority to declare emergencies at various levels depending upon the severity of the outbreak. Emergency declarations allow both state and the federal government to require livestock producers to use specific vaccines, including vaccines MWEM. The only regional emergency in the past decade was an Exotic Newcastle outbreak in unvaccinated backyard poultry and game fowl. No vaccination program was used in this emergency because USDA determined that most commercial poultry operations in the area, whether conventional or organic, had already vaccinated their birds for this disease.

The working group also learned that disease eradication programs authorized by the federal government may include mandated use of vaccines. The two recent eradication programs, Brucellosis in cattle and Pseudorabies in swine both required vaccines. These two eradication programs used vaccines that allow blood tests to differentiate between those animals that have an immune response due to the vaccine and those animals that have an immune response due to the disease. In order to differentiate between vaccinated animals and animals which had the disease, producers must use a modified live vaccine that results in a strong immune response, has mutations that alter at least one epitope and is not virulent. The Brucellosis vaccine was developed using cell culture passages, a presumably allowed technology in organic production. The Pseudorabies vaccines, several vaccines were approved for this eradication program, were developed using excluded methods. Based on discussions with APHIS, the working group believes that vaccines made with excluded methods may be USDA's preferred vaccine choice in future eradication programs.

APHIS' CVB regulates vaccines and vaccine manufacturers under the Virus-Serum-Toxin Act. CVB's primary role is to review and license vaccines based upon purity, safety, potency, and efficacy. CVB requires certain label terms depending upon specific configurations of the vaccine seed (form of the agent used to create

the vaccine). CVB also tracks vaccines that are made through the use of biotechnology. However, CVB's evaluation of whether a vaccine is produced through "biotechnology" does not align well with how "excluded methods" is defined under the USDA organic regulations. Because of this lack of alignment, it is difficult to know the extent to which vaccines on CVB's list of biotechnology derived vaccines overlaps with what could be considered produced through an "excluded method". CVB does review the use of biotechnology in manufacturing of the vaccines, e.g. if a vaccine is produced using cells made with excluded methods. However, if only the cell line used to culture the vaccine seed has a genetic insertion, deletion or other mutation, the vaccine itself is not considered to be a recombinant.

Finally, the working group could not identify a comprehensive path of "partial" alignment such that if a vaccine were identified as biotechnology derived by CVB then it is was definitely considered made with "excluded methods" as defined by the NOP.

It must also be noted that European organic standards allow the use of all vaccines if they are needed to prevent a disease in the area. Canadian organic standards forbid genetically engineered vaccines outright. In addition, Canadian organic livestock producers may only use a nongenetically engineered vaccine that was grown in a cell culture system that included genetic modifications if no other vaccine is available.

After considering background research, information from other USDA agencies and public comments, the Working Group came to the conclusion that developing criteria for certifiers and Material Evaluation Programs (MEPs) to use to identify vaccines MWEM would be the only approach to allow the organic industry to determine which, if any, vaccines made with excluded methods are being used and if there are reasonable alternatives to these vaccines.

The working group considered creating a list of all vaccines produced with (or without) use of excluded methods. This would be the easiest resource for organic livestock producers and certifiers to use. However, creation of a negative and/or positive list is difficult for a variety reasons, including the lack of precise criteria to decide whether something should be considered produced through excluded methods. Furthermore, for such lists to be useful, the lists would need to specify the branded vaccine products that livestock producers purchase and use, not just generic names of the disease or pathogen that is being used to create the vaccine. Another reason the working group chose not to create a list is that the CVB does not differentiate vaccines based upon excluded methods. USDA is concerned that creating such a list would imply a deficiency of vaccines MWEM, which would not be scientifically accurate within USDA's responsibility to regulate the purity, safety, potency, and efficacy of vaccines. The working group was also concerned 1) with liabilities due to the possibility of inaccurately placing a specific vaccine on a list, and 2) the possibility of not being able to obtain necessary vaccine manufacturing information, which is often submitted as confidential business information to APHIS CVB.

The working group identified criteria that would allow certifiers and MEPs to identify vaccines MWEM. The three criteria to be used in conjunction are:

- _Label Guidelines
- _Product Codes
- _Methods of Production Analysis

Label Guidelines: CVB regulations require that certain vaccine seed configurations have specific terms on the labels of branded vaccine products. These terms are required for a subset of biotechnology derived vaccines. While these terms are not added to the labels because an excluded method was used, CVB states that all such vaccines were created using methods that the NOP would exclude. The terms on labels that identify vaccines were made with excluded method are "Subunit," "Vector," and "Chimera." Because these

vaccines are labeled with the identified terms, CVB can disclose a trade names list for all of these vaccines.

Vaccines must be labeled with the term “Subunit” when the vaccine is an extracted or purified protein that was expressed in a recombinant system. These vaccines do not contain any genetic information (DNA). These vaccines only contain the protein antigen that induces an immune response. To create “Subunit” vaccines, the gene for the antigenic protein is inserted into an expression vector or expression system. The gene from the pathogenic organism may be expressed in prokaryotic or eukaryotic cell culture systems. The expressed protein is then extracted or purified and used in the vaccine. Currently there are no active licenses for subunit vaccines.

Certain modified live vaccines must be labeled with the term “Vector” or “Chimera” to denote that the vaccine contains DNA from two pathogens. These vaccines are created by identifying a viral structure that induces a strong immune response. This viral structure is termed the expression vector. In many cases, the expression vector is a virus that in its unaltered form can cause a disease in the target species. The vector will then have at least one gene from another disease causing agent inserted into the viral genome. Vaccines labeled with “Vector” may be efficacious against two diseases, the disease caused by the unaltered vector and the disease caused by the source of the gene that was inserted into the vector or only be efficacious against the disease caused by the source of the gene that was inserted into the vector. Vaccines labeled with “Chimera” are similar to “Vector” labeled vaccines, except that certain genes required for replication competency are supplied by the added genes and not contained in the expression vector.

Product Code: The CVB requires that every biologic, including vaccines, produced must have a product code. The CVB guide on true names and product codes notes that the 5th digit of the product code may contain “D” or “R.” The letter “D” in the fifth digit signifies that the vaccine is a nucleic acid vaccine. Such vaccines, also called DNA vaccines, are made with excluded methods and depend upon foreign genes being expressed in some of the cells of the vaccinated animals. The letter “R” in the fifth digit signifies the vaccine has a recombinant component or is a subunit protein derived from a recombinant organism. The recombinant designation only applies to components in the vaccine and not to methods used to make the vaccine such as genetically engineered cells that are used for cell culturing the vaccine seed.

In public comments, some certifiers stated that they were aware of the R code in the fifth digit of the product code as designating that a component in the vaccine was recombinant or recombinant-derived. However, these certifiers were not able to translate the product code information to actual vaccines on the market. CVB is unable to provide a list of the trade names of the vaccines with a “D” or “R” in the product code because confidential business considerations will not permit discussion of production methods, unless the biologics firm specifically agrees to disclose the information. The working group was unable to develop a method to identify the trade names of vaccines and other biologic products that have a D or R in the product code other than the trade names that are already identified as MWEM, e.g. are labeled as containing a “Vector” or “Chimera.” Vaccines that have a “D” or “R” in the product code may or may not be made with excluded methods since the production methods may not be identified for evaluation. The working group requested input from the NOSB and the organic community to identify methods of linking product codes to trade names in a manner that clearly identifies whether or not an excluded method was used. The pilot project by one certifier in 2013 and by the ACA in 2014 provided some analysis of the use of vaccines in practice.

Method of Production Analysis: Some firms have waived confidentiality by describing how the vaccines were made in public comment to the NOSB. However, some vaccines were and in the future may be made with methods that are not clearly excluded or allowed in organic production. The working group requested

input from the NOSB and the organic community to provide comments on this issue.

Modified live vaccines generally have been found to produce greater immune responses in vaccinated animals and have become more common in new vaccines than killed vaccines. Live vaccines require that the genome of the disease causing organism be modified to create a living, but not virulent, pathogen which can be packaged in the vaccine. The excluded methods definition (205.2) includes methods which genetically modify organisms or influence their growth and development by means not possible under natural conditions or processes which are not considered compatible with organic production. The definition identifies some of the methods that are excluded including recombinant DNA technology (gene deletion, gene doubling, introducing a foreign gene and changing the positions of genes when achieved by recombinant DNA technology). The definition states that some methods to genetically modify organisms are allowed, including traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture.

Many of the older non-biotechnology derived modified live vaccines were made by using bacterial culture, cell culture or tissue culture with multiple passages to induce genetic modifications, including gene deletions, to the disease causing pathogen. The various cultures were then screened to identify a modified version that induced an immune response but that was no longer virulent. This is a process of random genetic modification followed by screening for the desired phenotype. The Brucellosis vaccine that is part of the Brucellosis eradication program was produced by growing the parent strain in various concentrations of an antibiotic cocktail over several passages to induce random mutations in the genome of the bacteria. These random mutations resulted in a non-virulent bacterial strain that did not produce the O-chain component of the lipopolysaccharide that was one of the epitopes for immune response. This change in at least one epitope was required for eradication programs so that vaccinated animals could be differentiated from animals infected by the actual pathogen.

The working groups assumed other genetic modification methods that would be allowed are exposure to chemical or physical mutagens. Physical mutagens include ionizing radiation, UV radiation and radioactive decay. These mutagens create genetic modifications in a random manner through a variety of ways. Some chemical mutagens break the double stranded DNA, allowing a recombination event to occur which can cause gene deletion and changing the position of genes. Other mutagens cause DNA bases to switch to other bases, errors in DNA repair or errors in replication. These mutagens all genetically modify organisms in a random manner that is not targeted. Generally, the vaccines working group considered chemical and physical mutagens to be traditional breeding techniques. Biological mutagens are excluded if they are considered to be a recombinant technology. Recombination is the process by which double stranded DNA is broken, rearranged and then rejoined. Recombination naturally occurs between chromosomes during the process of meiosis to form gametes for sexual propagation, in plants, animals and other organisms. Recombination naturally occurs during high frequency recombinant (Hfr) conjugation in which part of the chromosome from one bacterium is transferred to another bacterium, resulting in homologous recombination which genetically modifies the target bacteria. These are just two examples of genetic modifications through recombination events which are allowed by the current definition of excluded methods.

Some biological mutagens are clearly excluded by the current definition. Restriction enzymes are naturally occurring proteins in many bacteria that will cleave DNA at specific sequences. These enzymes are defense against phage (viruses that target bacteria) which insert their genetic material, usually but not always DNA. Restriction enzymes have been used to cleave a gene of interest and then through a targeted recombination event create a specific gene deletion, clone the gene in a vector or cause a changing of positions of genes in a controlled, nonrandom manner.

Other biological mutagens are neither explicitly allowed or excluded and may be allowed when used one way but not when used in a different way. Specifically, the working group discussed the methods used to create a vaccine which the manufacturer has stated, in public comments to the NOSB, was not made with excluded methods. This particular gene-deleted product was created using transposons and phage transduction. Transposons and phage transduction both result in genetic modifications mediated through recombination events. However, the working group was divided as to whether or not these methods were excluded. Are these methods considered traditional breeding techniques?

Transposons, also called transposable elements are naturally occurring, double stranded DNA sequences with a defined structure. Each end of the transposon includes inverted repeats. In prokaryotes, the internal structure includes at least one gene for transposase and may contain many more depending upon the type of transposon. Genes for antibiotic resistance, one example of the types of genes within the transposon occur both naturally and sometimes as a marker in lab modified transposons. When the transposase gene is expressed, the protein binds to the inverted repeats of the transposon, cleaves the genomic DNA and excises the transposon. Transposase can then cleave the genomic DNA at another spot and recombine the transposon into a new position in the genome.

In order to evaluate the use of transposons in vaccine production, the working group considered if transposons would fit into the allowance for traditional breeding techniques. The working group was not clear at which point traditional breeding techniques are divided from modern or non-traditional breeding techniques. Is there a time point at which all techniques before that time are considered traditional and all new techniques developed after that time are not considered traditional? The definition of excluded methods allows all traditional breeding techniques, so the distinction is important for organic producers.

The other method used by the vaccine manufacturer under discussion was transduction, which is the process through which the genomes of bacteria can be modified with the use of bacterial virus, called a phage. Some types of phage attach to the bacterial cell wall and insert the viral genome into the cell. The viral genome may then be inserted into the bacterial genome through a recombination event which is part of the lysogenic cycle. After receiving a trigger, the viral genome will be excised and the lytic cycle will be triggered. The excision of the viral genome is not perfect and in some cases, parts of the bacterial genome will be excised and packaged into the new phage. The phage can then be used to infect additional bacteria. The bacterial genetic material in the phage will be inserted into the newly infected cell. A homologous recombination event may occur so that some of the genes from the originally infected cell's genome will replace the genes in the newly infect cells. This method can stably introduce genetic mutations into the new bacteria.

The working group did not come to a decision about the status of vaccines developed using these methods. Certifiers and MEPs who examine vaccines for compatibility with the organic regulations will need guidance on future determinations of other vaccines as well.

Public Comment on the Interim Report of the Working Group, and the subsequent efforts of Certifiers to clarify how to verify use of vaccines not Made With Excluded Methods, clearly reflects the frustration of certifiers and producers seeking to be fully compliant with the regulations, while needing to ensure the health of organic livestock.

Here are some samples of public comment:

“Any expectation of verifying vaccines made with excluded methods will need a clear and practical framework of how to determine compliance. Even with a stricter rule regarding GM vaccine use, there will likely need to be some exceptions because some critical vaccines are only available from GM sources.”

“We find that the technology itself is quite difficult for the layperson to understand, and phrases such as “excluded methods” and “traditional breeding” are surprisingly challenging to define. “

“One of the most difficult aspects of understanding the use of genetic engineering in vaccines is the lack of disclosure to the public or public understanding about these techniques. Without government regulation and increased disclosure, it will be very difficult for organic agriculture to make strides in the goal of refraining from the use of vaccines developed using excluded methods.”

“Developing a clearer definition of “excluded methods,” although outside of the scope of the Vaccines Working Group’s Interim Report, was discussed as an option in that report.”

“It seems clear that the definition needs to be revised. Certifiers experience difficulty interpreting “excluded methods” at present, especially because the language of the NOP’s definition does not always align with the language used by vaccine manufacturers. However, revision of terminology must be done extremely carefully. We ask that, in any revision of the definition, or tightening of restrictions on vaccines, be done with consideration of the following questions:
1) GE is an evolving technology. How are producers, veterinarians, certifiers, and the NOP to keep up with the knowledge needed to interpret these evolving techniques?
2) When considering implementation of a stricter rule with regard to GM vaccine use, how far back into the development or manufacture of a substance should the excluded methods prohibition apply? How far back is practical and verifiable? As indicated in the recent discussion document, many challenges exist in this area.”

“We are informed that Canadian Organic Standards prohibit all GE vaccines. How are Canadian certifiers able to verify this, especially given the international nature of the pharmaceutical supply chain? In terms of implementing a system of transparency in this area, is there anything we can learn from Canadian certifiers?”

“In the case that a reliable system of disclosure is developed and implemented, it will be essential for the National List to include certain vaccines that, while essential, are not available except through genetic engineering. One of our foremost concerns is a Salmonella vaccine for poultry. We also need to take into account emergency situations and eradication programs that may require the use of vaccines developed by excluded methods. Overall, food safety needs to be our largest concern.”

“In our experience, it is too much to expect certifiers and material review organizations to be able to analyze the effects of each method to determine if the genetic modifications are random or targeted. In order to make this determination on a consistent basis, the organizations would have to have geneticists or equally qualified staff. This is simply too difficult to achieve on a regular basis, given the amounts of vaccines and combinations of brand names that certifiers have to review every year. Thus, it is logical to suggest that a given technique should be declared excluded or allowed.”

“Vaccines are also used in other countries as well. Those vaccines are regulated and labeled differently internationally and we cannot expect that international certifiers should be held to different standards. Please consider the international implications of any final recommendation that the livestock subcommittee proposes.

A veterinarian commented: “The working group is to be commended for their extensive work on this subject. The relevant issues have been identified and described. The group has solicited input from certifiers and the greater organic community. This is not a simple topic with clearly defined boundaries and limits. I encourage the NOSB and NOP to approach this area with a system of regulation that is not rigid but will be open to further review and rule modification as time progresses and technology continues to evolve.”

In summary: Organic livestock producers, certifiers and material evaluation programs can, theoretically, identify certain vaccines as being produced with excluded methods by the presence of the words “chimera,” “vector,” or “subunit” on the label of the vaccine. However, in practice, this is an extremely difficult process, and thus there is lack of consistency in verification that livestock vaccines used in organic livestock production are not Made with Excluded Methods. Given this complexity and the need for revision of the definition of excluded methods, as detailed in this report, NOP Guidance is needed on how to make a determination of whether a vaccine has been produced with Excluded Methods. Actions could eventually include a rule change. It is certainly clear that the definition of excluded methods seems to be a less than ideal fit with vaccine production methods.

Motion: The Livestock Subcommittee requests that the NOP review this document and provide Guidance to the NOSB, certifiers and MRO’s on the use of Vaccines MWEM in organic Livestock production.

Motion by: Jean Richardson
Seconded by: Colehour Bondera

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recusals: 0

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB, August 26, 2014

National Organic Standards Board
Crops Subcommittee
Protecting Against Contamination in Farm Inputs
Preliminary Bibliography and Discussion Document
August 19, 2014

I. Introduction

Organic farmers have always made use of organic materials from a wide range of on-farm and off-farm sources—in compost, some plant materials without prior composting, mined minerals, and animal by-products such as fish or slaughterhouse waste. OFPA addresses residues of such materials in agricultural harvested crops. However, residues of pesticides, heavy metals, genetically engineered organisms, and other contaminants are problems not only for the consumer, but also for the grower, and the regulations require their management in a way that protects crops, soil, and water. Residues may reach the organic farm through different media, but here we are concerned about protecting the farmer from contamination coming from off-farm inputs used directly from these sources.

The purpose of this discussion document is to share the research results obtained by the Crops Subcommittee so far and collect public input, with the aim of identifying more experts and ultimately proposing a process for addressing contamination of inputs that may be brought onto the farm. It is the plan of the Subcommittee to meet with experts and receive additional public comments as part of the process for determining whether the NOSB should propose recommendations on this subject.

This review identifies resources that document issues associated with contamination of farm inputs --those materials that are brought into or added to the organic system and may be contaminated with residuals of synthetic or natural materials not permitted in organic production. Of course, there are also concerns with unavoidable residual environmental contaminants, which are a separate but related issue. For example, there may be some land areas that are so contaminated by background levels or ongoing contamination (through water and air) that the viability of the organic operation is threatened.

To ensure the quality of organic food, investigating sources of potential contaminants and ultimately adopting uniform preventive measures to avoid contamination of organic systems is important. Some examples of topics that have become issues in the last few years include:

- Heavy metal contamination of manure, compost, mined minerals and fish products.
- Neonicotinoid residues that could harm pollinators when taken up by plants.
- Insecticide residues such as bifenthrin that can be detected in compost
- Excessive foreign materials in compost and green waste.
- Antibiotic residues in manures that can result in tetracycline-resistant bacteria.
- Genetically engineered plant material that may or may not break down in compost and soil.

This review starts with an examination of pathways by which contaminants may enter organic production systems, products, and eventually consumers.

II. Some Contamination Incidents

In 2010, bifenthrin was found in commercially available composts. California Department of Food and Agriculture prohibited use of compost from three producers in organic production.[1] NOP allowed use of the compost as unavoidable residual environmental contamination (UREC).[2]

A 2005 ATTRA publication advised that, "Poultry litter applied at agronomic levels, using good soil conservation practices, generally will not raise arsenic concentrations sufficiently over background levels to pose environmental or human health risks. However, recent studies show that more than 70% of the arsenic in uncovered piles of poultry litter can be dissolved by rainfall and potentially leach into lakes or streams. Thus, organic producers must take care when they handle and apply poultry litter."[3] In 2011, Consumers Reports documented significant arsenic concentration in rice, including organically grown rice.[4]

III. Pathways

A. Fertilizers/Soil Amendments

Fertilizers contain trace amounts of heavy metals as impurities, which may build up in the soil. Application of certain phosphate fertilizers also adds heavy metals to the soil, including cadmium, fluorine, mercury, and lead.

Heavy metal contamination may come from inputs of organic matter:
The application of numerous biosolids (e.g., livestock manures, composts, and municipal sewage sludge) to land inadvertently leads to the accumulation of heavy metals such as As, Cd, Cr, Cu, Pb, Hg, Ni, Se, Mo, Zn, Tl, Sb, and so forth, in the soil…. Although most manures are seen as valuable fertilizers, in the pig and poultry industry, the Cu and Zn added to diets as growth promoters and As contained in poultry health products may also have the potential to cause metal contamination of the soil. The manures produced from animals on such diets contain high concentrations of As, Cu, and Zn and, if repeatedly applied to restricted areas of land, can cause considerable buildup of these metals in the soil in the long run.[5]

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. Nevertheless, "Considerable remediation of the hazardous wastes or contaminated plants, soils, and sediments can be accomplished by composting. High microbial diversity and activity during composting, due to the abundance of substrates in feedstocks, promotes degradation of xenobiotic organic compounds, such as pesticides, polycyclic aromatic hydrocarbons (PAHs), and polychlorinated biphenyls (PCBs)."[6]

[1] OMRI, 2010. Composts Disallowed in California and An Update on Pesticide Residues, http://www.omri.org/news/81937/compost-update-pesticide-residues
OMRI, 2010. An Update on Pesticide Residues in Compost- Part 2, http://www.omri.org/news/85720/update-pesticide-residues-compost-part-2

[2] USDA, 2010. NOP 5016, Guidance: Allowance of Green Waste in Organic Production Systems.

[3] Barbara C. Bellows, 2005. Arsenic in Poultry Litter: Organic Regulations, www.attra.ncat.org/attra-pub/PDF/arsenic_poultry_litter.pdf

[4] http://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm Arsenic in your food: Our findings show a real need for federal standards for this toxin.

[5] Raymond A.Wuana and Felix E. Okieimen, 2011. Heavy Metals in Contaminated Soils: A Review of Sources, Chemistry, Risks and Best Available Strategies for Remediation. ISRN Ecology, Volume 2011, Article ID 402647.

[6] Allen V. Barker and Gretchen M. Bryson, 2002. Bioremediation of Heavy Metals and Organic Toxicants by Composting. *The Scientific World JOURNAL* (2002) 2, 407–420.

Heavy metals cannot be destroyed by composting, but may be converted into organic compounds or chelates that are less bioavailable than inorganic metal compounds. On the other hand, heavy metals may also become concentrated because of the removal of carbon in the composting process. [7]

Contamination with herbicides is a particular problem because it can cause damage to plants.[8] It is recognized that although composting destroys many pesticide residues, it does not necessarily eliminate toxic impacts:

"The nature of the organic contaminant, composting conditions and procedures, microbial communities, and time all affect mechanisms of conversions in composts or soils…. The Büyüksönmez review noted that mineralization of organic pesticides was only a small fraction of pesticide degradation, with other prominent fates of the pesticides being partial degradation to secondary compounds, adsorption to compost, and volatilization….The secondary compounds may be as, or more, toxic than the original pesticide. Losses by volatilization essentially mean that the pesticide has been moved from one place to another. If recalcitrant materials, including metals, are present in feedstock, they may be unchanged or concentrated during composting. Recalcitrant pesticides are persistent and may show no changes during composting or have a half-life of a year or more. …Destruction of pesticides depends on the pesticide and on the substrate in which the pesticide is undergoing co-composting…. The general conclusion from research with pesticide degradation by composting was that pesticide concentrations were lowered to nonhazardous levels for crops in soils receiving the composts. However, if pesticides that are persistent or recalcitrant to degradation are present in the feedstock, special care may be needed not to use the compost on sensitive crops in the year in which the compost was made. Caution may need to be taken in some cases not to grow plants in 100% compost in containers." [9]

Herbicides of the class known as pyridine carboxylic acids, which includes aminopyralid, clopyralid, fluroxypry, picloram, and triclopyr, are registered for use on pasture, grain crops, and lawns, among other sites. "[S]ome of these herbicides can be persistent and may remain active in the hay, straw, grass clippings, and manure, even after they are composted. Some of these herbicides have a half life of 300 days or more and aminopyralid has been reported to remain active in compost for several years…. Most of these herbicides have a rotational crop restriction of at least 18 months for vegetable crops. When used as

[7] Allen V. Barker and Gretchen M. Bryson, 2002. Bioremediation of Heavy Metals and Organic Toxicants by Composting. *The Scientific World JOURNAL* (2002) 2, 407–420.

[8] Herbicide Carryover in Manure and Hay: Caution to Organic Farmers and Home Gardeners http://compostingcouncil.org/admin/wp-content/uploads/2012/07/Herbicide-Carryover.pdf
United States Composting Council, 2011. Composter Alert: New DuPontTM Herbicide "ImprelisTM" Will Persist in Compost. http://compostingcouncil.org/admin/wp-content/uploads/2011/05/Imprelis-alert-final1.pdf
EPA, 2011. Imprelis stop sale letter. http://www.epa.gov/pesticides/regulating/imprelis-stopsale-letter.pdf
US Composting Council, 2013. USCC Position: Persistent Herbicides. http://compostingcouncil.org/admin/wp-content/plugins/wp-pdfupload/pdf/9199/USCC%20Position%20Statement%20on%20Persistent%20Herbicides%20FINAL.pdf
US Composting Council, 2014. USCC comments on registration of picloram. http://compostingcouncil.org/admin/wp-content/plugins/wp-pdfupload/pdf/9199/USCC%20Picloram%20Reregistration%20Comments%20Final.pdf
Frederick C. Michel, Jr. and Douglas Doohan, Clopyralid and Other Pesticides in Composts. Ohio State University Extension, publication AEX-714-03. http://ohioline.osu.edu/aex-fact/pdf/0714.pdf

[9] Allen V. Barker and Gretchen M. Bryson, 2002. Bioremediation of Heavy Metals and Organic Toxicants by Composting. *The Scientific World JOURNAL* (2002) 2, 407–420.

directed on the labels, these herbicides should not cause these problems. The problems arise when the hay, manure, grass clippings, etc. leave the hands of the individual who applied the herbicides."[10]

The U.S. Composting Council has been particularly concerned about contamination of compost with persistent herbicides. In a position paper on persistent herbicides, it says,[11]

> "Herbicide-contaminated compost is not a new problem. The first incidents of herbicide contamination in compost were reported in 2000 in Spokane, Washington, where compost produced from yard trimmings contaminated with clopyralid damaged vegetable and garden crops….
>
> Since the first incident, evidence of compost contamination by persistent herbicides has been documented throughout the United States, including California, Oregon, Pennsylvania, Texas, Maine, New Jersey, New York, Kansas, Idaho, North Carolina, Minnesota, and Vermont….
>
> In Vermont in 2012, the Green Mountain Compost facility (owned by the Chittenden Solid Waste District, CSWD) received 510 confirmed complaints of herbicide damage to a variety of garden plants and ended up paying 449 claims. Settling those complaints and retrieving unsold product from its resellers, cost CSWD an estimated $270,000. CSWD incurred another $372,000 for testing and legal assistance to address the issue. The loss in value added sales of products that could not be made or sold due to the presence of persistent herbicides added another estimated $150,000. CSWD's costs totaled approximately $792,000. The culprit? Mainly aminopyralid, although other primary persistent herbicides of concern (clopyralid and picloram) were also found in compost. That regulators were unable to identify all sources of contamination is a most troubling aspect of this incident.
>
> Other troubling aspects of the Vermont experience:
>
> The compost was found to cause plant damage with concentrations of aminopyralid as low as 1 ppb.
> No government or independent lab exists in the United States that can adequately test for aminopyralid in compost at or below the 1 ppb level.
> Only the persistent herbicide manufacturers (Dow AgroSciences and DuPont) are currently capable of testing for herbicides in complex matrices with high organic content such as composts and manures at the low part-per-billion levels at which sensitive garden plants are impacted.
> Lack of testing capability contributed to Green Mountain Compost's loss of value added sales.
> Regulators could not determine the source of the contamination; that is, which feedstock accepted by the facility was contaminated with aminopyralid.
>
> …The most common pathway known for persistent herbicides making their way into compost is through manures and bedding, although grass clippings and other yard debris can be contaminated as well."

Persistent insecticides are also a problem in compost and mulch materials. As mentioned above, bifenthrin was found in commercially available composts in 2010. California Department of Food and Agriculture

[10] Jeanine Davis, 2009. Herbicide Carryover in Manure and Hay: Caution to Organic Farmers and Home Gardeners. North Carolina State University, Mountain Horticultural Crops Research and Extension Center. http://compostingcouncil.org/admin/wp-content/uploads/2012/07/Herbicide-Carryover.pdf

[11] US Composting Council, 2013. USCC Position: Persistent Herbicides. http://compostingcouncil.org/admin/wp-content/plugins/wp-pdfupload/pdf/9199/USCC%20Position%20Statement%20on%20Persistent%20Herbicides%20FINAL.pdf

prohibited use of compost from three producers in organic production.[12] NOP allowed use of the compost as unavoidable residual environmental contamination (UREC).[13]

Neonicotinoids pose a more defined threat. They are applied to seeds and plants, and are taken up by the plants. They remain in plant residues and accumulate in soils, and can later be taken up by other plants. Very minute quantities are hazardous to honeybees and other pollinators that might consume pollen, nectar, or sap from plants containing residues of these insecticides.[14]

Another form of contamination in compost is heavy metals, especially arsenic, from poultry litter. Composting concentrates arsenic in poultry litter. Water and carbon dioxide lost during composting reduce the litter volume by 25 to 50% and the litter weight by 40 to 80%. Thus, poultry litter that contains 30 ppm arsenic before composting will contain 50 to 150 ppm arsenic after composting.[15]

Newspaper is used both as a mulch and as an ingredient in compost. There is a lack of clarity about contaminants in newspaper, derived from both paper processing and inks. The current listing on §205.601 is for "newspaper or other recycled paper, without glossy or colored inks." The U.S. Composting Council argues that paper is a beneficial addition to compost. "Paper products contain very low levels of contaminants, in most cases below those found in yard waste."[16] However, a 1991 risk assessment considered the cancer risk associated with applying newspaper to farmland:

Newspaper consists primarily of carbon black dye, mineral oil, and paper. Carbon black contains approximately 0.1% polycyclic aromatic hydrocarbon (PAH) impurities. The EPA has found that certain paper products contain 10–100 ppt dioxin. Newsprint has not yet been evaluated. Since the production of newsprint is unlikely to create many dioxins, the lower range figure of 10 ppt was used. The cancer risk from vegetarian vegetable consumption, based on the levels of these two contaminants, was evaluated for both a 200 and 5 ton/acre application rate. The potential risk from contaminated vegetable exposure ranged from 1×10^{-3} to 2.5×10^{-5} for PAH and from 7.2×10^{-6} to 1.8×10^{-7} for dioxin.[17]

This risk, which does not include glossy or colored inks, exceeds EPA's "negligible risk" level of 10^{-6}. On the other hand, a 1992 study found no significant differences in heavy metals in soils mulched with newspapers compared to soils not receiving newspaper.[18] Although blogs and popular literature abound with claims that since today's newspapers are printed with soy-based inks, there should not be a risk associated with newspapers as mulch or a compost ingredient, these claims do not appear to be based on scientific research, so more investigation is needed.

[12] OMRI, 2010. Composts Disallowed in California and An Update on Pesticide Residues, http://www.omri.org/news/81937/compost-update-pesticide-residues
OMRI, 2010. An Update on Pesticide Residues in Compost- Part 2, http://www.omri.org/news/85720/update-pesticide-residues-compost-part-2
[13] USDA, 2010. NOP 5016, Guidance: Allowance of Green Waste in Organic Production Systems.
[14] Goulson, D. (2013), REVIEW: An overview of the environmental risks posed by neonicotinoid insecticides. Journal of Applied Ecology, 50: 977–987.
[15] Barbara C. Bellows, 2005. Arsenic in Poultry Litter: Organic Regulations, www.attra.ncat.org/attra-pub/PDF/arsenic_poultry_litter.pdf
[16] US Composting Council, 2010. Factsheet: The Benefits of Including Paper in Composting. http://compostingcouncil.org/admin/wp-content/uploads/2010/09/Benefits-of-Including-Paper-in-Composting.pdf
Although dated 2010, all references are much older.
[17] J. A. Bukowski , 1991. Cancer Risk from the Application of Newspaper to Farmland. The Analysis, Communication, and Perception of Risk Advances in Risk Analysis Volume 9, pp 267-274.
[18] David A. Munn, 1992. Comparisons of Shredded Newspaper and Wheat Straw as Crop Mulches. HortTechnology 2(3): 361-366. http://horttech.ashspublications.org/content/2/3/361.full.pdf

Manure from animals raised in nonorganic agriculture often contains residues of antibiotics fed to the animals. These residues may or may not decompose during composting. Dolliver et al studied the effects of three forms of composting –a manure pile with no disturbance after initial mixing, a compost pile turned weekly and adjusted for moisture, and compost made in a rotating drum—to determine whether the practices made a difference in the decomposition of four antibiotics. There was no difference among treatments, but there was a substantial difference among antibiotics. Chlortetracycline degraded almost completely (>99%), monensin and tylosin were reduced 54-76%, and sulfamethazine did not degrade at all.[19]

Pesticide products used in organic production or that end up in composted material may be contaminated with substances that are active ingredients in other products.[20] EPA's Pesticide Registration Manual states,

EPA evaluates the composition data to determine whether impurities could constitute a significant component of the residues in food and feed commodities. Impurities that arise in the manufacture of pesticides can become a residue problem if they are not identified before tolerances are established. Dioxins and nitrosamines are the best-known examples of significant impurities of toxicological concern. If impurities are at levels that may lead to toxicologically significant residues in crops or the environment, then adjustments to the manufacturing process or additional purification steps will be necessary to reduce the impurities to a safe level.[21]

A level that is not "toxicologically significant" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) may nevertheless be considered the addition of a nonpermitted material in organic production if not put on the National List. Information about impurities in pesticide products is not easily available, but arsenic levels from 3 to 100 ppm (3, 7.2, <10, <10, 10, <25, 100) have been found in copper sulfate products available as fertilizers, according to the Washington State Department of Agriculture fertilizer database.[22]

Six fertilizers containing rock phosphate and approved for use in organic production by the Washington State Department of Agriculture contain arsenic at levels from <1 to 75 ppm, cadmium from 2 to 49 ppm, and lead from 5 to 47 ppm.[23] However, a 2004 report by the California Department of Food and Agriculture found that in most cases, applications of phosphate and micronutrient fertilizers resulted in little increase in soil concentrations of arsenic, cadmium, and lead.[24]

B. Irrigation

The three main problems that can arise from the quality of irrigation water are salinity, sodicity or alkalinity, and toxicity.[25] Pathogens may also be a problem in some cases.[26] Sundquist (2007) summarizes the extent of the problem for the U.S. and California.[27]

[19] Holly Dolliver, Satish Gupta, and Sally Noll, 2008. Antibiotic Degradation during Manure Composting. J. Environ. Qual. 37:1245–1253.

[20] EPA, 1996. Toxicologically Significant Levels of Pesticide Active Ingredients. PR Notice 96-8. http://www.epa.gov/PR_Notices/pr96-8.pdf

[21] EPA, 2010. Pesticide Registration Manual: Chapter 11 –Tolerance Petitions. http://www.epa.gov/pesticides/bluebook/chapter11.html

[22] http://agr.wa.gov/PestFert/Fertilizers/FertDB/Product1.aspx

[23] http://agr.wa.gov/PestFert/Fertilizers/FertDB/Product1.aspx

[24] Andrew C. Chang, Albert L. Page, and Natalie J. Krage, 2004. Role of Fertilizer and Micronutrient Applications on Arsenic, Cadmium, and Lead Accumulation in California Cropland Soils, final report submitted to California Department of Food and Agriculture. www.cdfa.ca.gov/is/docs/cdfafinalreport.pdf

[25] I.P. Abrol, J.S.P. Yadav, and F.I. Massoud, 1988. Salt-Affected Soils and their Management. Ch. 6, Water Quality and Crop Production. FAO Soils Bulletin 39 Food and Agriculture Organization of the United Nations, Rome.

In the U.S.,

- 20% of irrigated land suffers from salinization.
- About 21% of irrigated cropland is fed by drawing down water tables.
- About 25% irrigated land suffers from some degree of salinization or waterlogging.
- Salt accumulation is lowering crop yields on 25-30% of irrigated land.
- 25% of irrigated soils were salty or alkaline to the point where productivity was lowered.
- Dry cropland areas in the western US where production has ceased or is significantly reduced due to increased salinity is growing at 10%/ year.

In California,

- About 25% of irrigated land has undergone moderate- to heavy salinization.
- The amount of water-storage capacity lost through aquifer compaction in the Central Valley is over 40% of the combined storage capacity of all human-made reservoirs in California.
- Some 1620 km^2 of irrigated farmlands in San Joaquin Valley are affected by high, brackish water tables, resulting in a 10% reduction in productivity since 1970.
- San Joaquin Valley crop yields have declined 10% ($31.2 million) since 1970 because of high saline water tables. Losses are expected to increase to $321 million/ year if action is not taken.
- Not far below the surface of San Joaquin Valley and Imperial Valley (like the Tigris-Euphrates Valley) is a tight layer of material that blocks water passage. Hence saltwater builds up. When it meets the roots of plants, salt is drawn up to the surface, destroying the irrigation system.
- Imperial Valley (Southern California) experienced about 90% of the agricultural damage from salinity in the US portion of the Colorado River Basin.
- 85% of the water reaching rivers in the Grand Valley is irrigation water, carrying salt from marine shales that lie under local farms.

All irrigation water contains salts that may harm plants, and most are left in the soil after the water evaporates from the soil or leaves through transpiration. Unless salts are leached from the root zone, they will eventually accumulate in quantities that will affect growth of most crops. Management practices for efficient use of high salinity water include more frequent irrigation, selection of salt tolerant crops and varieties, use of extra water for leaching, conjunctive use of fresh and saline waters, and cultural practices.[28]

Sodicity or alkalinity "develops when irrigation water contains relatively more sodium ions than divalent calcium and magnesium ions while the total concentration of salts is generally not very high. Accumulation of sodium ions on to the exchange complex results in a breakdown of soil aggregates responsible for good soil structure needed for free movement of water and air through the soils." Management practices for efficient use of water presenting a sodicity hazard include application of amendments, mixing with an alternative source of water, irrigating more frequently, growing crops with lower water requirements,

[26] Irrigation Water as a Source of Contamination, www.ugacfs.org/producesafety/Pages/Basics/Water.html
[27] Bruce Sundquist, 2007. Irrigated Lands Degradation: A Global Perspective. Ch. 5, Degradation of Irrigated Land. http://home.windstream.net/bsundquist1/ir5.html
[28] I.P. Abrol, J.S.P. Yadav, and F.I. Massoud, 1988. Salt-Affected Soils and their Management. Ch. 6, Water Quality and Crop Production. FAO Soils Bulletin 39 Food and Agriculture Organization of the United Nations, Rome.

growing tolerant crops, and adding organic matter. Water treatments, such as the addition of sulfurous acid, have also been used to treat alkalinity. [29] Sulfurous acid for this purpose is on the National List.[30]

Toxic substances such as boron or heavy metals may be introduced through irrigation water. Boron, for example is an essential element for plant growth and nutrition, but is needed only in trace quantities. High concentrations can have a toxic effect on the growth of many plants. Similarly, other ions, e.g. chloride, sodium, etc., could prove toxic to specific crops if present in excessive quantities. Other elements that may be present --such as lithium, selenium, molybdenum, fluoride and chromium—may exert toxic deleterious effects on plants or animals at very low concentrations. [31]

Starting in 1985, the National Irrigation Water Quality Program (NIWQP) conducted a series of field investigations at 26 areas in the Western United States to examine the impact of irrigation drainage on fish, wildlife, humans, and beneficial uses of water. It examined samples of water, bottom sediment, and biota for analysis of trace elements and pesticides and identified contaminants most commonly associated with irrigation drainage by comparing concentrations in water with established criteria. "Selenium was the trace element in surface water that most commonly exceeded chronic criteria for the protection of freshwater aquatic life; more than 40 percent of the selenium concentrations in surface-water samples exceeded the U.S. Environmental Protection Agency (USEPA) aquatic-life chronic criterion (5 micrograms per liter)." Other significant contaminants were boron, molybdenum, arsenic, and uranium. The most common pesticides exceeding criteria were DDT and its degradation products DDD and DDE, and chlordane in bottom sediments.[32]

The Food and Agriculture Organization concludes:

> Field practices that can eliminate or reduce the hazard due to presence of toxic elements include irrigating the crops more frequently. Frequent irrigations reduce the effective concentration of toxic constituents and therefore their adverse effect. Occasional application of excess water to leach the salts will further reduce the amounts of toxic elements in the root zone. Accumulation of sodium in plant parts can usually be reduced by maintaining a favorable concentration of calcium ions in the soil solution. Adequate quantities of calcium in the irrigation water and soil solution prevent excessive uptake of sodium by plants. Application of amendments, such as soluble calcium salts or sulphuric acid, can therefore greatly reduce the toxicity hazard due to excess sodium. Blending of water supplies, planting less sensitive crops, improving drainage conditions through profile modification, use of fertilizers in optimum doses to obtain otherwise vigorously growing plants etc. are some of the other practices that will help overcome toxicity problems. [33]

[29] I.P. Abrol, J.S.P. Yadav, and F.I. Massoud, 1988. Salt-Affected Soils and their Management. Ch. 6, Water Quality and Crop Production. FAO Soils Bulletin 39 Food and Agriculture Organization of the United Nations, Rome.
[30] NOSB final recommendation for sulfurous acid,
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5078046&acct=nosb
Harmon Systems International petition for sulfurous acid to be added to §205.601.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057561
[31] I.P. Abrol, J.S.P. Yadav, and F.I. Massoud, 1988. Salt-Affected Soils and their Management. Ch. 6, Water Quality and Crop Production. FAO Soils Bulletin 39 Food and Agriculture Organization of the United Nations, Rome.

[32] Ralph L. Seiler, Joseph P. Skorupa, David L. Naftz, *and* B. Thomas Nolan, 2003. Irrigation-Induced Contamination of Water, Sediment, and Biota in the Western United States—Synthesis of Data from the National Irrigation Water Quality Program. U.S. Geological Survey Professional Paper 1655.
[33] I.P. Abrol, J.S.P. Yadav, and F.I. Massoud, 1988. Salt-Affected Soils and their Management. Ch. 6, Water Quality and Crop Production. FAO Soils Bulletin 39 Food and Agriculture Organization of the United Nations, Rome.

Water used both in production and processing of leafy greens may be a source of pathogens. High demand and pollution of water resources mean that high quality water for these purposes has become increasingly scarce, leading to increased reuse of water, which may increase the hazard of biological contamination with pathogens. [34]

C. Genetically Engineered Plant Material

Studies have shown that some DNA from genetically engineered plants may persist in the soil.[35] Genes may move via horizontal gene transfer to soil bacteria, with unknown impacts on soil communities.[36] Composting appears to greatly reduce the amount of transgenic DNA.[37]

D. Contamination in the Field

As mentioned above, heavy metal contaminants cannot be destroyed by composting, but may be converted into organic compounds or chelates that are less bioavailable than inorganic metals. On the other hand, heavy metals may also become concentrated because of the removal of carbon in the composting process. [38] Although many pesticides and other contaminants may be destroyed by composting before reaching the field, "The effects of composting on pesticides are not always favorable. The secondary compounds may be as, or more, toxic than the original pesticide."[39]

Goulson (2013) notes that although data on persistence of neonicotinoids taken up by plants are scarce, some studies indicate long term persistence in plant tissue, which could lead to contamination of organic soils if those plants (e.g., wheat straw) were used as mulch or compost additions. Limited studies show significant accumulation of imidocloprid with repeated applications.[40]

IV. Testing Resources for Avoiding Contaminated Inputs

The U.S. Composting Council (USCC) has a seal of testing assurance (STA) program that analyzes compost for ten properties: pH, soluble salts, nutrient content (total N, P2O5, K2O, Ca, Mg), moisture content, organic matter content, bioassay (maturity), stability (respirometry), particle size (report only), pathogen

[34] Irrigation Water as a Source of Contamination, www.ugacfs.org/producesafety/Pages/Basics/Water.html This website provides a list and highlights of articles examining the prevalence and fate of pathogens in environmental water sources; a table listing the results from several surveys examining the prevalence of pathogens in environmental water sources; and a list of review articles *dedicated to the discussion of pathogens in environmental water sources.*

[35] Kari E. Dunfield and James J. Germida, 2004. Impact of Genetically Modified Crops on Soil- and Plant-Associated Microbial Communities. J. Environ. Qual. 33:806–815. Franco Widmer, 2007. Assessing Effects of Transgenic Crops on Soil Microbial Communities. Adv Biochem Engin/Biotechnol (2007) 107: 207–234. Alessandra Pontiroli, Pascal Simonet , Asa Frostegard , Timothy M. Vogel, and Jean-Michel Monier, 2007. Review article: Fate of transgenic plant DNA in the environment. Environ. Biosafety Res. 6 (2007) 15–35.

[36] Kari E. Dunfield and James J. Germida, 2004. Impact of Genetically Modified Crops on Soil- and Plant-Associated Microbial Communities. J. Environ. Qual. 33:806–815. Franco Widmer, 2007. Assessing Effects of Transgenic Crops on Soil Microbial Communities. Adv Biochem Engin/Biotechnol (2007) 107: 207–234. Alessandra Pontiroli, Pascal Simonet , Asa Frostegard , Timothy M. Vogel, and Jean-Michel Monier, 2007. Review article: Fate of transgenic plant DNA in the environment. Environ. Biosafety Res. 6 (2007) 15–35.

[37] Lasse Dam Rasmussen, Jacob Møller and Jakob Magid, 2004. Composting rapidly degrades DNA from genetically modified plants. Newsletter from Danish Research Centre for Organic Farming, June 2004, No. 2. http://www.darcof.dk/enews/june04/gmo.html

[38] Allen V. Barker and Gretchen M. Bryson, 2002. Bioremediation of Heavy Metals and Organic Toxicants by Composting. *The Scientific World JOURNAL* (2002) 2, 407–420.

[39] Allen V. Barker and Gretchen M. Bryson, 2002. Bioremediation of Heavy Metals and Organic Toxicants by Composting. *The Scientific World JOURNAL* (2002) 2, 407–420.

[40] Goulson, D. (2013), REVIEW: An overview of the environmental risks posed by neonicotinoid insecticides. Journal of Applied Ecology, 50: 977–987.

(Fecal Coliform or Salmonella), and trace metals (Part 503 regulated metals.) The protocols for the various tests that are used are contained in 'Test Methods for the Examination of Composting and Compost' ('TMECC'), jointly published by the USDA and USCC.[41] TMECC does not include standards against which the test results can be measured, nor does it include methods for residues of pesticides, antibiotic, or other anthropogenic chemicals. Bioassays provide a low cost method to test for herbicide residues.[42] The National Organic Program Handbook contains guidance for residue testing, including choosing a lab for testing of pesticide residues.[43]

V. Experts

The Crops Subcommittee has identified the following as areas of expertise in which it should identify possible experts for consulting with the subcommittee:

- Testing, known levels of contamination, problem identification.
- Compost professionals who are familiar with contaminants in compost.
- Laboratory people who work with organic who know how to test and what shows up.
- Organic agronomists who can discuss loading rates (application rates over time) of various materials.
- Certifiers and government officials who have had to investigate problems where contamination may or may not have been behind the problem.
- Researchers who have studied uptake by plants from raw manure.

VI. Questions

The Crops Subcommittee seeks input in the following areas:

1. Contamination incidents in the past.
2. Contaminants of concern.
3. Contamination pathways of concern.
4. Experts and other resources that would assist the subcommittee in its goal of ultimately proposing a process for addressing contamination of inputs that may be brought onto the farm.

VII. Committee Vote:

The Crops Subcommittee moves to accept this document and present it to the public and for full Board discussion at the fall 2014 NOSB meeting:
Motion by: Jay Feldman
Seconded by: Zea Sonnabend
Yes: 5 No: 2 Abstain: 0 Absent: 1 Recuse: 0

[41] http://compostingcouncil.org/admin/wp-content/plugins/wp-pdfupload/pdf/34/TMECC%20Purpose,%20Composting%20Process.pdf TMECC overview, http://compostingcouncil.org/seal-of-testing-assurance/ USCC testing, http://compostingcouncil.org/test-methods-parameters/ USCC test methods and parameters.
[42] http://www.calrecycle.ca.gov/organics/threats/Pesticides/Clopyralid/Bioassays.htm WF Brinton, E Evans, and TC Blewett, 2006. Reliability of Bioassay Tests to Indicate Herbicide Residues in Compost of Varying Salinity and Herbicide Levels. Compost Science and Utilization 14(4): 244-251.
[43] http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateR&navID=ProgramHandbookNOPNationalOrganicProgramHome&rightNav1=ProgramHandbookNOPNationalOrganicProgramHome&topNav=&leftNav=NationalOrganicProgram&page=NOPProgramHandbook&resultType=&acct=noppub

Appendix A
Atmospheric Contamination and Siting Concerns

The question of siting organic farms seems to be one that cannot be ignored because of atmospheric contamination.

Contaminants may enter organic farms through the air. A study in India found increased concentrations of heavy metals in the leafy portions of plants grown in open air, compared to those grown organically in a field covered with a greenhouse.[44]

[44] J. Pandey, Usha Pandey, 2009. Accumulation of heavy metals in dietary vegetables and cultivated soil horizon in organic farming system in relation to atmospheric deposition in a seasonally dry tropical region of India. Environmental Monitoring and Assessment, Volume 148, Issue 1-4, pp 61-74.

Sunset 2015 Review
Meeting 2 - October, 2014
Crops Subcommittee
Sulfurous Acid

August 20, 2014

As part of the National List Sunset Review process, the NOSB Crops Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

Sulfurous Acid *Synthetic*

Use - As plant or soil amendment.

Listing: Sulfurous acid (CAS # 7782-99-2) - for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

Technical Reports: 2010 TAP; 2014 TR

Original Petition: Sulfurous Acid (2008)

Past NOSB Actions: Recommended for addition to the National List on 5/2009

Regulatory Background: Proposed rule (including justification) published 1/12/2010 (75 FR 1555). Added to National List 7/6/2010 (75 FR 38693).

Sunset Date: 7/7/2015
Reference 7 CFR 205.601(j)(9)

Subcommittee Review

The Crops Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Summary:

Sulfurous acid was added to the National List in 2009, with the annotation, "on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section." The Crops Subcommittee has received a Technical Review that contains new information that needs to be considered in the Sunset review:

1. The TR contains information about environmental impacts of sulfurous acid, particularly on soil organisms;
2. There is information on alternative materials and practices that was not considered by the board in 2009;
3. It appears that sulfurous acid might be used to correct the impacts of unsustainable irrigation practices;
4. This use of sulfurous acid is not permitted in organic agriculture in other countries

The Crops Subcommittee posed the following questions in the Spring 2014 meeting announcement:

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

acid? Are there management practices that can be used by the grower to affect whether the transformation occurs and the sulfate is available to crops? Are there evaluation tools that can be used by farmers and certifiers to determine which of the above soil conditions are present?

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

The Crops Subcommittee received 8 comments in favor of relisting sulfurous acid and 5 comments opposing relisting. Comments in favor of relisting included the following:

1. Sulfurous acid is tool organic growers can use to counteract soil salinity and alkalinity.
2. Sulfurous acid does not act as a sulfate fertilizer because the sulfate is present only at a parts per million level while sulfur is a secondary level nutrient (along with calcium and magnesium) that is needed at much higher quantities to influence plant growth.
3. Sulfurous acid is a water treatment for poor quality irrigation waters; it is not a remedy for unsustainable farming practices.
4. The soil and ecological conditions resulting in the build-up of hydrogen sulfite, sulfate, or other products of sulfurous acid would only happen in anaerobic soils with complete water saturation. This is unlikely to happen in the western portion of the United States because farmers here are very familiar with the conditions under which irrigation is needed.
5. It increases the sustainability of agricultural soils in alkaline environments as its use keeps soil pore space open to the air and water helping to leach away toxic salts.
6. Many small berry growers –especially blueberry growers—depend on this technology.

Comments opposing relisting included the following:

1. Specific uses must be delineated as well as conditions under which it can be used.
2. International standards do not allow sulfurous acid in crop production.
3. There are potential adverse impacts that have not been evaluated by the NOSB.
4. The NOSB needs to ask whether the "need" for sulfurous acid reflects unsustainable farming practices.

Conclusion

In reviewing the 2014 Technical Review and materials submitted by commenters, the Crops Subcommittee finds new evidence relating to OFPA criteria. There are concerns about compatibility with organic and sustainable systems, and also evidence of overall value to organic agriculture especially when saline/alkaline irrigation water quality problems exist. For more information, see the attached evaluation checklist. The subcommittee supports research to gather additional information needed to address the issues in the checklist.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA): **[OFPA criteria at 7 U.S.C. 6158(m),** (7) its compatibility with a system of sustainable agriculture.

Motion to remove Sulfurous Acid from the National List

Motion by: John Foster

Seconded by: Harold Austin

Yes: 4 No: 3 Abstain: 0 Recuse: 0 Absent: 0

Minority Statement on Motion to Remove

While the minority of the CS agrees with the majority that the full NOSB should vote on sunset materials, in voting against this motion it is following what we believe are required procedure of AMS/USDA as established by the September 16, 2013 Federal Register notice (78 FR 56811), which states that motions to remove be justified by criteria established by the Organic Foods Production Act. Because of concern that a change in NOSB procedures should be disclosed to the public before taking effect, the minority does not accept the compatibility criteria from 7 U.S.C. 6158(m)(7) that was provided in this case. Furthermore, AMS/NOP has said that no action by the NOSB maintains a sunset material on the National List.

Evaluation Criteria (checklist for criteria in each category)

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

Substance Fails Criteria Category: 2, 3

NOSB Evaluation Criteria for Substances Added To the National List (Optional Checklist)

Category 1. Adverse impacts on humans or the environment? Sulfurous Acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X			There is a potential for damage to the local ecosystems from improperly maintained sulfurous acid generators. TR lines 330-331.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X			Depends on fossil fuel production. TR lines 251-253.
3. Are there any adverse impacts on biodiversity? (§205.200)				Overuse of sulfurous acid and subsequent acidification will cause the metabolism of microorganisms involved in compost and organic matter breakdown in treated streams and runoffs to be suppressed along the acidity gradient, and can lead to a decrease in humus production (Simon, et al., 2009). TR lines 333-336.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		TR line 229.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		?		The primary purpose of sulfurous acid for crop production is reducing the pH of irrigation water to alleviate the effects of specific saline/sodic soil conditions or the effects caused by saline or sodic irrigation. TR lines 295-297
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X			Sulfurous acid is slightly irritating to the skin, and strongly irritating to the eyes. TR lines 364-365.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Hydrogen sulfite present in the solution is metabolized by sulfite reducing bacteria and plants that recycle sulfurous acid into bioavailable sulfur compounds. Water and other dissolved compounds leach into the soils. Functionally, sulfurous acid serves to condition soils by adjusting pH. TR lines 261-264.

8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]	?			It would be harmful if it discourages adoption of farm methods that prevent alkalinization and salinization of the soil, which have broader impacts than the particular farm where sulfurous acid might be used – such as creating a progressively more alkaline groundwater supply.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		?		Overuse of sulfurous acid and subsequent acidification will cause the metabolism of microorganisms involved in compost and organic matter breakdown in treated streams and runoffs to be suppressed along the acidity gradient, and can lead to a decrease in humus production (Simon, et al., 2009). TR lines 333-336.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		?		Overuse of sulfurous acid and subsequent acidification will cause the metabolism of microorganisms involved in compost and organic matter breakdown in treated streams and runoffs to be suppressed along the acidity gradient, and can lead to a decrease in humus production (Simon, et al., 2009). TR lines 333-336.

Category 2. Is the Substance Essential for Organic Production? Sulfurous Acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			TR lines 250-256.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		Generally, the source of the sulfur is from fossil fuels. TR lines 250-253.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See questions #2 and 3.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Organic matter, pure sulfur, gypsum, compost, citric acid. TR lines 385-388.
8. Are there any alternative substances? [§6518(m)(6)]	X			See #7. Also, aquatic plant extracts, elemental sulfur, lignin sulfonate, humic acids and liquid fish extracts TR lines 395-397.

9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Proper irrigation, control of evapotranspiration, lining irrigation canals, salt-tolerant crops. TR lines 408-426.

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

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Not permitted in other countries. TR lines 184-215. IFOAM specifically states, "Operators shall prevent or remedy soil or water salinization where these pose a problem. Sulfurous acid is used as a remedy for salinization of soil" TR lines 214-215 Synthetic fertilizer. TR lines 146-147; 261-263.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Used to correct impacts of poor irrigation practices. TR lines 127-141.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds	X			
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Sunset 2015 Review
Meeting 2 - October, 2014
Crops Subcommittee
Sodium Carbonate Peroxyhydrate

August 19, 2014

As part of the National List Sunset Review process, the NOSB Crops Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production

Sodium Carbonate Peroxyhydrate *Synthetic*

Use - as an algaecide

Listing: Sodium carbonate peroxyhydrate (CAS # 15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

Technical Report: 2006 (PDF); 2014 (PDF)

Petition(s): : Sodium Carbonate Peroxyhydrate (2005)

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

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

Sunset Date: 12/14/2015
Reference: 7 CFR 205.601(a)

Subcommittee Review

The Crops Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Summary:

Sodium Carbonate Peroxyhydrate[1] was added to the National List in 2007 with the hope that growers would use this as an alternative to more problematic materials such as copper and chlorine. However organic producers had had no previous experience to draw from with this product and in particular its use in rice, which has only been registered since 2010.

A new TR was commissioned in 2014 to address alternatives, and use patterns. The material is used as an algaecide in ponds, ditches and irrigation lines. It can also be used in rice production for scum disease. New information provided in that TR was used to prepare this review.

Summarized points from the TR:

- The material is a precursor to hydrogen peroxide and is used widely in household cleaners and detergents as well as water bodies. (TR lines 89-100).

[1] Sodium Carbonate Peroxyhydrate is the active ingredient in products such as the brands GreenClean, GreenClean Pro, Terracyte Pro, and PAK 27 Algaecide

- While most international standards do not mention sodium carbonate peroxyhydrate by name, they do allow both hydrogen peroxide and sodium carbonate which are the components and the precursors of this substance. (TR lines 164-202).
- There are no new concerns since the earlier review about human health or environmental effects. (TR lines 391-434)
- Of the alternatives presented, copper sulfate is clearly the most problematic and also the most widely used (on 97,757 acres vs. 1,177 acres in 2010, representing 17.4 and 0.3% of California rice acreage) (TR lines 448 - 457).
- Some proposed alternative controls, such as Chinese herbs, garlic extracts, or panchagavya, have not been tested in the U.S. and may not be available. (TR lines 487 - 497).

The Crops Subcommittee (CS) posed the following question in seeking public comment on this substance in the first posting in Spring 2014:
The subcommittee is seeking input on the comparison of this material to copper sulfate for control of algal scum in rice production and whether it can replace copper sulfate for that use.

Only 5 comments were received. Another 4 were received for the cancelled Fall 2013 meeting. While some of the comments were against renewing it at sunset and one was in favor, the only one that addressed the question posed was the one in favor which came from the original petitioner. The ones against did not mention any actual first-hand experience with the substance or the alternatives.

Points raised in favor of renewing substance:

- It has provided better control of algae and its breakdown components of water and oxygen are a needed relief from elemental copper accumulation associated with copper based chemistries.
- In 2014 copper labels have been restricted to a label that is rendered useless when treating algae.
- Sodium carbonate peroxyhydrate has been approved for use in drinking water by the NSF and has also been Kosher certified.
- When utilized in irrigation ponds Sodium carbonate peroxyhydrate has less corrosion issues with irrigation equipment than copper sulfate.

Points raised against renewing substance:

- It was found by the NOSB in its 2007 recommendation not to meet the OFPA criteria of essentiality, compatibility with organic production, and no impacts on human health and the environment.
- SCP is not permitted in organic production internationally (lines 164-202).
- The TR mentions several materials and a number of alternative practices to reduce algae in ponds and rice paddies: Alternatives are available for control of algae: Rice straw, Allelopathic plants, Herbivorous fish
- SCP does not fit any OFPA categories.

Additional point raised:

- The annotation for this material is confusing and difficult to interpret for products that are manufactured outside of the U.S. or are labeled for other uses beside a pesticide.
- The annotation indicates it is restricted to only those food crops on the label. However, if used as an irrigation cleaner, it wouldn't necessarily have food crops on the label to indicate to the end user whether they are in compliance with this annotation.

It is likely that the growers who use or have tried this material did not write in because they did not recognize the generic name as being the active ingredient in the product they are using. Therefore the CS hopes that product users will submit comments this time, particularly about the efficacy and relevance of the alternatives mentioned above and in the TR such as rice straw, allellopathic plants, and herbivorous fish.

The CS did some further investigation into points raised in public comment. In particular the 2007 report of

the California Rice Research Board that studied the efficacy of this material[2] and found that it did not work well enough to recommend it for rice paddies. Further investigations into controlling algae by the same group in 2010[3] indicated that management of phosphorus fertilization can influence the severity of algal growth. Reducing phosphate concentrations in rice field water was not mentioned in the TR but may be a promising alternative practice.

Motion to Remove:
This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA): **[OFPA criteria at 7 U.S.C. 6158(m),** (7) its compatibility with a system of sustainable agriculture.

The subcommittee found no concerns regarding the continued listing of Sodium Carbonate Peroxyhydrate. The justification for this motion is that the whole NOSB needs to consider and vote on each material, rather than just a subcommittee.

Motion to remove Sodium Carbonate Peroxyhydrate from the National List
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 4 No: 3 Abstain: 0 Recuse: 0 Absent: 0

Minority Statement on Motion to Remove

While the minority of the CS agrees with the majority that the full NOSB should vote on sunset materials, in voting against this motion it is following what we believe are required procedures of AMS/USDA as established by the September 16, 2013 Federal Register notice (78 FR 56811), which states that motions to remove be justified by criteria established by the Organic Foods Production Act. Because of concern that a change in NOSB procedures should be disclosed to the public before taking effect, the minority does not accept the compatibility criteria from 7 U.S.C. 6158(m) (7) that was provided in this case. Furthermore, AMS/NOP has said that no action by the NOSB maintains a sunset material on the National List.

[2] Spencer, David 2007. Annual Report Comprehensive Research on Rice. Project Title: Assessing alternative methods for managing algae in California Rice fields. http://www.carrb.com/07rpt/2007%20Spencer%20RP-14.pdf
[3] Spencer, David 2010. Annual Report Comprehensive Research on Rice. Project Title: Assessing alternative methods for managing algae 2010. http://www.carrb.com/10rpt/Algae.htm

Sunset 2015 Review
Meeting 2 - October, 2014
Crops Subcommittee
Aqueous Potassium Silicate

August 19, 2014

As part of the National List Sunset Review process, the NOSB Crops Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

Aqueous Potassium Silicate *Synthetic*
205.601(e)), 205.601(i)

Use: As insecticides (including acaricides or mite control). As plant disease control.

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

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

Petition(s): Aqueous potassium silicate; Aqueous potassium silicate supplemental

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

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

Sunset Date: 12/14/2015
Reference: 7 CFR 205.601(e)(2)

Subcommittee Review

The Crops Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Summary:
In 2007, the Crops Subcommittee recommended against listing Aqueous Potassium Silicate[1] (APS) because "multiple substitutes are available" and it is a "synthetic soil applied fertilizer not compatible with organic farming regulations." The rationale given for NOSB approval was, "Public comment at Nov. 2007 NOSB meeting well supported listing the substance as plant disease control by providing historical 2003 NOSB consideration of the material as well as more information from petitioner and other interested stakeholders."

New information has been provided in a new Technical Review. That information supports the conclusions below. (Citations are line numbers in January 6, 2014 TR.)

- Dermal exposure can lead to low to medium systemic toxicity and skin irritation (577-579);

[1] Aqueous Potassium Silicate is the active ingredient in products such as the brand Sil-Matrix Fungicide/Miticide.

- Silicon reduces the availability of elements such as manganese, iron, and aluminum to roots (471-473);
- Treatment with potassium silicate may not be appropriate when crops are used for feeding or as forage for livestock because it makes some forages less digestible (477-481);
- The addition of potassium silicate as a foliar nutrient may result in the production of less tender fruits and vegetables or forage for grazing animals (479-481);
- Silica supplementation can result in elongation and thickening of stems, delayed antithesis and flower deformation in some species (487-490);
- In addition to morphological changes, changes in micronutrient in plants may occur as a result of silica supplementation (490-491);
- New alternative materials suggested include other forms of silica that are available as approved supplements for the soil that can provide the same protection over a longer term against plant disease and compost made with silica-rich plants (592-594);
- The TR suggests the following alternative practices: soilscaping, choice of variety and planting time, balancing silica accumulators and nonaccumulators, moisture management, choice of mulch and ground cover, and scouting (661-706); and
- Internationally (Japan, Canada, EEC, CODEX, or IFOAM), natural sources of silica, not APS, are allowed (258-296).

The Crops Subcommittee invited comment on these conclusions, as well as well as on two major issues of concern at the Spring 2014 meeting:

1. Potassium silicate makes plants more resistant to disease and herbivory, at least in part by concentrating silica. Humans and livestock are herbivores who might be consuming the treated plants. Does the foliar application of potassium silicate might have impacts on the nutritive value of treated foods that would exceed the impacts of silica obtained by the plant from natural soils? The TR addressed this to some extent (See #3, 4, and 6 above.) How should the NOSB weigh this impact on the nutritive value of treated plants?
2. The central issue in the essentiality question is whether organic management systems that conserve and build available silicon in the soil are alternatives to potassium silicate. Thus, the subcommittee received some information on this issue (see #7 and 8 above) and is interested in comments concerning nonsynthetic materials and practices (involving soil management as well as foliar treatments) that would build comparable resistance to insects and fungi, while precluding the need for synthetic potassium silicate.

The NOSB received two comments supporting renewed listing and eight comments opposing renewal. Some specific comments that were received are:

- When APS enters the soil from plant treatment it is indistinguishable from silicates already present in the ground.
- APS is used as a foliar application not for roots.
- “Management systems can be used to build the Si in the soil to improve the plant’s resistance to disease and reducing the likelihood of needing a pesticide treatment. However, when an infestation occurs and a treatment is required, APS should be an available option for organic farmers.”
- Information is needed on accumulation of silica in plants.
- International standards do not allow aqueous potassium silicate in crop production.
- Organic methods of soil conservation make its use unnecessary.

Conclusion

In reviewing the 2014 Technical Review and materials submitted by commenters, the Crops Subcommittee finds new evidence relating to OFPA criteria. There are concerns about impacts on human health and the environment, essentiality given alternative materials and practices, and the fact that APS is not allowed in organic production in other countries. There is also information that APS fills a need when a problem occurs. The subcommittee supports research to gather additional information needed to address the issues identified in the attached checklist.

Motion to Remove:
This proposal to remove will be considered by the NOSB at its public meeting.

Based on the Subcommittee's review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA): **[OFPA criteria at 7 U.S.C. 6158(m),** (7) its compatibility with a system of sustainable agriculture.

Motion to remove Aqueous Potassium Silicate from the National List

Motion by: Harold Austin

Seconded by: Carmela Beck

Yes: 4 No: 3 Abstain: 0 Recuse: 0 Absent: 0

Minority Statement on Motion to Remove

While the minority of the CS agrees with the majority that the full NOSB should vote on sunset materials, in voting against this motion it is following what we believe are required procedure of AMS/USDA as established by the September 16, 2013 Federal Register notice (78 FR 56811), which states that motions to remove be justified by criteria established by the Organic Foods Production Act. Because of concern that a change in NOSB procedures should be disclosed to the public before taking effect, the minority does not accept the compatibility criteria from 7 U.S.C. 6158(m) (7) that was provided in this case. Furthermore, AMS/NOP has said that no action by the NOSB maintains a sunset material on the National List.

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

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

Substance Fails Criteria Category: 1, 2, 3

NOSB Evaluation Criteria for Substances Added To the National List (Optional Checklist)

Category 1. Adverse impacts on humans or the environment? Substance: Aqueous Potassium Silicate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X			Since potassium silicate is sprayed onto plants, there is a probability of contamination.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X			CO2 produced by manufacture. High energy cost, use of fossil fuels. Strong alkaline solution produced in manufacture. TAP, pp. 2, 4, 9-12.
3. Are there any adverse impacts on biodiversity? (§205.200)	X			Potassium silicate has not been tested for ecotoxicity. It is not persistent in aquatic systems, but is highly alkaline in solution form and can be harmful to aquatic life if not diluted and disposed of properly. TAP, p. 4.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]	X			It is/was a List 3 "inert." TAP, p. 3.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	X			The substance may react in storage with ammonium salts to form hydrogen gas, and care should be taken to avoid contact with raw manure in closed storage. Potassium silicate solutions have a high pH, and applications may have adverse effects if used on alkali sensitive crops. TAP, p. 3. During storage of the compound, care must be taken to avoid wetting the material. Spills are slippery. Reacts with acids, ammonium salts, reactive metals and some organics. TAP, p. 9 Potassium silicate gels and generates heat when mixed with acid and may react with ammonium salts resulting in the evolution of ammonia gas. Flammable hydrogen gas may be produced on contact with aluminum, tin, lead, and zinc. TR lines 451-453.[2]
6. Is there a toxic or other adverse action of the		X		No carcinogenicity, mutagenicity, or

[2] Line numbers for TR refer to January 6, 2014 final.

material or its breakdown products? [§6518(m)(2)]				developmental toxicity data are available for potassium silicate. TAP, p. 5. Potassium silicate has no chronic hazards, does not bio-concentrate in the food chain, nor make volatile or toxic organic compounds when used as recommended. TAP, p. 11.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		"little to no potential to contaminate or persist in the environment." TAP, p. 9. Use will not result in hazardous of environmentally persistent byproducts. TAP, p. 11. When dissolved in water, the active ingredient potassium silicate dissociates into potassium cations, hydroxide anions, and mono- and polysilicic acids. When used as a pesticide, potassium silicate residues are low relative to naturally present concentrations and other uses in the environment. TR lines 522-523; 398-399.
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]	X			Acute overexposure may cause skin and respiratory tract irritation. The substance has not been tested for primary eye irritation, but is regarded as an eye irritant on the basis of its high alkalinity and its similarity to sodium silicate (Blumberg 2001). Respiratory problems in the agricultural sector due to inhaled dust are a proven concern (Schenker 2000). TAP, p. 4 Potassium silicate has not been tested for ecotoxicity. It is not persistent in aquatic systems, but is highly alkaline in solution form and can be harmful to aquatic life if not diluted and disposed of properly. TAP, p. 4. Not buffered, and a buffered natural system is not likely to be affected. TR 387-391. Agricultural use of potassium silicate is subject to the Worker Protection Standards (WPS), requiring Personal Protective Equipment (PPE) a long-sleeved shirt, long pants, socks, shoes and gloves, plus a 4 hour Restricted Entry Interval (REI). TR lines 568-569. "Results of the acute dermal toxicity study indicated moderate to low toxicity at the maximum dose tested, although dermal irritation was observed." TR lines 577-579.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]	?			Potassium silicate effects on metabolic interactions are not well characterized if at all. TAP, p. 9. Protective effects would apply to weeds as well as crop plants. If used on pastures, could affect the pattern of grazing, thus affecting species composition. TR lines 494-497.

10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]	X			Successive silicate fertilizer applications have been shown to increase soil pH to levels that adversely affect plant growth (Miayke and Takahashi 1983), but soils with high organic matter content tend to buffer this effect, and additions of organic material were effective in correcting soil pH. TAP, p. 5. Most impacts on soil are positive. TAP, pp. 2, 5, others. . Silicon reduces the availability of elements such as manganese (Mn), iron (Fe), and aluminum (Al) to roots of plants such as rice and sugarcane. TR lines 471-473. Treatment with potassium silicate may not be appropriate when crops are used for feeding or as forage for livestock since its addition hardens some plants, making them both more difficult to chew and digest. Furthermore, monosilicic acid naturally strengthens the phyto-skeleton, thus the addition of potassium silicate as a foliar nutrient may result in the production of less tender fruits and vegetables or forage for grazing animals. TR lines 477-481. Silica supplementation can result in elongation and thickening of stems, delayed antithesis and flower deformation in some species depending on the level of accumulation of silica by the plant species, the type of silica supplement used and the method by which it was applied. In addition to morphological changes, changes in micronutrient in plants may occur as a result of silica supplementation. TR lines 487-491 Makes certain forage grasses less digestible. TR lines 494-497.

Category 2. Is the Substance Essential for Organic Production? Substance: Aqueous Potassium Silicate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Potassium silicates are manufactured using a calcination process that combines silica sand (SiO2) and potassium carbonate (K2CO3) at 1100-2300°F for up to 15 minutes (NOP Petition; Rawlyk and McDonald 2001). The two substances fuse into glass, which can be dissolved with high-pressure steam to form a clear, slightly viscous fluid, or cooled and

				ground into a powder. Carbon dioxide is evolved from this reaction. The solution can be dried to form hydrous powder crystals of potassium silicate. TAP, p. 2
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Potassium silicates are manufactured using a calcination process that combines silica sand (SiO2) and potassium carbonate (K2CO3) at 1100-2300°F for up to 15 minutes (NOP Petition; Rawlyk and McDonald 2001). The two substances fuse into glass, which can be dissolved with high-pressure steam to form a clear, slightly viscous fluid, or cooled and ground into a powder. Carbon dioxide is evolved from this reaction. The solution can be dried to form hydrous powder crystals of potassium silicate. TAP, p. 2
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		Petitioned material is synthetic, but some natural aqueous potassium silicate is present in volcanic soils. TR, line 72.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Fertilizer: glauconite, TAP p. 6. Azomite, p. 8. Disease: A number of foliar treatments to control fungal disease are currently used in organic agriculture, with research ongoing; some of these are agricultural products. In one study, an aqueous solution of burnt rice husks (400 q/ha) was shown to be as effective and economically viable as a 1% commercial sodium silicate solution for treatment of rice blast (*Pyricularia oryzae*) (Hsieh and Hsieh 1989). Sulfur is by far the most widespread treatment for powdery mildew and botrytis bunch rot on grapes. Others…TAP p. 6. More studies are required to definitively state that silica is useful to prevent fungal infections in other crops. The necessity of potassium silicate for organic production has not been demonstrated. P. 10. There is no known natural substance producing the same short term effect on plant health as aqueous potassium silicate in a foliar spray. However, other forms of silica and application methods for these substances are available as approved supplements for the soil that can provide the same protection over a longer term against plant disease. TR lines 591-594. Compost made with silica-rich plants. TR lines 596-605. Biopesticides. TR lines 609-633.

8. Are there any alternative substances? [§6518(m)(6)]	X			See #7.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Organic practices including rotation, green manures, compost. TAP p. 8, 10. In addition, soilscaping, choice of variety and planting time, balancing silica accumulators and nonaccumulators, moisture management, choice of mulch and ground cover, and scouting. TR lines 661-706.

Category 3. Is the substance compatible with organic production practices? Substance: Aqueous Potassium Silicate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Unnecessary synthetic input. Synthetic fertilizer. Internationally (Japan, Canada, EEC, CODEX, or IFOAM), natural sources of silica, not APS, are allowed. TR lines 258-296.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Unnecessary synthetic input. Synthetic fertilizer. High energy requirement for manufacture.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			Minerals.
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Sunset 2016 Review Summary
Meeting 1: October 2014
Request for Public Comment
Crops Substances

September 2014

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production which must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2016. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until spring 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the fall 2014 public meeting. These comments should be provided through www.regulations.gov by October 7, 2014 as explained in the meeting notice published in the Federal Register on September 8, 2014.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

***For Comments That Support Substances Under Review*:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

(1) not harmful to human health or the environment;

(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:
Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

Written public comments will be accepted through October 7, 2014 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2016 Review Summary
Meeting 1 - Request for Public Comment
Crops Substances
August 27, 2014

SUNSET 2016: CROPS SUBSTANCES

Ferric phosphate *Synthetic*

Use - As a synthetic substance allowed for use in organic crop production

Listing: Ferric phosphate (CAS # 10045 - 86 - 0). As slug or snail bait

Technical Report: Ferric Phosphate 07/2004, Ferric Phosphate 6/2010, Supplemental TR 07/2012

Petition(s): Ferric Phosphate 5/01/03

Petition to remove: 07/07/09

Past NOSB Actions: NOSB review and recommendation for addition to the National List 3/2005

Recommendation to renew: 04/2010

NOSB vote on motion for removal from the National List 10/2012

Regulatory Background:

Proposed for addition to National List 9/16/05 70 FR 54660

Added to National List 09/11/06 71 FR 53299

Renewed 08/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.601(h)

Additional information requested by NOSB

The Crops Subcommittee has no additional questions

Hydrogen chloride *Synthetic*

Use - As a synthetic substance allowed for use in organic crop production

Listing: Seed preparations. Hydrogen chloride (CAS # 7647 – 01 - 0) - for delinting cotton seed for planting.

Technical Report: Hydrogen Chloride 2003 TAP, 5/2014 Limited Scope TR

Petition(s): Hydrogen Chloride 10/30/02

Past NOSB Actions: NOSB review and recommendation for addition to the National List 05/2004

Recommendation to renew 11/2009

Regulatory Background:

Proposed for addition to National List 9/16/05 70 FR 54660

Added to National List 09/11/06 71 FR 53299

Renewed 08/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Reference: 7 CFR 205.601(n)

Additional information requested by NOSB

The Crops Subcommittee is interested in comments regarding:

Hydrogen chloride is used in gaseous form to remove linters (fuzz) on cotton seeds that would interfere with the flow of seeds during planting. Acid delinting is the industry standard, and other acids, sulfuric acid for example, are sometimes used in non-organic applications. Hydrogen chloride needs extreme care when used, but it is not clear that suitable alternatives are sufficiently available for organic cotton growers.

The TR indicated that some research shows that novel mechanical delinting techniques may clean cotton seed while improving cotton lint yield in a research context. The Crops Subcommittee is interested in hearing from the organic community as to the relative efficacy of mechanical delinting techniques and whether these techniques are feasible and available in commercial scale organic cotton production. The Crops Subcommittee is also interested in hearing whether the NOSB can encourage safer methods of delinting seeds.