



National Organic Standards Board Meeting
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National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Terminology – Proposal
February 23, 2016

Introduction and Background

In April 2013 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 is in need of re-examination and updating due to rapid advances in recombinant DNA biotechnology since 1995 that have made for gray areas for the organic standards regarding interpretation and enforcement.

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 the last few years the rise of gene editing with no insertion of foreign DNA, synthetic biology, and the genetically engineered insects that are starting to appear make this effort even more important.

The first NOSB Discussion Document on excluded methods in 2013,¹ discussed each of the terms in the above definition, defined and discussed other terms involved in traditional breeding, such as mutagenesis and conjugation, and brought up new terms that may be considered to be genetic engineering. 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.

The second NOSB Discussion Document posted in September, 2014 and in April 2015² analyzed the comments received and proposed several options for an updated definition, and principles and criteria to use when evaluating the various genetic modification issues. Additional terms were collected and the beginnings of some definitions were started. A structure was proposed similar to the one in use by FiBL in Europe that involves an itemized chart with a yes/no column where the specific techniques could be itemized and evaluated. A recommendation was informally made by the subcommittee, but not voted upon, that these revisions to the definition and structure for evaluating techniques be regulated through NOP guidance rather than additional rulemaking. Lastly it was acknowledged that there will be some unresolved issues that will need continued public discussion because they pose enforcement challenges, are totally hidden from view, or not enough is known about them yet.

Goals of This Proposal/Document

The need for forward motion on this subject is more pressing every month. The fact that over 1000 pages of scientific references were submitted in public comment, with most of it being papers that came out since the NOSB GMO ad hoc Subcommittee was formed in 2012, indicates that the biotech community is rapidly outpacing any regulatory structure. The U.S. Department of Agriculture (USDA) has already ruled that certain plants produced with novel approaches to genetic manipulation will not be regulated as genetically modified organisms in the United States³. It is more imperative than ever that the organic community be very clear about where the line is drawn regarding genetic engineering.

Public Comment from the past two years has indicated strong support for this effort on the whole, although there is not consensus on some details. Every organic stakeholder is clear that genetic engineering is an imminent threat to organic integrity. Every effort must be made to protect that integrity to the extent that the NOSB is able to contribute to that.

The Materials Subcommittee is ready to move forward to create a structure for reviewing new technologies and disseminating the results of this review in a transparent manner. To this end, the proposal portion of this document includes supplements to the definition in the rule based on internationally accepted language, criteria to use in the reviews based on that definition, and a chart of those techniques that are clearly "excluded methods" based on the definition and criteria.

A separate discussion document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Definitions

In the previous Discussion Document we suggested a couple of possible definitions that would update the text in the rule to a more comprehensive one that would be flexible enough to accommodate future technologies and terms. We were inclined to favor the definitions in use by the Cartagena Protocol that are also in use by Codex Alimentarius.

During the course of public comment and subsequently, it has become clear that more than one definition is important to the organic community, but that all the terms we suggest defining here would fall under the Excluded Methods definition in the rule and would not change, but would strengthen that definition. These definitions are to be used in Guidance to supplement and update the definition in the regulations, while leaving the rule itself intact. It is important to adopt some definitions that are widely accepted internationally and thus give some common ground with other countries who are concerned about GMOs in organics.

In October 2015 the International Federation of Organic Agriculture Movements (IFOAM) put out a Discussion Paper on a proposed revision to their Position on Genetic Engineering.⁴⁵ Since they do not use the concept of "Excluded Methods" in other countries, they proposed new definitions for three terms: Genetic Engineering (GE), Genetically Modified Organism (GMO), and Synthetic Biology. After examining their definitions, the Materials/GMO Subcommittee (MS) agrees that these three terms are important to define in the guidance we are proposing. However, we do not wish to take the old approach (that IFOAM is still using) of trying to capture all the methods and terms into one definition, because it will be out of date as soon as the next round of new technologies arrives.

Therefore we are suggesting the following definitions of terms and acronyms, with sources, be adopted by the NOSB as being Excluded Methods:

Genetic engineering (GE) – A set of techniques from molecular biology (such as recombinant DNA and RNA) by which the genetic material of plants, animals, micro-organisms, cells and other biological units are altered and recombined (first sentence modified from IFOAM Position cited above)

Genetically Modified Organism (GMO) – A plant, animal, or microorganism that is transformed by genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources (first sentence from IFOAM Position cited above, second sentence modified from their definition)

Modern Biotechnology – (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. (From the Cartagena Protocol⁶ and also used by Codex Alimentarius)

Non-GMO – The term that is used to describe or label a product that was produced without any of the excluded methods defined here. It is consistent with the NOP process-based standard that does not imply freedom from GMOs but does indicate that processes to prevent GMO contamination have been used (from the public comment by the Organic Trade Association, April 2015⁷)

Synthetic Biology⁸ – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding,

design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity⁹)

This series of definitions provide a better framework than solely the existing definition to further elaborate the various technologies that would be prohibited as well as those which would be allowed. We propose to combine these definitions, the principles and criteria discussed below, and the Terminology chart presented into this Proposal for Guidance on Excluded Methods.

Principles and Criteria

The NOSB has its own set of Principles of Organic Production and Handling in the Policy and Procedures Manual¹⁰. They start with:

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

One of the points following this is in regard to Genetic Engineering:

1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (geo/gmo's) and products produced by or through the use of genetic engineering are prohibited.

The following principals of Organic Agriculture are used by IFOAM¹¹ and summarize well the guidance for developing a position on GMO technology.

- Principle of Health: Organic Agriculture should sustain and enhance the health of soil, plant, animal, human and planet as one and indivisible.
- Principle of Ecology: Organic Agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them.
- Principle of Fairness: Organic Agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities.
- Principle of Care: Organic Agriculture should be managed in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment.

Using the principles above, biotechnology processes will be reviewed to the following criteria to determine if they are excluded methods:

- 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). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.

- 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).¹²
- Novel proteins must be prevented from being introduced into the soil and water ecosystems and into the organic food supply.
- The exchange of genetic resources is encouraged and any patenting of living organisms, their metabolites, gene sequences or breeding processes are refrained from.¹³

Most of the techniques that are considered to be genetic engineering are clearly not compatible with the principal of ecology because they do not work within living ecological systems or sustain them. They are also at odds with the Principal of Fairness because they are not available equally to all stakeholders and are often patented or used to create patented traits. There are significant questions around the Principle of care for the health and well-being of future generations and the environment. These concerns do not change just because a technique cannot be tested for or does not use DNA foreign to the target organism.

The secondary effects from the use of GMOs are starting to emerge clearly in parallel with the new technologies. Issues such as reduction in diversity on farms where GMOs are grown, the demise of beneficial species both above and below the soil, the decline in soil fertility and resilience from increased use of herbicides, the evolution of weeds resistant to those herbicides, the altered nutritional profiles of the GMO crop products, and the displacement of small farmers from their land are all violations of the principals of organic agriculture.¹⁴

In the accompanying discussion document there will be additional discussion of how these concepts might be used in organic plant breeding.

Process and Product

Since the whole underpinning of the U.S. organic regulations is a process-based system, it makes 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 GMOs¹⁵, or handle other issues such as pesticide residues or water quality standards.

Newer technologies, known as Targeted genetic modification (TagMo) or targeted genome editing, are emerging and being adopted quickly.¹⁶ These are very clearly genetic engineering techniques but are not regulated by the current government structure because they do not involve DNA from a "pest" under the USDA APHIS regulatory structure. Many of these techniques involve precise changes in existing DNA without using foreign DNA from a different species. These new technologies make genetic modification much more accessible and less expensive. The resulting plants may not show up as genetically engineered in the commonly used testing methods because they contain no foreign DNA, just native DNA that has been changed at the allele level by humans.

Forward Movement towards Structure

FiBL Research Institute for Organic Agriculture from Switzerland submitted a comment in 2013 that included a chart that describes methods with a yes/no column for compatibility with organic standards for both plants and animals¹⁷. The NOSB posed adopting such a chart on the methods that receive consensus and can be incorporated into guidance. It is important to identify all of these terms so that it is clear that they fall under the definition of excluded methods, but these terms do not need to be added to the definition itself.

The first version of such a chart for the NOSB is presented here. Appendix A provides a brief description of each term with additional citations for those who want to find out more about the terms. There is so much terminology and so many techniques with similar or multiple names that we have added a column for additional names and types used for each general process. Along with lack of regulation of some of these processes, there is lack of standardization of the terms, so that new names and sometime proprietary ones are emerging all the time.

We would especially like to acknowledge the work done by the Center for Food Safety in their public comment for the April 2015 meeting. They have helped organize all the various terminology and provided substantial scientific papers that discuss all the terms.¹⁸ The technologies are grouped by the tasks that the methods accomplish and the types of changes made to the engineered organism. In the context of this proposal we are not able to discuss most of the terms at length so please see the Appendix and the CFS cited comment for the full reference list.

The ones marked "TBD" in the chart below are discussed further in the accompanying Discussion Document.

Terminology Chart			
Method and synonyms	Types	Excluded Methods	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via oligonucleotides CRISPR-Cas system* TALENs** Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System (RTDS) (Cibus)	YES	Most of these new techniques are not regulated by USDA and are hard to test for.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	
Accelerated plant breeding	Reverse Breeding	YES	These may pose

techniques	Genome Elimination FasTrack Fast flowering Dupont Seed Production Technology (SPT)		an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems.	YES	
Embryo transfer in animals	Embryo rescue in animals	YES	FIBL distinguishes embryo rescue in plants from animals.
Cloned animals and offspring	Somatic nuclear transfer	YES	
Plastid Transformation		YES	
Marker Assisted Selection		NO	
Protoplast Fusion		TBD	
Cisgenesis		TBD	
Intragenesis		TBD	
Transposons		TBD	
Transduction		TBD	
Cell Fusion within Plant Family		TBD	
Embryo rescue in plants		TBD	
TILLING	Eco-TILLING	TBD	
Agro-infiltration		TBD	
Doubled Haploid Technology		TBD	
Induced Mutagenesis		TBD	

* CRISPR-Cas = Clustered regularly interspaced short palindromic repeats and associated protein genes.

** TALENs = Transcription activator-like effector nucleases.

Proposal

This proposal has three sections, to be used in NOP Guidance on Excluded Methods:

1. Approve the definitions of Genetic Engineering (GE), Genetically Modified Organism (GMO), Modern Biotechnology, Non-GMO, and Synthetic Biology as written above.
2. Approve the Principles and Criteria above that will be used in the evaluation of new technologies and terminologies.
3. Adopt the Terminology chart proposed above and the listings in it as presented, recognizing that this will be added to as further deliberations occur in the future.

Subcommittee Vote

The NOSB Materials/GMO subcommittee approves the three sections of this proposal as stated above.

Motion by: Zea Sonnabend

Second: Tracy Favre

Yes: 5 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Appendix A –

Brief Description and Additional Citations for Terms used in Excluded Methods Terminology Chart.

Only terms that are marked YES or NO as Excluded Methods are defined here. All those marked TBD are still being worked on in discussion. Those marked "syn." are defined in cited reference from Center for Food Safety Public Comment in April 2015¹⁹. Some other definitions are from the NOSB previous Discussion Document²⁰ and from the FiBL 2015 plant breeding dossier.²¹

Targeted genetic modification (TaqMo) (Kuzma and Kokotovich 2011, Kokotovich and Kuzma 2014) - 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.

- syn. Synthetic gene technologies (Then 2015)
- syn. Genome engineering (Voytas and Gao 2014)
- syn. Gene editing (Puchta and Fauser 2013)
- syn. Gene targeting (GT) (Puchta and Fauser 2013, Endo et al. 2015)
- syn. Sequence-specific nucleases (SSNs) (Voytas and Gao 2014):
- syn. Meganucleases (Gao et al. 2011, as cited in FSANZ 2013)
- syn. Site directed mutagenesis via oligonucleotides, zinc finger nuclease (ZFN) (Dow, APHIS 2012) - 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.
- syn. Clustered regularly interspaced short palindromic repeats and associated protein genes (CRISPR-Cas system) (NYTs 3/20/2015) – a protein called Cas9 enables breaks in DNA at specific spots so that additional pieces of DNA and RNA can be inserted.
- syn. Transcription activator-like effector nucleases (TALENs) (Sprink et al. 2014).
- syn. Oligonucleotide directed mutagenesis (ODM) (Lusser et al. 2011)
- syn. Cibus Rapid Trait Development System (RTDS) (Beetham et al. 2012 patent) - Similar to the oligonucleotide targeted DNA modification it does not leave behind transgenic material, only uses it to create a change in a precise area of a gene.

Gene silencing via RNAi and DNA methylation - Interfering with the regulation of gene expression through inserting methyl groups onto RNA and DNA that then suppress the expression of the gene. Can occur in nature, but is used as a recombinant technique in cancer research and plant breeding.

- syn. RNA-dependent DNA methylation (RdDM) (Lusser et al. 2011)
- syn. Gene silencing via RNAi pathway (Casacuberta et al. 2015, Baier et al. 2014, Lubasik and Zielenkiewicz 2014, Hirschi 2012, Heinemann et al. 2013, Lundgren and Duan 2013, Wagner et al. 2015) – A technique in which a small strand of RNA is inserted into a DNA sequence to regulate the expression of the gene. There is no change to the DNA sequence, but there is technical interference with the genome.

- RNAi-based pesticides (Palli 2014, Zhu 2013) – RNA interference (RNAi) is a technique in which gene silencing RNA strands are inserted into a target genome in order to regulate the expression of target genes. It was used to engineer rootworm resistant corn as well as to genetically engineer insects themselves.

Accelerated Plant Breeding Techniques

- Reverse Breeding (Dirks et al. 2009) – 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.
- Genome elimination (Comai 2014)
- FasTrack (Waltz 2012) – 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.
- Fast flowering (Flachowsky et al. 2011)
- DuPont’s Seed Production Technology (SPT) (Waltz 2012)

Synthetic Biology (see definition in main document)

- Synthetic chromosomes (Shenoy and Sarma 2010, pp. 12-13; Gaeta et al. 2012)

Embryo Transfer in 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.

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

Marker Assisted Selection – Molecular markers are used as diagnostic aids to determine differences in the DNA sequence. They can help in selecting desired traits. The markers do not change the DNA of living plants and are not considered to be genetic engineering.

¹ NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5102656>

² National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.

³ Waltz, E. (2012). Tiptoeing around transgenics. *Nature Biotechnology*, 30, 215-217. doi:10.1038/nbt.2143

⁴ IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture.

https://gallery.mailchimp.com/75bdf144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf

⁵ IFOAM – Organics International, 2002, Position on Genetic Engineering and Genetically Modified Organisms, P01, https://gallery.mailchimp.com/75bdf144a46c1e451eecd10/files/IFOAM_GMO_Position_Paper.pdf

⁶ Convention on Biological Diversity. 2013. The Cartagena Protocol on Biosafety. Available at:

<http://bch.cbd.int/protocol>.

⁷ Organic Trade Association Comments to the NOSB, <http://www.regulations.gov/#!documentDetail;D=AMS-NOP-15-0002-0814>

⁸ Two other definitions were looked at when this one was chosen: **Synthetic Biology** – Designing and constructing biological devices, biological systems, biological machines and biological organisms using a range of methods derived from molecular biology and biotechnology, including in virtually all cases the techniques of genetic engineering or genetic modification (from IFOAM Position cited above). **Synthetic biology** is a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems, as well as the re-design of existing, natural biological systems for useful purposes.” (from SynBerc, the University of California/Department of Energy synthetic biology research consortium)

⁹ Link to the European Commission's draft definition with discussion:

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihc_consultation_21_en.htm

¹⁰ NOSB Policy and Procedures Manual: <https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf>

¹¹ http://www.ifoam.bio/sites/default/files/poa_english_web.pdf

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

¹³ FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

¹⁴ IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture.

https://gallery.mailchimp.com/75bdf144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf

¹⁵ Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. *EMBO reports* 12: 883–888.

¹⁶ Kokotovich A, Kuzma J (2014) Conflicting Futures: Environmental Regulation of Plant Targeted Genetic Modification. *Bulletin of Science, Technology & Society* 34: 108–120.

¹⁷ FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

¹⁸ CFS Comments to the NOSB, 2015, Docket #AMS_NOP_15-0002-0874

¹⁹ CFS Comments to the NOSB, 2015. Reference List. <http://www.regulations.gov/#!documentDetail;D=AMS-NOP-15-0002-0875>

²⁰ National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.

²¹ FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

**National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Terminology – Third Discussion Document
February 23, 2016**

Introduction and Background

In April 2013 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):

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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 is in need of re-examination and updating due to rapid advances in recombinant DNA biotechnology since 1995 that have made for gray areas for the organic standards regarding interpretation and enforcement.

Please see the Excluded Methods Terminology Proposal from this same date for a full elaboration of the background and progress to this point.

This Discussion Document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Discussion

There are several areas for future discussion and work on this subject:

- Additional criteria for evaluating technologies that need to be considered.
- How to detect those technologies that are excluded but may not provide detectable genetically engineered DNA when tested.

- Enforcement of the excluded method provisions of the rule when they are not traceable and undetectable.
- Additional technologies and terms that may not be clearly prohibited as excluded methods.
- Whether the concepts adopted in the proposal should or could lead to Organic Plant Breeding standards and the regulation of the term "Organically Bred Variety (or Animal)"

Once the proposal section in the accompanying document is voted on the structure will be in place to continue looking at these issues. We are interested in input from the organic public on these issues and will continue to have a transparent process to keep excluded methods out of organic production.

A. Additional Criteria

In the 2015 publication on Plant Breeding from FiBLⁱ, the Research Institute for Organic Agriculture from Switzerland, there are several more criteria mentioned than we have adopted in our proposal. These include:

- 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 cyto-plast fusions).
- A variety must be usable for further crop improvement and seed propagation. This means that the breeders' exemption and the farmers' right are legally granted and patenting is refrained from, and that the crossing ability is not restricted by technical means (e.g. by using male sterility without the possibility of restoration).
- The creation of genetic diversity takes place within the plant specific crossing barriers through fusion of egg cell and pollen. Forced hybridization of somatic cells (e.g. through cell fusions) is refrained from.

B. Detection and testing

Many in the organic community have proposed that there be some testing of at-risk seeds and crops for the presence of GMOs and a threshold beyond which the crop could not be sold as organic. Consumers throughout the world clearly want to know if their food has been genetically engineered. These tests are reliable indicators of DNA that has had foreign components introduced at the genome level.

However, in the newer gene splicing and gene editing technologies there is no foreign DNA introduced. The DNA in the genes has been moved around, or sequences introduced from within the same genome that change the expression of certain traits. Many if not most of these methods are not detectable with the existing tests for GMOs. While it is likely that such testing may be developed in the future, it becomes very challenging for the National Organic Program (NOP) and Accredited Certifying Agents (ACA) to determine if any new variety was produced with one of the newer excluded technologies.

Ideas for addressing this have included creating a website for plant varieties that are excluded, or some sort of affidavit system for ACAs to use for varieties known to be introduced from these methods. Any workable ideas for accomplishing a way to tell which varieties are excluded are welcome.

C. Enforcement

Hand in hand with the above detection issue is the question of how to enforce the exclusion of new technologies when they cannot be detected. Enforcement needs to be equal across all ACAs and there has to be adequate training for ACAs in how to recognize newer strains of GMOs and what to do about them. The same process that could be developed for detection could also tie into enforcement, but some creative approaches are needed for these issues since they are not being addressed by the USDA as a whole.

D. Additional technologies and terms

The chart presented in the Proposal document has a number of terms that are marked "TBD" in the Excluded Methods column. These are the ones that need further discussion to determine which of these should be added to the chart and which may not be appropriately deemed and excluded method. Some may be excluded for some uses but not others depending on exactly how the technique is carried out. They are repeated below, with a few notes:

Terminology Chart			
Method and synonyms	Types	Excluded Methods	Notes
Protoplast Fusion		<i>TBD</i>	There are many ways to achieve protoplast fusion and until the criteria about cell wall integrity is discussed, these technologies cannot yet be evaluated.
Cisgenesis		<i>TBD</i>	A very broad term that may need to be divided into some allowed and some excluded techniques.
Intragenesis		<i>TBD</i>	Similar to cisgenesis but gene sequences may be re-arranged.
Transposons		<i>TBD</i>	Used in animal vaccines. May be excluded in some situations but not others.
Transduction		<i>TBD</i>	Most sources think not excluded, but more study needed.
Cell Fusion within Plant Family		<i>TBD</i>	Subject of an NOP memo in 2013, the issue of detection of these varieties needs to be addressed before further policies can be adopted.

Embryo rescue in plants		<i>TBD</i>	Many sources including FiBL think this is not excluded but more study of the methods is needed.
TILLING	Eco-TILLING	<i>TBD</i>	Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.
Agro-infiltration		<i>TBD</i>	<i>In vitro</i> nucleic acids are introduced to plant leaves to be infiltrated into them. More study needed.
Doubled Haploid Technology		<i>TBD</i>	There are several ways to make double haploids and some do not involve genetic engineering but some do.
Induced Mutagenesis		<i>TBD</i>	This is a very broad term and needs to be divided and classified based on what induces the mutations, chemicals, radiation, or other stresses.

E. Organic Plant Breeding

Some groups in Europe are moving ahead with developing a full set of organic plant breeding standards. If this become regulation there, then a label could be given for an "Organically Bred Variety". This is far from being able to be achieved in the U.S.A. with a very different approach to seed regulations as a whole. However, it is a potential next step and may be appropriate to tie into the discussion of some of the remaining terms above. For more information about this see the FiBL dossier cited above.

For instance a variety created with a cell fusion event for brassica male sterility might be allowed as seed in organic farming (as it is now) but prohibited from being used in a variety labeled as "Organically Bred Variety" with an organic breeding standard.

Discussion Questions

1. Are there any additional criteria for evaluating technologies that need to be considered?
2. Do you have any insights on how to detect those technologies that are excluded but may not provide detectable genetically engineered DNA?
3. Please offer any suggestions for enforcement of the excluded method provisions of the rule when they are not traceable or detectable.
4. Opinions are welcome on the terms in the chart above that may or may not be clearly prohibited as excluded methods.

Subcommittee Vote

Motion to adopt the third discussion document on Excluded Methods

Motion by: Zea Sonnabend

Second: Emily Oakley

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

^{i i} FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

**National Organic Standards Board
Materials/GMO Subcommittee
Discussion Document on Next Steps for Improving Seed Purity
February 23, 2016**

Introduction

For several years now the National Organic Standards Board (NOSB) has been collecting public input on the issue of Seed Purity from GMOs. After two discussion documents, a report¹, a collection of Prevention strategies to keep GMOs out, and an expert panel on seed purity, we are still not to the point of making a comprehensive proposal.

The obstacles are immense, and have been thoroughly vetted in our past posted documents. Suffice to say the obstacles are not shrinking with the passage of time, but the need for action is growing. This paper is a springboard to what are the next activities/recommendations/policies that could be undertaken to move forward on this issue. Some of these ideas are brought forward here, while any other new approaches are also welcome.

Background

At the spring 2015 NOSB meeting the expert panel on Seed Purity addressed many of the challenges around adopting any testing protocol or threshold. The NOSB had proposed instituting a seed purity testing requirement for only non-organic seed of at risk crops as part of the overall prevention strategies. As a result of the Expert Panel Discussion, this section was withdrawn from the final proposal on prevention strategies because it was felt more work was needed. That language is provided as an Appendix to this paper.

There are a number of good reasons to require a seed purity declaration for non-organic seed, including:

- Provides incentive for growers to use organic seed.
- Shifts the burden of routine GMO testing from organic seed producers to suppliers of non-organic seed.
- Reduces the inadvertent introduction of GMOs into organic crops through seed.
- Fits in with the organic regulations to prohibit excluded methods by providing ACAs with a tangible method of verification.

We are mindful of this quote from Matthew Dillon, from Clif Bar & Company, in his testimony to the NOSB during the expert panel, "We often say that seed work is slow work. It takes seven, ten, twelve years to breed a new variety and get it into the commercial marketplace. Sometimes longer. Seed work is slow work and we have to be deliberate in our approach to seed, whether it's in breeding and production or in our decisions regarding regulations."²

¹ Report on Seed Purity from GMOs

<https://www.ams.usda.gov/sites/default/files/media/materialstx.pdf>

² NOSB meeting transcript, Spring 2015, La Jolla, CA

<https://www.ams.usda.gov/sites/default/files/media/transcript.pdf>

Themes from Public Comment

Several clear themes have emerged from both the public comment received from the past several years of discussions and the expert panel from the spring 2015 NOSB meeting. These are summarized below and should be used as a framework to be mindful of as we design the next steps.

1. We need more data.

- Everyone agrees that contamination is occurring, but very little is known about how much comes from seed as opposed to pollen drift or co-mingling in harvest and cleaning. Without knowing a background level (or adventitious presence) in seed before planting, it is impossible to determine further sources that contribute to contamination.
- Although baby steps are being taken to enable more data to be collected, it is not enough or soon enough to tackle the problem of contamination. Most of the data now collected is proprietary to seed companies or grain buyers who do their own testing.
- It all starts with seeds and so this is a good place to start in data collecting activities.
- Seed companies could generate and provide some of their data if it was collected in a systematic way and if the organic seed guidance was strengthened.

2. The responsibility for genetic contamination should lie with the polluters.

- The organic movement worldwide believes that organic producers should not be penalized for the trespasses of others and genetic contamination is trespass.
- Organic seed producers are already overcoming great hurdles to produce seed, from limited genetic resources to all the extra prevention strategies they must use. Burdening them with extra costs of testing is penalizing them such that their viability is at stake.
- A realistic balance must be sought between the need to keep genetically engineered content out of organic production and the practicality of keeping an organic seed industry alive and viable.
- The NOSB is limited in scope to what can be achieved through the organic regulations. Making polluters accept responsibility is outside of that scope. Only by being proactive in keeping these issues in the public eye and communicating them to the Secretary, can the NOSB make a difference.
- A recommendation with this statement in it will not be able to be published by the NOP. In order to keep this message in circulation, the concept needs to be expressed as part of other more achievable language.

3. All crop species are not the same

- There may need to be separate requirements for the different at-risk crops, because the pollination, geographic, and economic differences result in large differences in how fast progress can be made away from GMO contamination.
- Soybeans, being largely self-pollinating, are already able to meet a fairly stringent threshold requirement.
- Cotton has only one or two commercial seed companies providing non-GE seed in the USA and one is threatened. There is only one public cotton breeder in the US. While many growers save their own seed, the cotton seed supply worldwide is under serious threat from GMOs but without access to clean varieties, this will not be able to change.

- Canola production for organic has almost entirely left the U.S. because of GMO contamination.
- Corn has very limited availability of inbred parent lines that are not contaminated and the seed companies providing them often prohibit GMO testing in them. Therefore the genetic diversity available to organic seed companies is much lower and this crop is particularly at risk from lack of genetic diversity. Also the special skill set needed to produce organic hybrid corn is now resting with only about 20 growers in the US. Corn pollen can travel several kilometers and so contamination is extremely likely no matter what steps are taken to prevent it.
- One suggestion floated several times has been to exempt breeding lines grown in organic systems from the treated seed prohibition in the rule. Many of the breeding lines are only available with seed treatments. Since these lines are not used to produce a crop, but only to produce the seed that then needs to be increased for sale, there might be a variance for the seed treatments that would give breeders access to a much larger assortment of germplasm.

4. Let the marketplace guide the way

- The best way to gain more credibility in the USDA and conventional agricultural industry is to gain enough market share that they have to pay attention.
- Labelling of GMOs will eventually cause enough awareness in the marketplace for the tide to turn. Continued efforts are needed to make labelling a reality, but this is not the role of the NOSB.
- The marketplace is doing a lot of testing now, but are not required or inspired to share their results in any way to provide anonymous collective information to regulators or researchers. If a structure could be set up to have a central data collection system in which individual results could remain anonymous and no penalty assessed for contamination while the data was collected, the whole organic community would benefit.
- Whatever policy is adopted as to be workable for producers of all sizes and not solely favor the larger scale enterprises.

5. Thresholds and testing are a tool to be used responsibly

- The best use of testing is in specified situations, such as when negligence is suspected or to assess if established safeguards are sufficient.
- Many organic producers are suffering severe economic consequences already if all their hard work to prevent GMOs still results in contamination that lowers the value of their crop or is not accepted by their buyers.
- Without addressing many of the specific issues above, and also the appropriate repercussions when a test is failed or a threshold not met, the organic community is not ready for a one-size-fits-all threshold requirement.
- That being said, aiming to move towards establishing crop specific thresholds and standardized testing protocols is worthwhile and has a role in maintaining organic integrity.

Discussion

The following are some solution-oriented suggestions that have arisen from public comment and from discussions within the organic community. These are broad ideas at this point and we have not attempted to fully flesh out the logistics of how any of these would work. They are not mutually exclusive for the most part. We are suggesting them as a way to get reaction from stakeholders on what the NOSB should work on next in this arena and what should inform that work. We are also open to any brand new ideas that aim to bring the organic industry towards consensus on improving seed purity of seed used in organic systems.

A. Enabling Data Collection

"A first step of action to protect organic seeds and crops from GMO contamination could be to require the evaluation of the non-GMO status of **nonorganic** seeds intended for use in organic production." This sentence is quoted from our previous work on this subject (in the Appendix).

We could start by recommending through guidance (but not an absolute requirement subject to violations and penalties) for ACAs to collect a seed purity declaration from non-organic seed of high risk crops being planted on organic farms (preferably on the seed tag of each bag of seed with a lot number). If there is no seed tag, an inspector could collect a sample that could be sent to the ACA for an inexpensive GMO strip test. There would be no threshold, the test results would not be made public except as compiled anonymous data, nor would the ACA take any action concerning any level stated in the test. At first this program would only be for growers large enough to plant a whole sack or more of at-risk seed.

Waiting for the government to collect data, using non-objective data from the trade, or expecting the polluters to suddenly pay for this is clearly not happening soon. The tests could be paid for by seed companies who value organic customers, by growers themselves, by their contracted buyers, or by ACAs who have some funds allocated for testing. This would share these expenses across the supply chain without undue burden for penalties looming. Those who absolutely could not afford it would not be forced to do the testing in the first two years.

This would be a big start to the data we are looking for to make future recommendations, as long as there was an identified home for the data to go until it is used. ACAs could turn in their collected data once or twice per year to a central location. The need for assembling this data is so great that perhaps the NOP could provide a grant to an NGO or other third party entity to compile the data. Possible homes might include AOSCA (American Organization of Seed Control Officials,) or the U.S. Testing Network, or other entities who might be willing or designated by the NOP. Crops grown from those reported seeds could also be tested in the marketplace and then matched (by ID number) in the data collection system. This would enable buyers who test to turn in some of their data anonymously also so that it could be correlated with seed.

If this much could be achieved for 2 to 3 years successfully then it could possibly branch into testing organically grown seed as well. It might also provide guidance into where contamination comes from, how it spreads and magnifies, and what a realistic and appropriate threshold might be. Other areas of expansion of these testing efforts could include buffer zones and various distances from a contamination source. This knowledge could lead to more fine-tuned

guidance on isolation distances and amount of buffers needed, and also what separation might be needed in timing of plantings of corn.

Only when at least several years of data were collected would there start to be policies set regarding protecting organic integrity from contamination coming from seeds. While there certainly might be flaws in this approach, it seems the most likely to enable some data to be collected in a way that is as timely, fair, and systematic as possible.

B. USDA Task Force

The NOSB could recommend that the USDA establish a Seed Purity Advisory Task Force. The task force members would be appointed by the USDA, primarily through NOP but possibly in conjunction with the AC21 FACA board.

The task force would design a feasibility study based on testing that would be administered and carried out by USDA. The study would be crop specific and would evaluate what a rigorous yet realistic threshold might look like, focusing on non-organic seed. The task force would design a 3 - 5 year action plan, after which time the testing could begin and data from it could be collected.

During this time the NOSB would request the funding mechanism be established so that the USDA pay for all the GMO testing. The testing would not start until the funding and logistical details were in place.

C. Strengthening the Organic Seed requirement

Members of the Expert Panel stated that the cost of maintain each inbred line used for corn breeding is \$8000 to \$10,000 for the lab work to verify purity. This clearly is a very large investment for an organic breeding program or even for organic seed increase efforts. While the State of the Seed report will show that organic seed use is increasing, the progress has not been sufficient to sustain the work needed in at-risk crops. The whole viability of any efforts to keep GMOs out of organic are predicated on increasing the supply of organic seed with reasonable purity.

One of the areas that the NOSB can continue to work on is strengthening the organic seed provisions in the regulation through the guidance process. Many stakeholders felt that the NOP seed guidance issued in March 2013 did not go far enough to address the NOSB recommendation or the public comment in response to the draft guidance. Further suggestions are needed to move towards continuous improvement in this area, or what organic seed people are calling, "closing the loophole".

Several of the ideas for the NOSB to discuss for further recommendations include:

- How to determine continuous improvement in seed sourcing. For both ACAs and producers this may mean setting a percentage goal by acreage or variety, changing the "3 seed sources" guidance into something more specific if it is not leading to improvement, or asking for more measurable progress in the context of the Organic System Plan.
- The role of variety trials and research in compliance efforts.

- Handlers who require certain seeds for their contracted growers should be subject to the organic seed requirements and procurement efforts as well as growers themselves. There also needs to be some oversight of export traders as handlers who slip through the cracks of the organic seed regulations.
- NOP should provide meaningful training to ACAs annually on how to monitor progress in complying with the need for continuing improvement in seed sourcing. Particularly equal verification/enforcement for all scales of production was a frequently mentioned concern.

D. Start with a Soybean Testing Project

Numerous public commenters at NOSB meetings and in public gatherings have stated that soybean purity is relatively easily achievable compared to other at-risk crops. The NOSB could advance just a soybean testing mandate for both organic and non-organic seed to the proposal level at the next meeting. We need to determine still what the appropriate testing protocol, sample size, and threshold is for soybeans, as well as what happens when a test is failed. Starting with just one crop could provide valuable learning that would make it easier to adopt a more tailored proposal in the future to other crops.

E. Your ideas are welcome!

Discussion Questions

1. Do you think that any of the suggestions above (A - D) are workable? What would you change to make them better?
2. Do you have a new suggestion to add under letter "E"?
3. If you think that A is workable how and where would you suggest for the testing data to be collected and compiled?
4. If you think that C should be taken up by the NOSB, are there other portions of the Seed Guidance that should be strengthened?
5. If you think that D is feasible at this time, please provide input on sample size and testing protocol for soybeans.

Subcommittee Vote

Motion to adopt the discussion document on Next Steps for Improving Seed Purity

Motion by: Zea Sonnabend

Second: Emily Oakley

Yes: 4 No: 0 Abstain: 0 Absent: 2 Recuse:0

Appendix

Discussion document on Prevention Strategies Seed Purity language, NOSB Spring 2015.
(Withdrawn from the final Recommendation.)

Seed Purity Requirement for Non-organic Seed

The longer we wait to set limits for controlling contamination in organic seed, feed and crops, the further we fall behind market demand, and the longer organic farmers are subject to the variability of the private market vs. the requirements of the organic regulations. A first step of action to protect organic seeds and crops from GMO contamination could be to require the evaluation of the non-GMO status of **nonorganic** seeds intended for use in organic production.

- The regulations require that non-organic seed be non-GMO. Organic producers must provide ACAs with supporting evidence that non-organic seed is non-GMO. To address this requirement, NOP could in guidance request that ACAs collect a seed purity declaration for high risk crops made (preferably on the seed tag of each bag of seed with a lot number) by the seed supplier or organic operation to verify the non-GMO status of non-organic seed.
- Since organic seed must comply with the organic standards and is subject to residue sampling by ACAs, requiring seed purity declaration for organic seed could undermine confidence in the process-based standards. For organic seed, an organic certificate is adequate. However, requiring a seed purity declaration on **non-organic seed** would obligate seed suppliers or organic operations to test non-organic seed for GMOs and to withhold seeds that were contaminated from entering the organic supply chain. A suggested threshold for planting seed is 0.1%, a figure in common use.

Requiring a seed purity declaration for non-organic seed would:

- Shift the financial burden of routine GMO testing from organic seed producers to suppliers of non-organic seed;
- Significantly reduce the inadvertent introduction of GMOs into organic crops through seed;
- Show confidence in the processed based standards that have proved successful in preventing pesticide contamination on organic products; and
- Incentivize the expansion of the organic seed industry
- However, such a requirement might reduce crop seed and variety options for organic producers if seed suppliers were unwilling to test non-organic seeds for GMOs.

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal - Hypochlorous Acid
February 16, 2016

Summary of Proposed Action:

On May 29, 2015 the NOP received a petition to add hypochlorous acid (CAS #7790-92-3) to the National List of synthetic substances allowed for use in organic production and handling (7 CFR §205.600-606) at §205.605. This material is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products.

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water. That was a memo issued as a response to requests asking for the National Organic Program to clarify whether electrolyzed water (EW) was allowed as a sanitizer and antimicrobial agent for use in organic production and handling.

The NOP felt that the allowance of EW by a certifier or a material evaluation program (were based on an incorrect interpretation of the allowance for chlorine materials on the National List of Allowed and Prohibited Substances at 7 CFR 205.600-606. The NOP requested that certifiers ensure that the use of EW was not allowed in organic handling or production and that any party wishing for further consideration of EW for use in organic handling or production, should then submit a petition to get it added to the National List. Thus, the rationale for the petition currently before the Handling subcommittee and the full NOSB is in response to the NOP policy memo.

Manufacture and Uses of the Substance:

Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode, but permits specific ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochloric acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. (TR lines 48-68)

The effectiveness of hypochlorous acid as an active sanitizing agent is determined in large part by the solution pH. Hypochlorous acid exists interchangeably with other chlorine species, including chlorine, hydrogen chloride (aqueous and gaseous) and hypochlorite. In a controlled pH environment, hypochlorous acid will exist as the dominant chlorine species under pH conditions ranging from 2 to 7. (TR lines 84-89)

At a pH of 6.0-7.5 (neutral), EW contains primarily hypochlorous acid, hypochlorite ion and trace amounts of chlorine (TR 118-119). At pH <4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, and also creating human health and safety issue (TR 150-152). Therefore it is important that neutral EW be used for sanitizing, not acidic EW.

EW has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of EW water against foodborne pathogens on raw agricultural products and food contact surfaces. Applications of EW as a disinfectant for reducing microbial contamination have been reported for fresh fruits and vegetables, poultry

carcasses, shell eggs, cutting boards, and food processing surfaces. Some advantages of using EW water are: 1) EW is as effective as any chlorine treatment, 2) it is not necessary to handle potentially dangerous chemicals, e.g. chlorine gas, chlorine dioxide, bleach, 3) the apparatus to produce EW is relative inexpensive and easy to operate, 4) because only water and sodium chloride are used EW production is environmentally friendly and 5) the properties of the EW can be controlled at the preparation site. (TR lines 99-108)

Discussion:

In general, neutral hypochlorous acid (EW) at pH 6.5-7.5 is safer to use than other chlorine-containing disinfectants. The concentration of chlorine present in electrolyzed water is usually over ten thousand times less than household bleach. There is also the advantage of its production on site, alleviating the need to transport dangerous material. (TR lines 616-619)

Hypochlorous acid is the same active sanitizing ingredient that is present in sodium hypochlorite and calcium hypochlorite. The reason hypochlorous acid can be ten thousand times less concentrated than sodium and calcium hypochlorite solutions and still be an effective sanitizer is that sodium and calcium hypochlorite solutions (bleach) have a high pH. When the pH is high, the hypochlorous acid/hypochlorite chemical equilibrium strongly shifts towards the presence of hypochlorite, whereas at neutral pH the chemical equilibrium shifts towards the presence of hypochlorous acid, the effective sanitizing compound. Therefore, hypochlorous acid (EW) is a safer product, for the environment and for human health, than chlorine sanitizer materials currently on the National List.

Evaluation Criteria

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Classification Motion: Move to classify hypochlorous acid as synthetic.

Motion by: Francis Thicke
 Seconded by: Jean Richardson
 Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list hypochlorous acid as petitioned at §205.603 of the National List (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (iv) hypochlorous acid.

Motion by: Francis Thicke
 Seconded by: Jesse Buie
 Yes: 7 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Approved by Ashley Swaffar, Livestock Subcommittee Chair, to transmit to NOSB February 16, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Livestock

Category 1. Adverse impacts on humans or the environment? Hypochlorous 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		According to the petition electrolyzed water can be made on-site. In this process there would not be any residual product to dispose of. If produced off-site and sold as a finished product then there could be a possibility of environmental contamination as the result of an accident or a spill. The TR does state that in forms of hypochlorous acid that are at a pH<4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, but also creating possible human health and safety issues (Fisher, 2009). The more neutral, the pH of the material, the safer and more stable the substance appears to become.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		x		This substance is formed by the electrolysis of a sodium chloride solution. Any environmental concerns would be from a spill during manufacturing or transport of a formulated end product.
3. Are there any adverse impacts on biodiversity? (§205.200)	x			The TR, (lines 596-612) does state that hypochlorous acid in aqueous solutions at pH< 7. Was of minimal toxicity to birds, but could be very toxic to fish and freshwater invertebrates.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		Contaminants listed in the US Food and Drug Administration’s Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, are unlikely to be found in hypochlorous acid since it is the electrolysis product of two generally recognized as safe materials, salt and water (TR lines 568-571).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	x			The TR (lines 140-153) mentions that there can be a reaction with organic material (humic acid) which can lead to some potential concerns. It does go onto state though: It is generally accepted that carcinogenic and teratogenic trihalomethanes and haloacetic acids are not formed by the action of hypochlorous acid in neutral or near-neutral solutions (Satyawli et al., 2007).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		According to the TR (lines 602-612) hypochlorous acid solution decomposes very slowly in the dark but more rapidly in the presence of light, rapidly in full sun light by producing hydrogen chloride and oxygen. Released into the environment it is distributed into water and air, with an estimated half-life of 1-4 hours. A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity.
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		Information provided in the petition states that compared to other types of chlorine, electrolyzed water is usually used at an active rate that is ten thousand times less than that of common household bleach. The TR (lines 624-626) mentions that the human innate immune system uses hypochlorous acid to fight infection but also directs it against host tissue in inflammatory diseases (Kettle et al.,2013). Chlorine disinfectants have been shown to cause occupational dermatitis or skin irritation (TR line 662).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		x		See the answer to question #5 above.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		x		

Category 2. Is the Substance Essential for Organic Production? Hypochlorous 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			Electrolyzed water is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane. This process creates

				hypochlorous acid, hypochlorite ion, and hydrochlorite at the anode and sodium hydroxide at the cathode. (TR lines 48-68) August 13, 2015 TR.
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		
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 acids such as citric acid, lactic acid, malic acid, and vinegar are some alternative materials.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			Hot water can be used in some instances.
8. Are there any alternative substances? [§6518(m)(6)]	x			Some alternative substances are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peroxyacetic acid, citric acid, acetic acid, ascorbic acid, and vinegar. Copper sulfate is another possible alternative depending on the use.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		

Category 3. Is the substance compatible with organic production practices? Hypochlorous 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			Compared to many of the alternative materials currently being used electrolyzed water could provide a safer and effective alternative. (especially when produced using the on-site electrolysis process)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			See answer to question #1 of this category.
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);		x		
copper and sulfur compounds				
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			May be used to sanitize equipment

**National Organic Standards Board
Livestock Subcommittee
Proposal - Annotation Change for Lidocaine and Procaine Use in Livestock Production
January 19, 2016**

I INTRODUCTION:

Lidocaine and Procaine are local anesthetics. They are used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment of animals is critically important and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all. Based on new information received during Sunset Review in 2015 and public comment, the NOSB proposes a recommendation to reduce the withholding period for both lidocaine and procaine from the present 90 days to 8 days for slaughter stock and 6 days for milk.

II BACKGROUND:

When added to the National List in 1995, there was no scientific rationale for the 90 day withholding, and the NOSB analysis in their document entitled "Local Anesthetics" provided very little information.

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double FARAD times (when appropriate), on a number of livestock materials .

"..... As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank(FARAD).The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide "withholding period" (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP-DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB.USDA agrees with the position"

"...Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly, USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend

the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals“ (72 FR 70479) .

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Sunset Review took place in 2015, and lidocaine and procaine were approved for continued listing at the October 2015 NOSB Meeting in Stowe, Vermont. (On a motion to Remove, Vote 0:14)

III RELEVANT AREAS OF THE RULE:

Section 205.238 Livestock healthcare practice standard.

(a) The producer must establish and maintain preventive livestock healthcare practices, including ...

(5) performance of physical alterations as needed to promote the animal’s welfare and in a manner that minimizes pain and stress;

...

(c) The producer of an organic livestock operation must not: ...

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled or represented as organically produced.

Section §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable ...

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

...

7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

IV DISCUSSION:

During the 2015 Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the very extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

In FARAD the recommended withdrawal interval for lidocaine in cattle is listed as 1 day for meat and 24 hours for milk after epidural use of lidocaine, and 4 days for meat and 72 hours for milk after subcutaneous use of lidocaine.

FARAD provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. Procaine on its own is apparently not readily available in the US and public comment from veterinarians only suggests a similarity with lidocaine. Procaine was recommended for continued listing because no public comment was provided to recommend its removal on any criteria. However procaine appears to be rarely used in organic livestock production.

During Review of these materials the NOSB in its initial request for public comment asked:

- * Since this material was last reviewed have alternative materials emerged?
- * What is the scientific rationale for what appears to be an excessively long withdrawal period?
- * Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives to these materials, did not provide any scientific rationale for the lengthy withholding period, and recommendations were received suggesting that a very short withholding period would be scientifically acceptable. Public comment agreed with the rationale of using double the FARAD time for conventional production.

In contrast to butorphanol, which is a systemic anesthetic, lidocaine and procaine numb only the area to be worked on. Science indicates that the half-life of lidocaine and procaine in all animals studied is very short, typically less than one hour.

Based on new information and public comment during Sunset Review, the NOSB developed a Discussion Document to allow public comment on a possible annotation change. Public comment was received in Fall 2015 and discussion took place at the October 2015 NOSB meeting.

Public comment indicates that there appears to be broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90 day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supports a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. The public supports a recommendation for withholding for milk of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production.

V RECOMENDATION:

To amend Section 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

(7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Sub Committee Vote : - Two Motions

1. That the deleted language be removed and underlined language added at:
205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

Motion: Jean Richardson

Second: Francis Thicke

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

2. That the deleted language be removed and underlined language added at:

205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Motion: Jean Richardson

Second: Francis Thicke

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

**National Organic Standards Board
Livestock Subcommittee
Proposal to Amend Use of Parasiticides in Organic Livestock Production
January 19, 2016**

I. INTRODUCTION:

The use of parasiticides in organic production is strictly confined to emergencies. Parasiticides cannot be used routinely, but sick animals must be treated. Typically farmers bring clean animals into their herds or flocks, select breeds which have high resistance to parasites, and manage their land, especially pastures, in a manner which reduces the likelihood of parasite infection. If an increased parasite load is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, the farmer, working with the veterinarian, may need to use one of the synthetic parasiticides on the National List.

At the present time there are three (3) substances on the National List which are approved for use as parasiticides for organic livestock: ivermectin, moxidectin and fenbenzadole. All three of these materials were reviewed in 2015 as part of the regular five-year Sunset process. At the October 2015 meeting in Stowe, Vermont, after considerable discussion and extensive public comment, it was recommended that all three parasiticides continue to be listed. Ivermectin was renewed with great reluctance owing to the recent research indicating serious negative impact of ivermectin on dung beetles in pastures. A Discussion Document was also presented at the October 2015 meeting seeking public comment on possible changes in use of the parasiticides. Extensive public comment indicates broad support to propose amendments on parasiticide use.

All three materials have annotations and other language limiting usage. Such language was developed when ivermectin was first added to the National List. Recent data and information indicates that milk withholding and other restrictions could be modified in a manner which would be beneficial to the sick animal in emergency situations without jeopardizing the quality of the organic product. In conventional milk production, there is no withholding period for fenbenzadole or moxidectin. For organic production, there is a 90 day withholding period for organic milk. Synthetic parasiticides are prohibited in organic slaughter stock. Wool and fleece from organic fiber bearing animals, such as sheep, cannot be sold as organic even with a single use of a synthetic parasiticide. Organic regulations allowed moxidectin for internal use only. Fenbenzadole use requires a veterinarian order prior to use in organic production, but ivermectin and moxidectin do not have such a requirement.

As discussed below, in 2007 it was agreed that the NOSB could use double FDA or Food Animal Residue Avoidance Databank (FARAD) withholding periods.

This proposal recommends:

- * That parasiticides continue to be prohibited in slaughter stock.
- * That the milk withholding period after treatment with fenbenzadole or moxidectin be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.
- * That the listing for ivermectin remains as presently listed, with a 90 day withdrawal period.
- * That moxidectin be allowed for both internal and external use.
- * That fleece and wool from fiber bearing animals be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life.
- * That fenbenzadole be allowed without written order of a veterinarian.

Acronyms used herewith:

FDA – Food and Drug Administration

FARAD – Food Animal Residue Avoidance Databank

CVM – Center for Veterinary Medicine

NADA – New Animal Drugs Application – under the FDA

AMDUCA – Animal Medical Drug Use Clarification Act

NOEL – No Observable Effect Level is used by the FDA, CODEX etc.

NRP – National Residue Program

ADI – Adult Daily Intake

MRL – Maximum Residue Limit

TR – Technical Report

Trade names—examples:

Fenbendazole: Panacur, Safeguard

Ivermectin: Ivomec, Primatectin

Moxidectin: Cydectin

II BACKGROUND:

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only ivermectin had sufficient votes to be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation, “for control of internal parasites only,” was included for moxidectin for the given reason that, “There is much less chance of any kind of contamination if it is used for internal parasites versus external”. Moxidectin was added to the National List in 2012 (77 FR 28472).

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double Food Animal Residue Avoidance Databank (FARAD) times (when appropriate), on a number of livestock materials:

As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank (FARAD). The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide “withholding period” (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP-DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB. USDA agrees with the position stated in the comments...

Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly,

USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. (72 FR 70479)

In May 2008, Fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0 and added to the National List in 2012 (77 FR 28472). The Withholding period was the same as for Ivermectin.

Three Technical Reports are relevant for this proposal: A 1999 TAP (fenbendazole, ivermectin); a 2003 TAP for moxidectin; and a June 2015 Technical Report on all three parasiticides (fenbenzadole, ivermectin and moxidectin) requested by the Livestock subcommittee as part of its Sunset Review of these parasiticides.

In 2015, all three parasiticides were reviewed as part of the regular Five Year Sunset Review. At the October 2015 NOSB meeting in Stowe, Vermont:

- Moxidectin was recommended for continued listing on a Motion to Remove: 0 Yes; 12 No ; 2 abstentions.
- Fenbenzadole was recommended for continued listing on a Motion to Remove: 0 Yes ; 12 No ; 2 abstentions.
- Ivermectin was recommended for continued listing on a Motion to Remove: 6 Yes ; 4 No; 4 abstentions.

In addition a Discussion Document on parasiticides was presented at the October 2015 NOSB meeting. This is discussed below in the Discussion section.

III RELEVANT AREAS OF THE RULE:

The USDA organic regulations at 7 CFR part 205 describe required preventive health care practices and regulations for the use of synthetic parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
 - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
 - (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
 - (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
 - (18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
 - (i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
 - (ii) Ivermectin (CAS #70288-86-7).
 - (iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

IV DISCUSSION:

Fenbendazole, ivermectin and moxidectin are the only antihelmintics approved for use in organic livestock production. They represent two of five antihelmintic drug classes. Fenbendazole is in the benzimidazole group and Ivermectin and Moxidectin are in the polyene group within the macrocyclic lactone group. In organic livestock production they are never used on a routine basis, only in emergency situations. They are used in doses as indicated on the label, by body weight and species of animal, and, under veterinarian supervision can be used “extra label/off-label” (see detailed discussion below).

Parasiticide Uses:

Fenbendazole:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit oral administration of fenbendazole in dairy cattle for the removal and control of lungworm (*Dictyocaulus viviparus*); brown stomach worm (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*) and nodular worm (*Oesophagostomum radiatum*); in beef cattle (beef) for the removal and control of stomach worm (*Ostertagia ostertagi*) and tapeworm (*Moniezia benedeni*); in goats for the removal and control of stomach worms (*Haemonchus contortus* and *Teladorsagia circumcincta*); in swine for the removal and control of lungworms (*Metastrongylus apri* and *M. pudendotectus*), roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*), small stomach worms (*Hyostromylus rubidus*), whipworms (*Trichuris suis*) and kidney worms (*Stephanurus dentatus*) and in turkeys for the removal and control of round worms (*Ascaridia dissimilis*) and cecal worms (*Heterakis gallinarum*). Fenbendazole is sold by Merck Animal Health as Panacur® and Safe-Guard®. It is available in liquid suspension, as granules, as a paste and in blocks. Products are dispensed both by veterinarian’s prescription and over the counter, but must be used in organic production only

under veterinary supervision. For swine, turkeys, and wild sheep the NADA (141-144, 140-954, 136-116, 131-675) for fenbendazole is for use in medicated feed only. Other uses for these animals are extralabel. Furthermore, the use of fenbendazole in medicated feed for domestic sheep in food production is not permitted by the FDA. (TR 2015, 284-302).

Ivermectin:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of ivermectin in cattle for the treatment and control of gastrointestinal nematodes: *Haemonchus placei*, *Ostertagia ostertagi*, *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, *N. spathiger*, *Bunostomum phlebotomum*, lungworms: *Dictyocaulus viviparus*, grubs *Hypoderma bovis*, *H. lineatum*, sucking lice: *Linognathus vituli*, *Haematopinus eurytarnus*, *Solenopotes capillatus*, mites: *Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*, in reindeer for treatment and control of warbles (*Oedemagena tarandi*), in swine for treatment and control of gastrointestinal roundworms: *Ascaris suum*; red stomach worm, *Hyostrongylus rubidus*; nodular worm, *Oesophagostomum* species; threadworm, *Strongyloides ransomi*, somatic roundworm larvae-threadworm, *Strongyloides ransomi*, lungworms: *Metastrongylus* species, lice: *Haematopinus suis*, mites: *Sarcoptes scabiei* var. *suis* and ear mites: *Otodectes cynotis*, in american bison for the treatment and control of grubs: *Hypoderma bovis* and in sheep for treatment and control gastrointestinal roundworms: *Haemonchus contortus*, *H. placei*, *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. spathiger*, *S. papillosus* *Chabertia*, *Trichuris ovis*, lungworms: *Dictyocaulus filaria* and all larval stages of the nasal bot *Oestrus ovis*. Ivermectin is marketed by Merial, Inc. and other companies under a number of pharmaceutical labels. It is available as a drench, in liquid solution, for medicated feed, as a sustained release bolus and as a paste. Products are dispensed both by veterinarian's prescription and over the counter. (TR 2015, 303-321).

Moxidectin:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of moxidectin in cattle for treatment and control of internal and external parasites, gastrointestinal roundworms: *Ostertagia ostertagi*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. pectinata*, *C. punctata*, *C. spatulata*, *C. surnabada*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, lungworms: *Dictyocaulus viviparus*, cattle grubs: *Hypoderma bovis*, *H. lineatum*, mites: *Chorioptes bovis*, *Psoroptes ovis*, *P. communis* var. *bovis*, lice: *Linognathus vituli*, *Haematopinus eurytarnus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis* and horn flies: *Haematobia irritans* and in sheep for the treatment and control of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*. Moxidectin is sold by Boehringer Ingelheim Vetmedica, Inc. as Cydectin. It is available in liquid solution. Products are dispensed over the counter (TR 2015, 322-332).

Regulated approvals:

The use of fenbendazole for food animals is approved under six FDA New Animal Drug Applications (NADA) (TR 2015, Table 3). It is dispensed over the counter. The use of ivermectin for food animals is approved under nineteen FDA new animal drug applications. It is dispensed both by veterinary prescription and over the counter (Table 3). The use of moxidectin is approved under three NADAs. It is available over the counter. Moxidectin is in the polyene group and of macrolides and is not antibiotic in its function. (TR 105-113). The approved FDA NADA numbers for the eight additional anthelmintics

approved by the FDA are provided in Table 3 of the TR. (TR 2015, 243-248).

“Off label/ Extra label use”. Once a NADA is approved, the FDA, under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), can permit the use of the approved drug under specific conditions outside the designated or intended label use, e.g. use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses (FDA, 1994).

This “off-label use” is only permitted in the context of a valid veterinarian-client-patient relationship and is limited to treatments when the health of an animal is threatened or suffering or death may result from failure to treat.

A valid veterinarian-client-patient relationship is one in which: (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian; (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) The practicing veterinarian is readily available for follow up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept (FDA, 2015b). (TR 2015, 249-266)

For example, there is not an FDA approved use for fenbendazole in domestic sheep; however, it is used under veterinary supervision for this purpose. (TR 2015, 266-267)

There are some limitations for the AMDUCA including extra label use of an approved new animal or human drug by a lay person (except when supervised by a veterinarian). (TR 2015, 269-270).

The no observable effect level (NOEL) for parasiticides is determined by drug manufacturer and approved by the US Food and Drug Administration, Codex Alimentarius or other national or international standard setting organization. Protocols are provided by these federal agencies that detail testing and evaluation of the drugs. The NOEL is usually determined in an animal model. The NOEL values for fenbendazole, ivermectin and moxidectin are respectively, 0.7 milligram/kilogram body weight per day (mg/kg bd/day), 1.5 mg/kg bd/day and 10 mg/kg bd/day. The NOEL is used to determine the Adult Daily Intake (ADI) or the maximum residue limit (MRL). Withdrawal time is the time that it takes for the concentration in milk, eggs and meat that will be consumed by people to drop from the residue level at administration to the ADI, MRL, or safe level. (TR 2015 807-814)

Withdrawal periods for Milk:

Fenbenzadole: FDA—zero withdrawal; FARAD does not include recommendations.

Moxidectin: FDA—zero withdrawal, although some products state not established; FARAD—Cows: zero withdrawal when administered topically, and not established when administered subcutaneously; FARAD—Goats one day for topical administration and up to 18 days if administered orally (drench) (based on weight of animal and dosage)

International Use and Restrictions (TR 2015, 432-507):

CANADA:

The organic standards of Canada prohibit the use of parasiticides with exceptions: If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued, but **use in slaughter stock is allowed within limitations.**

The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan.

CODEX:

The organic standards of CODEX Alimentarius, do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventive animal husbandry practices and natural remedies have been used and not found to be effective. Withdrawal periods should be double that required by legislation, with a minimum of 2 days.

IFOAM:

Like the Canadian standards, IFOAM organic standards require that use of antihelmintics will cause animal to lose its organic status – But an exception is allowed when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. And **use in slaughter stock is allowed within limitations.**

The International Federation of Organic Agricultural Movements (IFOAM) Exception states that an animal can retain its organic status if the operator can demonstrate treatment is in compliance with IFOAM preventive animal husbandry practices, and natural and alternative medicines and treatments are unlikely to be effective to cure sickness or are not available to the operator, and the chemically synthesized allopathic veterinary medical products or antimicrobials are used under the supervision of a veterinarian, withdrawal periods are not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The exception is granted for a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year. (TR 2015 486-494)

EEC:

The European Economic Community states that preventive, routine use of parasiticides is not allowed but in the case of a sick animal needing immediate treatment the withholding period is double the withdrawal. And **use is allowed in slaughter stock.**

JAS:

The organic standards of Japan do not specify which parasiticides may be used. The withdrawal period is 2 days prior to slaughter for foods, milk or egg collection or twice the period of drug withdrawal. **Use in slaughter stock is allowed.**

NOP: Does not allow for use in slaughter stock, and this proposal does not recommend any changes to this prohibition.

Alternatives:

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with antihelminthic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

Livestock develop an immune response to nematodes and becomes resistant or tolerates them without signs of disease. Because young livestock do not have a mature immune system, they may not be able to mount an immune response upon infection. The same is also true for older and immuno-compromised animals. Worming with homeopathic and botanical remedies should begin strategically during the first autumn of life to accommodate the low body reserves expected with calves (Karreman, 2004).

Homeopathic wormers are available commercially that satisfy the organic rule. These are available as veterinary preparations with valid labeling systems so that their use may easily be audited (Brunetti and Karreman, 2006). Users of these remedies should be sure that the material has an appropriate potency and the source from which it was extracted is verified and correct. A list of natural wormers is provided in Table 11 of the TR. Herbal remedies with anthelmintic properties were commonly adopted and used as a part of traditional animal husbandry. Some have not been evaluated with modern techniques, but may cause toxic side effects, however in most cases they represent a good alternative to the use of synthetic drugs (Duval, 1997) (TR 2015, 828-840).

Brunetti and Karreman found that with proper pasture management, a good diet with plenty of forage for livestock and knowledgeable coaches to provide appropriate strategies for husbandry and treatment healthy animals can be sustainably raised without synthetic parasiticides (TR 2015 943-946).

Public comment included many producers, all species of livestock, who consistently use alternative natural materials and plants, pasture and browse, who never use any synthetic parasiticides. Emergency use of synthetic antihelmintics is not common in organic livestock production. This proposal only relates to milk production, not to slaughter stock, and only in emergency situations.

Confusion in present annotation language:

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

1. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian”. Ivermectin and moxidectin have no such requirement. That may lead producers to choose a potentially more environmentally detrimental parasiticide for convenience.
2. Moxidectin is annotated “for control of internal parasites only.” However, moxidectin is widely used as a pour-on in conventional livestock production, and when used in that form for control of external parasites it is also a de facto control for internal parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only”: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
3. §205.603(a)(18) requires a 90-day withholding period for organic milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) fenbendazole and moxidectin have no milk withdrawal time for use in conventional production. There is no scientific rationale for the 90 day withholding for milk. The 90 days reflects a desire to assure consumers that organic standards exceed conventional use of restricted materials.

Based on public comment during the first posting of these materials, in fall 2015 the NOSB posted a Discussion Document for public comment. The Discussion Document included the following questions:

1. Should the milk withholding period be modified for any or all of the parasiticides? If so, how many days for moxidectin, fenbenzadole and ivermectin?
2. Should minimal use of parasiticides be allowed in organic slaughter stock such as is permitted under Canadian Organic standards with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status)?
3. Should Sheep fleece and wool be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal’s life?
4. Should use of Moxidectin be changed to allow both internal and external use?
5. Should use of parasiticides be allowed only under Veterinarian advice?

Public Comment:

Considerable public comment was received from a broad range of stakeholder groups and producers.

To summarize public comment:

* There was strong support to reduce the withholding period for milk following use of either fenbenzadole or moxidectin. Recommendations, based on science and research, suggested adoption of a withdrawal period of between zero days and 14 days as opposed to the present 90 days.

One large dairy stated the following: “We support the NOP’s consistent position of an organic milk withdrawal period of twice what is required by the...FDA and/or...FARAD for substances on the National List. However... Fenbenzadole and Moxidectin have no FDA required milk withdrawal interval and therefore organic dairy livestock treated with either of these substances should have milk requirement

withdrawal of zero days. Three other commenters also suggested zero withholding and one researcher commented that science indicates that small ruminants metabolize fenbendazole even more rapidly than large ruminants. Research presented as part of public comment indicates Fenbendazole in blood samples peaks at 7 hours and is gone from the blood in 72 hours.

Veterinarians, consumer organizations, a trade organization, individual producers, certifiers, an inspector association, and dairy groups all supported reduction of the withholding period based on science and the FDA and FARAD.

* There was no support for reducing withholding from 90 days after treatment with ivermectin based on science and FARAD. Some commenters suggested the need to prohibit ivermectin treatment for lactating cows.

* One certifier (Western US) noted that synthetic parasiticides are rarely used in dairy production. Several producers stated that they never use parasiticides.

* There was widespread public comment to remove ivermectin completely from the National list especially in light of recent science indicating the negative impact of ivermectin on dung beetles in pastures. However, some producers, notably small ruminant producers, urged that ivermectin be kept on the list at present for the following reasons: the fact that ivermectin is well known; has been allowed for the longest time; is commonly available without prior veterinarian advice or prescription; lack of experience of use of fenbendazole. Veterinarians and a large dairy producer group recommended that ivermectin be prohibited for use on lactating cows. Since parasiticides, if used, are typically given to young stock, several public commenters requested that NOSB consider an annotation to state – Ivermectin- not for use in dairy animals of breeding age or older. Other commenters noted that because ivermectin is ONLY used in an emergency and not on a regular basis, dung beetle impact on organic pastures will be minimal.

* There was strong support to allow both external and internal use of moxidectin from individual dairy producers, larger dairy organizations, certifiers, an inspector organization, a trade group, and veterinarians. One certifier commented that the present annotation for internal and not external use makes verification difficult. A large dairy commented that moxidectin for both internal and external use is particularly critical in the Southern US states.

* There was little support for possible adoption of allowing parasiticide use in slaughter stock as per the Canadian Organic Standards. Consumer groups and dairy producer organizations expressed concern that this would reduce consumer confidence in organic food. Certifiers and veterinarians also did not support this suggestion. There were two individuals who felt that use of limited parasiticides could be allowed for slaughter stock.

* There was strong support for certification of sheep fleece and wool even after use of parasiticides. This support came from farmer producers, certifiers, veterinarians, farm producers in the West, consumer groups, an inspector organization, and trade groups. We were reminded that this is not a new idea, but one that was proposed to the NOSB in 1990 and never taken up by the NOSB.

* There was mixed response to requiring veterinarian advice before use of parasiticides. Certifiers like the idea that veterinarians would be involved as this would make the audit trail far easier to verify. One certifier stated:

Overall we support an annotation update that requires veterinarian advice because it would clarify how producers should document the emergency necessity for treatment and provide for a clear audit. Currently parasiticides are “allowed for emergency treatment,” which requires that organic producers describe and provide documentation about how they determined that it was an emergency (fecal tests, animal condition, etc.)...A vet recommendation requirement would be more straightforward to document and audit than the existing annotation...but...situations also exist when a veterinarian may not be available to assess the situation quickly, such as when animals are in a remote location.

Most, but not all, veterinarians support requiring veterinarian advice prior to use of parasiticides. This would ensure that the right dosage of the most effective parasiticide is given to the various animal species. One large cow dairy organization stated that there was plenty of most of the parasiticides available without veterinarian advice.

To quote one of the public comments:

In preparing this proposal to recommend amendments to use of parasiticides, the NOSB must be very mindful that we need to remember that livestock producers are raising multiple species in diverse geographic regions facing diverse climatic conditions.

V RECOMMENDATION:

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
- (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy animals stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic, as allowed under §205.603.
- (3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—~~only for use by or on the lawful written order of a licensed veterinarian.~~ Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Ivermectin (CAS #70288-86-7)—Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.

(iii) Moxidectin (CAS #113507-06-5)—~~for control of internal parasites only~~ Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Sub Committee Vote:

1. That the strikethrough language be removed, and the underlined language be added at:

Section 205.238(b)(2) Dairy ~~animals, stock when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.~~ as allowed under 205.603.

AND

205.603(a)(18) ...~~Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment .~~

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

2. That the underlined language be added at:

§205.238(b)(3) Fiber bearing animals, as allowed under §205.603.

AND

§205.603(a)(18) ... Allowed for fiber bearing animals when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled or represented as organic.

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

3. That the strike through language be removed and the underlined language added at:

205.603(a)(18)(i) Fenbendazole (CAS #43210-67-9)—~~only for use by or on the lawful written order of a licensed veterinarian.~~ Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

4. That the underlined language added at:

205.603(a)(18) (ii) Ivermectin (CAS #70288-86-7)—Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

5. That the strike through language be removed and the underlined language added at:

205.603(a)(18) (iii) Moxidectin (CAS #113507-06-5)—~~for control of internal parasites only~~ Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other animals.

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

**National Organic Standards Board
Policy Development Subcommittee
Policy and Procedures Manual Revision – Proposal
February 23, 2016**

Introduction and Background

The Policy and Procedures Manual (PPM) of the National Organic Standards Board (NOSB) was first adopted on October 19, 2002. Since its adoption the PPM has been revised 12 times with 11 revisions occurring from 2007-2011. Since April 11, 2012 this document has not been revised. The PPM was established to assist the board in the implementation of its duties under OFPA and to establish operating procedures and policies for the board. In order to bring the PPM in line with the current operations of the board the PDS has been undertaking revisions to the PPM and presented a draft version at the October 2015 NOSB meeting for discussion. Public comments were received and full board discussion occurred on the proposed revised PPM. The PDS has revised these comments, made revisions where necessary and is presenting this revised PPM for Board approval.

Objective

The objective of this proposal to revise the April 11, 2012 version of the PPM to reflect the current procedures for the collaborative and productive functioning of the NOSB. It is designed to assist the NOSB in its responsibilities to serve as a link to the organic community, advise USDA on the implementation of OFPA, propose amendments to the National List of Allowed and Prohibited Substances and protect/defend the integrity of organic standards. It complies and aligns with other governing documents including the Organic Foods Production Act (OFPA), the USDA organic regulations at 7 CFR Part 205, the NOSB Charter, FACA procedures and other government laws and regulations (ie FOIA) as applicable.

Public Comment Discussion

Brief summary of comments	PDS Response
Proposed changes to the PPM need to be more transparent. (6 comments)	The PDS acknowledges there were a number of formatting, ordering, grammatical as well as content changes that make comparing the April 2011 version to the proposed version difficult. The PPM was revised 11 times in a 5 year period and then not touched for 4 years - clearly a number of edits are needed bring this document up to date. To make the changes to the PPM more transparent a redline version of the document as well as a table of contents comparison are provided. Due to the global nature of the changes, the redline version provides limited value in comparing the two documents.
The PPM should reflect the public information disclosure requirements of FACA in addition to FOIA. (4 comments)	The PDS agrees that the PPM should align and comply with other governing documents the PDS has revised Section III I Additional Administrative Items bullet fourth and fifth bullet points to include FACA disclosure requirements along with FOIA.
Conflict of Interest policy of Technical Reviews (TR) and Technical Advisory Panels (TAP) need to be transparent and the authoring party needs to be listed on the TR/TAP. (4 comments)	The PDS agrees that the procedures for disclosing conflicts of interest are important and need to be transparent as well as aligned with the contracting procedures of the federal government. It is clarified in section VI H 3 in the sixth bullet point that the contracting party will be named on the TR/TAPs and the conflict of interest protocols to be followed for the contracting of TR/TAPs.

FACA definition of non-public information should be used in place of the FOIA definition. (3 comments)	The PDS agrees that the PPM should align and comply with other governing documents the PDS has revised Section III I Additional Administrative Items bullet fourth and fifth bullet points to include FACA disclosure requirements along with FOIA.
Changes to the PPM need to be approved by the full board. (1 comment)	The PDS agrees and added section IX to reflect this clarification.
NOSB and NOP collaboration section less collaborative than older version. (1 comment)	The PDS revised Section III E to reflect the importance of both NOP-NOSB collaboration as well as NOP-NOSB mutuality in their respective roles in the organic community.
The PDS's responsibilities do not reflect its role in reviewing and proposing changes to the PPM. (1 comment)	The PDS has revised Section IV A to reflect the PDS's role in revising the PPM and other internal policy documents.
Does not address section §6518(j) of OFPA, "The Secretary shall authorize the Board to hire a staff director." (1 comment)	The PPM should reflect the current operating procedures of the NOSB. Since the NOSB has never had the budget or the recognized authority to hire a staff director due to conflicting government regulations and laws - this is not included in this revision.
Removes NOSB authority to initiate agenda items. (1 comment)	The PDS revised Section III F to reflect the collaborative nature under which work plans are set with the program. The NOSB has the authority to initiate work agenda items and bring them to the Executive Committee and the NOP for confirmation. The proposed revisions bring the PPM into alignment with the NOSB Charter.
The section on the Advisory Committee Specialist (ACS) deletes this sentence: "The most important function of the ED is to facilitate the operation of the Board, while helping to maintain and strengthen its independence." (1 comment)	The PDS agrees that the most important function of the ACS is to facilitate the operations of the board along with facilitating communication and collaboration with the program. These section have remained. It is unfair and a conflict of interest to have this position take on the role of maintaining the board's independence.
Changes to the requirements for minority reports decrease the full understanding of the NOSB and the public. (1 comment)	The PDS disagrees with this comment. The minority view section was revised to better integrate the minority view into the final NOSB proposal and discussion as well as to facilitate a collaborative NOSB process. Objections raised by this commenter advocate for the NOSB to maintain an uncollaborative and potentially unproductive process with its own members - this is opposite to the objective of the PPM.
NOSB and NOP Conflict of Interest (COI) policies for NOSB members. (1 comment)	The PDS believe the COI procedures for NOSB members is clear and aligned with other governing documents.
NOSB policy for forced resignations needs to be better defined. (1 comment)	The NOSB has no authority to force the resignation of any of its members, this authority lies with the Secretary. This section only details circumstance where members should be encouraged to resign if they are not participating in the work of the NOSB.

Objections to greater meeting accessibility. (1 comment)	The NOSB strives to increase access to its meetings to members of the public and to its own members, regardless of their abilities to travel to the NOSB meeting. It would not be in the interest of the public, the NOSB and people of all abilities to limit access and refuse to use current common communication technology where the medical need is present.
The PPM should not adopt current Sunset procedures used by the Board.	The PPM should reflect the current operating procedures of the NOSB.

Attachments

Proposed Policy and Procedures Manual Draft February 23, 2016 (Clean)
 Redline Policy and Procedure Manual comparing Draft February 23, 2016 to April 11, 2012 version
 Table of Contents Comparison February 23, 2016 to April 11, 2012 version

Proposal

The NOSB moves to adopt the February 23, 2016 drafted version of the Policy and Procedures Manual.

Subcommittee Vote

The NOSB PDS subcommittee approves the three sections of this proposal as stated above.

Motion by: Tom Chapman
 Second: Lisa de Lima
 Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

PPM Change Table

Last revised PPM (April 11, 2012)	Proposed PPM (Mar 1 2016)	Change
I Introduction	I. Introduction	Updated
I NOSB Vision Statement	I.A NOSB Vision Statement	No material change
I NOSB Statutory Mission	I.B NOSB Statutory Mission	No material change
I NOSB Mission Statement	I.C NOSB Mission Statement	No material change
I Duties of Board and Officers	III.C Responsibilities of the Board Appendix I: Foundations	Updated
I Maintaining Professional and Ethical Standards	III.J Professional and Ethical Standards III.K Conflict of Interest	Updated
II Board Member Job Descriptions	I. Introduction III.A NOSB Membership	Updated
II Board Member Standards	III.J Professional and Ethical Standards	Updated
II Conducting Business	VIII.B Conducting Business	Updated
III Role of Executive Director	III.H Advisory Committee Specialist	Updated
III Officer Responsibilities	III.D NOSB Officers	Updated
III Election of Officers	VIII.F Election of Officers	Updated
III Executive Committee	IV.A Standing Subcommittees	Updated
III Meetings	VIII.A Board Meetings	Updated
IV Board Committees	IV.A Standing Subcommittees	Updated
IV Committee Meetings	IV.C Subcommittee Meetings	Updated
IV Standing Committees	IV.A Standing Subcommittees	Updated
IV Task Forces	IV.D Task Forces	Updated
IV Ad Hoc Committees	IV.B Ad Hoc Subcommittees	Updated
V Duties of Committee Chairs	IV.E Duties of Subcommittee Chairs and Vice Chairs	Updated
V Duties of Committee Vice Chairs	IV.E Duties of Subcommittee Chairs and Vice Chairs	Updated
V Procedures for transitioning of Committee Chairs	IV.F Transition of Subcommittee Chairs, Vice Chairs and Members (New and Continuing)	Updated
V Procedures for completing Committee Recommendations	IV.G Procedures for completing Subcommittee Proposals and Discussion Documents	Updated
V NOSB-NOP Collaboration	III.E NOSB-NOP Collaboration	Updated
VI Miscellaneous Policies	VIII.G Miscellaneous Procedures VIII.E Public Comment	Updated
VII NOSB Principles of Organic Production and Handling	Appendix I: Foundations	Moved
VII NOSB Guidance of Compatibility with a System of Sustainable Agriculture and Consistency with organic Farming and Handling	Appendix I: Foundations	Moved

VIII Committee Work Plans	III.F NOSB Work Agendas	Updated
VIII Materials Review Process	IV.H Substance/Materials Review Process	Updated
VIII Procedures for Handling Technical Reviews	IV.H Substance/Materials Review Process	Updated
VIII Handling Withdrawals of Petitions by the Petitioner	VI. Withdrawal of a Petition by a Petitioner	Updated
VIII Technical Advisory Panel Contract Procedures	IV.H Substance/Materials Review Process	Updated
VIII Information to be Included in a Petition	IV.H Substance/Materials Review Process	Updated
VIII Priority of Petitions Guideline	V. Prioritization of Petitions	Updated
VIII NOSB Committee Recommendation	-removed-	Moved to Member Guide
VIII Evaluation Criteria for Substance added to the National List	-removed-	Moved to Member Guide
VIII NOSB Recommended Decision Form	VIII.D NOSB Deliberations and Recommendations	Updated/Moved to Member Guide
VIII Procedures for the Materials Review Process for NOSB Members	IV.H Substance/Materials Review Process	Updated
VIII Sunset Review Process	VII Sunset Review Process	Updated
VIII Handling Technical Errors After an Item has been Placed in the Federal Register	-removed-	Removed
Appendix A Decision Making Procedures for the NOP	-removed-	Removed
Appendix B FACA Facts	Appendix II: Faca Facts	No material change
Appendix C Duties of the Designated Federal Officers	III.G Designated Federal Officer	Updated
Appendix D Parliamentary Procedures at a Glance	VIII.C Parliamentary Procedures	Updated/Removed
Appendix E Basic Chemistry	-removed-	Removed
	II.A OFPA	Added
	II.B FACA	Added
	II.C NOSB Charter	Added
	III.B Nomination and Appointment	Added
	III.I Additional Administrative Items	Added
	IX. Revisions to the Policy and Procedures Manual	Added

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
Revised November 19, 2008
Revised May 6, 2009
Revised November 9, 2009
Revised April 29, 2010
Revised October 28, 2010
Revised April 29, 2011
Revised December 2, 2011
Revised April 11, 2012
Draft Feb. 23, 2016

NATIONAL ORGANIC STANDARDS BOARD (NOSB) POLICY AND PROCEDURES MANUAL

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I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the OFPA, the USDA organic regulations at [7 CFR Part 205](#), and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title. (OFPA, Sec 2119 (a))

C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations
- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List

- Communicating with the organic community, including conducting public meetings, soliciting and reviewing public comments
- Communicating, supporting and coordinating with the NOP staff

II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The [NOSB charter](#) is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

III. NOSB ADMINISTRATION

A. NOSB Membership

OFPA specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;

- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. Nomination and appointment process

(NOSB recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five year term. The terms are staggered and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities. The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

C. Responsibilities of the NOSB

(OFPA, 7 USC 6518(k)):

- (1) **In General.** The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.
- (2) **National List.** The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this title.

(3) **Technical Advisory Panels.** The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) **Special Review of Botanical Pesticides.** The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.

(5) **Product Residue Testing.** The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

(6) **Emergency Spray Programs.** The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

Requirements. (OFPA 6518(l)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

- (1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;
- (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and
- (3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. the effect of the substance on human health;
5. the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. the alternatives to using the substance in terms of practices or other available materials; and
7. compatibility with a system of sustainable agriculture.

Petitions. (7 USC 6518(n))

The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

CHAIR

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings

- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

VICE CHAIR

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval

- Assists with the annual election of NOSB officers
- May delegate tasks to others, but retains responsibility for the official record

ADMINISTRATIVE TEAM

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. . This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference once or twice a month on an as-needed basis, to be determined by the Administrative Team.

E. NOSB-NOP COLLABORATION

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to “establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation” of the Act. Section 6503 (a) of the OFPA requires that the Secretary “shall establish an organic certification program ... and shall consult with the NOSB” (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as “Government in the Sunshine Act” (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the

need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope:** Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.
- **USDA and NOP Priority:** Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.
- **Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation. .

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List**
The NOSB has the statutory authority to consider and recommend materials for addition to,

or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

- **Changes to annotation or classification of materials**

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment.

- **Recommendation for modification of existing standards or new standards**

The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards**

The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

- **Compliance and Enforcement**

The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review**

The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

G. Designated Federal Officer

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee

meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling the meeting of the NOSB
- Approving the semi-annual meeting agenda
- Attending the semi-annual meetings
- Adjourning the meetings when such adjournment is in the public interest

H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

I. ADDITIONAL ADMINISTRATIVE ITEMS

- Official to whom the Committee Reports
The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer, the Agricultural Marketing Service's NOP Deputy Administrator.
- Staff Support
The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

- **Estimated Number and Frequency of Meetings**
The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.
- **Recordkeeping**
Records of the NOSB shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Information about the NOSB is available online at:
<http://www.ams.usda.gov/rules-regulations/organic/nosb>

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions, and the outcome of voting.

FACA requires (5 U.S.C. App. Section 10 (b)): “Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.”
Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- **Freedom of Information Act (FOIA; 5 U.S.C. 552).** Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. PROFESSIONAL AND ETHICAL STANDARDS

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

1) NOSB Member Professional Conduct Standards

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust.
- Put forth an honest effort in the performance of their NOSB duties.
- Make no commitments or promises of any kind purporting to bind the Government.
- Act impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings
- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any “specific party matters” (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP’s Advisory Board Specialist any specific party matter in which the member’s immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board’s recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB’s advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2) Additional Standards of Conduct

NOSB members should adhere to the following basic “standards of conduct” while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.

- Do not engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.
- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

3) **Failure to participate**

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary encourage the Board member to resign.

K. **DECLARATION OF INTERESTS/Conflict of Interest**

NOSB members are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe..."). As such, NOSB members are not expected to provide independent expert advice,

but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionately benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

Declarations of Interest/Conflicts of Interest Procedures

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

At the Subcommittee Level

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.
- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the subcommittee.

- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.
2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).
3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP – working with the USDA office of ethics as needed - will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.
4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.
5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the board chair, the DFO will state: "the following board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera)."
6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." This is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.
7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state "recuse" when it is his or her time to vote.

IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

- Executive (ES)
- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

Executive Subcommittee (ES)

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Subcommittee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACS)

The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)

The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)

The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)

The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)

The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS.

In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees.

Policy Development Subcommittee (PDS)

The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

B. AD HOC SUBCOMMITTEES

At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a “joint” Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the Executive Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of

conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS

Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Subcommittee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair's absence
- The Vice Chairs of the Crops, Livestock and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.

F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning

on January 24 and ending the following January 23). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

After the election of NOSB Officers at the Fall Meeting:

1. The new NOSB Chair takes Office

Immediately after the election, on the final day of the NOSB meeting, the new Chair takes office.

2. Appointment of Subcommittee Chairs

The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience.

3. Appointment of Subcommittee Vice Chair

Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

4. Timeframe for Appointments

Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

5. Review of Subcommittee Files

New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work

6. Mentorship Period

The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair of their Subcommittee until seated in their positions at the beginning of the new term on January 24. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

7. Appointment of New NOSB Members:

The Board Chair will appoint each new NOSB member to appropriate

Subcommittees as soon as possible, so that on January 24 all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

Changing Subcommittee Appointments

Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Subcommittee.

Filling a Subcommittee Chair and/or Vice Chair vacancy

If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. Development of proposals

Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

- A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
- By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting.
- When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.

A minority view should:

- Be short and concise, and include reasons for opposing the Subcommittees recommendation;
- Should not include any data or information not introduced on a Subcommittee call;
- Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;

- Will be included as a separate section at the end of the recommendation.
- The NOP will post the proposal or discussion document for public comment.
- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.
- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. Types of Proposals

(See Member Guide for examples)

There are several formats for writing proposals and discussion documents, based on the subject under review:

- Proposals related to material petitions, sunset reviews, annotation changes, or classification changes.
- Proposals for policy or procedure changes
- Discussion documents

3. Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings

NOSB Subcommittees and task forces should follow the outline below when presenting proposals or discussion documents for consideration by the Board:

1. **Introduction:** A brief summary of the issue or statement of the problem.
2. **Background:** An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
3. **Proposal:** A concise explanation of the recommended action.
4. **Subcommittee Vote:** The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, and the other a motion to list.
5. **Public Comment:** A brief summary of the public comments
6. **Minority View:** If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is “to assist in the development of standards for substances to be used in organic production” (OFPA 6518 (a)). “The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary ...” (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year “sunset” review by NOSB of all substances on the National List. The Materials Review Process is a

collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions (currently January 18, 2007 [72 FR 2167]).

1. Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines if a Technical Review (TR) is needed.
3. Technical Report is completed and sent to the Subcommittee for review.
4. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
5. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
6. The NOSB members analyze comments and votes on the proposal at the public meeting.
7. The NOSB Chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
 - OFPA Checklist, NOP 3005-1
 - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;

- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

Step 2: Determine whether a Third Party Technical Review is required

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)

OFPA states: “The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List.”(7 USC 6518 (k)(3))

The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations

In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 3: Third Party Technical Review

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 4: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor.

Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 5: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, and recommendations of a contracted panel of experts when utilized.

- Subcommittee members will prepare a written review the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.
- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 6: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

2. Changes to annotations or classification of materials.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.

- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

3. Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee makes a determination on the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.
- The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.

Link: <https://www.acquisition.gov/far/current/pdf/FAR.pdf>

4. Definitions

Technical Review - A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Technical Advisory Panel (TAP) - Group of third party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1**, above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

Priority 2: A petition to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2**, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

Priority 3: A petition to **add** a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as **Priority 3**.

Priority 4: A petition to **reconsider** adding a material that had previously been rejected by a Board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition.”

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two-thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial **Sunset List Summary** for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews**, which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees.

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in

Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

- At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances.

Note: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation or re-classifying a material, a subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

B. CONDUCTING BUSINESS

NOSB public meetings in brief:

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a

quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases of a medical situation preventing attendance in person, a virtual presence is permitted.

Decisive votes: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

Calculation of Decisive Votes

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

C. PARLIAMENTARY PROCEDURES

The NOSB adopted the use of Robert’s Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

*** Substantive vs. non-substantive amendments.**

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal
- The extent to which the effects of the recommendation differ from the effects of the proposal

Procedure for submitting final recommendations to NOP

Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

Each proposal lead prepares the following documents:

- A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
- The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, sign and date them, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Before Public Meetings:

Written submissions: allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

Oral Comments

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

Comments at In-Person Public Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- Persons will be called upon to speak according to a posted schedule. However, speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comments may be scheduled according to topic.
- Individuals providing public comment shall refrain from making any personal attacks or remarks that might impugn the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)

The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position.
- An NOSB member may self-nominate or may be nominated by another member of the NOSB.
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Subcommittee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term.
- Members may serve more than one term in any officer position.

Voting schedule

- Officers shall be elected for one-year terms by majority vote at the fall NOSB meeting.
- Newly elected officers will assume their positions at the conclusion of the fall NOSB meeting, and assume the responsibilities thereof at that time.
- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

Counting of Votes

- Voting will be by secret ballot immediately following nominations for each office
- Ballots for officers will be cast in the following order:
 1. Chair
 2. Vice Chair
 3. Secretary
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations.
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote.
- The Secretary will tally the votes after each officer nomination and the Chair will verify the results.
- The candidate receiving the greatest number of votes will be elected.
- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote or may be given the opportunity to withdraw at their discretion.
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.

G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.
- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.
- Speakers must be approved and invited by the NOP.

If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.

Speakers are expected to disclose any financial interests that he or she has that can be reasonably assumed to influence his or her presentation content.

2. Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Subcommittee before they are submitted for approval to USDA, and
- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

X. APPENDICES

A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

1.2 An organic production system is designed to:

- 1.2.1 Optimize soil biological activity;
- 1.2.2 Maintain long-term fertility;
- 1.2.3 Minimize soil erosion;
- 1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
- 1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
- 1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
- 1.2.7 Minimize pollution of soil, water, and air; and
- 1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

- 1.3.1 Providing good quality organically grown feed;
- 1.3.2 Maintaining appropriate stocking rates;
- 1.3.3 Designing husbandry systems adapted to the species' needs;
- 1.3.4 Promoting animal health and welfare while minimizing stress; and
- 1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

- 1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
- 1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;

- 1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;
 - 1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and
 - 1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.
- 1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
- 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
- 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
- 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
- 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
- 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.
- 1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

(NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

Duty of Care

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

Duty of Loyalty

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In discharging their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.
- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

Duty of Obedience

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

B. Appendix 2 – FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
 - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
 - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
 - Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage:
<http://www.gsa.gov/portal/content/100916>

This is a comparison document between the currently posted version of the NOSB Policy and Procedures Manual (April 11, 2012) and the new Feb. 29, 2016 draft. Revisions are shown in ~~strikeout~~ for deletions, and with underline for additions or rearranging.

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

- Adopted October 19, 2002
- Revised August 18, 2005
- Revised March 29, 2007
- Revised November 30, 2007
- Revised May 22, 2008
- Revised November 19, 2008
- Revised May 6, 2009
- Revised November 9, 2009
- Revised April 29, 2010
- Revised October 28, 2010
- Revised April 29, 2011
- Revised December 2, 2011
- Revised April 11, 2012
- Draft Feb. 29, 2016

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NATIONAL ORGANIC STANDARDS BOARD (NOSB-)
POLICY AND PROCEDURES MANUAL
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I. INTRODUCTION/PURPOSE

This document ~~is intended as a guide~~ provides procedures for all members the functioning of the National Organic Standards Board (NOSB). ~~Board members are entrusted with a strong responsibility to treat the business of the Board as fiduciaries for all members of the organic community and the public at large.~~

~~The Board's primary role is to advise, rather than administer and implement. As in every business, the Board's success depends heavily upon the ability to understand each other's respective role, and to develop the working relationship necessary within those roles.~~

~~This manual) and~~ is designed to assist the ~~Board~~NOSB in its responsibilities. ~~New Board~~This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the ~~Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New~~OFPA, the USDA organic regulations at 7 CFR Part 205, and the NOSB Member Guide. ~~Existing members~~Members are advised to periodically review the contents to refresh their understanding of the ~~Board's~~NOSB's role and ~~their~~ duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

—
Serve

~~New policies and revisions to existing policies and procedures will be incorporated into the NOSB Policy and Procedures Manual from time to time, as determined by the Board.~~

SECTION I

~~This section presents the NOSB's vision and mission statement as well as specifics on NOSB members' duties, and professional and ethical standards.~~

- ~~• as a link to the organic community~~
- ~~• Advise USDA on the implementation of OFPA~~
- ~~• Propose amendments to the National List of Allowed and Prohibited Substances~~
- ~~• Protect and defend the integrity of organic standards~~

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

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B. NOSB STATUTORY MISSION

“(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title.” (OFPA, Sec 2119 (a))

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C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

In carrying out the mission, key activities of the Board include:

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Assist

- Assisting in the development and maintenance of organic standards and regulations;
- REVIEW/Reviewing petitioned materials for inclusion on or DELETION/removal from the National List of Approved and Prohibited Substances (National List);
- RECOMMEND/Recommending changes to the National List;
- COMMUNICATE/Communicating with the organic community, including conducting public meetings, soliciting and TAKING/reviewing public comments **PROVIDE TIMELY INFORMATION AND EDUCATION ON THE NOP, MAKING REASONABLE USE OF A VARIETY OF COMMUNICATION CHANNELS.**
- COMMUNICATE, SUPPORT AND COORDINATE/Communicating, supporting and coordinating with the NOP staff;

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DUTIES OF THE BOARD AND OFFICERS

II. - AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The NOSB charter is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

III. NOSB ADMINISTRATION

A. NOSB defines Membership

OFPA specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;
- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry;
and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. Nomination and appointment process

(NOSB recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five year term. The terms are staggered and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following specific responsibilities for the Board starting at Sec 2119:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying

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(except the provisions of section ~~2112~~6511 of this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

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~~(Additional Duties included in Requirements. (OFPA but not limited to):~~

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~~6518(n) PETITIONS. The~~) In establishing the proposed National List or proposed amendments to the National List, the Board shall establish procedures under which persons may petition the Board for the purpose

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(1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;

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(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and

(3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List, the NOSB shall consider:

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- ~~6509(d) (2) STANDARDS.~~ the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
- the effect of the substance on human health;
- the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- the alternatives to using the substance in terms of practices or other available materials; and
- compatibility with a system of sustainable agriculture.

Petitions. (7 USC 6518(n))

The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

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Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board ~~SHALL RECOMMEND TO~~ has reviewed such exemption or prohibition as provided in this section within 5 years of such

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exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

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D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

CHAIR

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings

- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

VICE CHAIR

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval
- Assists with the annual election of NOSB officers
- May delegate tasks to others, but retains responsibility for the official record

ADMINISTRATIVE TEAM

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. . This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference once or twice a month on an as-needed basis, to be determined by the Administrative Team.

E. NOSB-NOP COLLABORATION

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to “establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation” of the Act. Section 6503 (a) of the OFPA requires that the Secretary “shall establish an organic certification program ... and shall consult with the NOSB” (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as “Government in the Sunshine Act” (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope:** Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.
- **USDA and NOP Priority:** Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.
- **Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List**
The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

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● **Changes to annotation or classification of materials**

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from [public comment](#).

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● **Recommendation for modification of existing standards or new standards**

The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. [The request will be posted on the NOP web site.](#)

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● **Advice on NOP policy and interpretation of standards**

The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

● **Compliance and Enforcement**

[The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.](#)

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● **Management Review** ~~IN ADDITION TO THOSE IN PARAGRAPH (1) FOR THE CARE OF LIVESTOCK~~

The NOSB may review the quality management system and internal audits to ensure that ~~SUCH LIVESTOCK IS ORGANICALLY PRODUCED~~ the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

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To fulfill their responsibilities, Board members agree to adhere to three duties as described in this Manual:

● **Duty of Care**

● **Duty of Loyalty**

● **Duty of Obedience**

—Duty of Care

~~The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:~~

- ~~• Be reasonably informed—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.~~

- ~~• **Participate in decisions**—Board members are bound by responsibility to be active participants in decision-making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.~~

- ~~• Make decisions with the care of an ordinary prudent person in a similar position—The law does not expect Board members to act as super human. It simply requires Board members to exercise judgment of an ordinary prudent person who may be faced with a similar issue.~~

~~**Duty of Loyalty**~~

~~The Duty of Loyalty requires Board members to exercise their power in the interest of the public and not in their own interest or the interest of another entity or person. A Board member's loyalty is to the organic community and the public at large. In discharging their Duty of Loyalty, Board members must:~~

- ~~• **Address conflicts of interest**—Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Board members may have interests in conflict with those of the public interests. Board members must be conscious of the potential for such conflicts and act with candor and care in dealing with such situations. Board members must abide by the NOSB conflict of interest policy.~~

- ~~• Recognize corporate opportunity—Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act or decline to act in regard to such transaction.~~

~~**Duty of Obedience**~~

~~Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:~~

~~**G. Act within the requirements of the law**—Board members must uphold all state and federal statutes, including the **Designated Federal Advisory Committee Act (Officer**~~

- ~~• FACA—and its implementing regulations (5 U.S.C. App. 2 et seq.) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.~~

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- ~~Follow the responsibilities of the Board as defined by the Organic Foods Production Act of 1990.~~

~~Follow the~~ The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling the meeting of the NOSB
- Approving the semi-annual meeting agenda
- Attending the semi-annual meetings
- Adjourning the meetings when such adjournment is in the public interest

H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements **SPECIFIED IN THE NOSB POLICY AND PROCEDURES MANUAL** are implemented

-

Maintaining Professional and Ethical Standards

- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

I. ADDITIONAL ADMINISTRATIVE ITEMS

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- Official to whom the Committee Reports

The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer, the Agricultural Marketing Service's NOP Deputy Administrator.

- Staff Support

The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

- Estimated Number and Frequency of Meetings

The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.

- Recordkeeping

Records of the NOSB shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Information about the NOSB is available online at:

<http://www.ams.usda.gov/rules-regulations/organic/nosb>

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions, and the outcome of voting.

FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist."

Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- Freedom of Information Act (FOIA; 5 U.S.C. 552). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with

USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. PROFESSIONAL AND ETHICAL STANDARDS

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards ~~for the conduct of all activities~~ both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

1) NOSB Member Professional Conduct Standards

~~Public service is a public trust, requiring~~ NOSB members shall:

- ~~Observe~~ ethical principles above private gain in the service of public trust.
- ~~NOSB members shall put~~ Put forth an honest effort in the performance of their NOSB duties.
- ~~NOSB members shall make~~ Make no commitments or promises of any kind purporting to bind the Government.
- ~~NOSB members shall act~~ impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings
- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any “specific party matters” (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP’s Advisory Board Specialist any specific party matter in which the member’s immediate family,

Act

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relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

All NOSB members, committee members and task force members shall not engage in a financial transaction using nonpublic information, not allow the improper use of nonpublic information to further his/her own private interest or that of another, whether through advice or recommendation, or allow the unauthorized disclosure of nonpublic information.

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Nonpublic information is members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB's advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2) Additional Standards of Conduct

NOSB members should adhere to the following basic "standards of conduct" while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.
- Do not engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing working documents with the public. Working documents are defined as information that **THE** board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public. **THIS INCLUDES INFORMATION THAT IS "ROUTINELY EXEMPT FROM DISCLOSURE IN 5 U.S.C. 552 (FREEDOM OF INFORMATION ACT) OR OTHERWISE PROTECTED FROM DISCLOSURE BY STATUTE, EXECUTIVE ORDER OR REGULATION; IS DESIGNATED AS CONFIDENTIAL BY THE AGENCY OR PROGRAM; OR HAS NOT ACTUALLY BEEN DISSEMINATED TO THE GENERAL PUBLIC AND IS NOT AUTHORIZED TO BE MADE AVAILABLE TO THE PUBLIC UPON REQUEST."**; e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.

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~~NOSB members, committee members and task force members shall keep confidential all information identified by petitioners as confidential business information.~~¹

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• To the maximum extent possible, NOSB members should speak with one voice.

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Although there may be disagreements within NOSB ~~COMMITTEE~~Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

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3) Failure to participate

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary encourage the Board member to resign.

K. DECLARATION OF INTERESTS/Conflict of Interest

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NOSB members are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe..."). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. **True conflicts of interest** arise when an interest:

- Directly and disproportionately benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

Declarations of Interest/Conflicts of Interest Procedures

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

At the Subcommittee Level

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.
- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the subcommittee.
- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP’s DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.
2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).
3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP – working with the USDA office of ethics as needed - will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.
4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.
5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the board chair, the DFO will state: “the following board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera).”
6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: “if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time.” this is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.
7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state “recuse” when it is his or her time to vote.

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IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB’s responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

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- Executive (ES)
- Certification, Accreditation, and Compliance (CACs)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

Executive Subcommittee (ES)

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Subcommittee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACs)

The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)

The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)

The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)

The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)

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The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS. In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees.

Policy Development Subcommittee (PDS)

The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

B. AD HOC SUBCOMMITTEES

At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a "joint" Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the Executive Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable

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- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS

Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Subcommittee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair's absence
- The Vice Chairs of the Crops, Livestock and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.

F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending the following January 23). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

After the election of NOSB Officers at the Fall Meeting:

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1. The new NOSB Chair takes Office

Immediately after the election, on the final day of the NOSB meeting, the new Chair takes office.

2. Appointment of Subcommittee Chairs

The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience.

3. Appointment of Subcommittee Vice Chair

Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

4. Timeframe for Appointments

Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

5. Review of Subcommittee Files

New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work

6. Mentorship Period

The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair of their Subcommittee until seated in their positions at the beginning of the new term on January 24. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

7. Appointment of New NOSB Members:

The Board Chair will appoint each new NOSB member to appropriate Subcommittees as soon as possible, so that on January 24 all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

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Changing Subcommittee Appointments

Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Subcommittee.

Filling a Subcommittee Chair and/or Vice Chair vacancy

If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. Development of proposals

Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

- A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
- By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting.
- When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.

A minority view should:

 - Be short and concise, and include reasons for opposing the Subcommittees recommendation;
 - Should not include any data or information not introduced on a Subcommittee call;
 - Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;
 - Will be included as a separate section at the end of the recommendation.
- The NOP will post the proposal or discussion document for public comment.
- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.
- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. Types of Proposals

(See Member Guide for examples)

There are several formats for writing proposals and discussion documents, based on the subject under review:

- o Proposals related to material petitions, sunset reviews, annotation changes, or classification changes.
- o Proposals for policy or procedure changes
- o Discussion documents

3. Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings

NOSB Subcommittees and task forces should follow the outline below when presenting proposals or discussion documents for consideration by the Board:

1. **Introduction:** A brief summary of the issue or statement of the problem.
2. **Background:** An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
3. **Proposal:** A concise explanation of the recommended action.
4. **Subcommittee Vote:** The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported: one for classification of the material as a synthetic or non-synthetic, and the other a motion to list.
5. **Public Comment:** A brief summary of the public comments
6. **Minority View:** If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is "to assist in the development of standards for substances to be used in organic production" (OFPA 6518 (a)). "The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary ..." (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year "sunset" review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions (currently January 18, 2007 [72 FR 2167]).

1. Steps in the material review process for a new petition:

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1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines if a Technical Review (TR) is needed.
3. Technical Report is completed and sent to the Subcommittee for review.
4. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
5. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
6. The NOSB members analyze comments and votes on the proposal at the public meeting.
7. The NOSB Chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
 - OFPA Checklist, NOP 3005-1
 - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

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Step 2: Determine whether a Third Party Technical Review is required

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During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)

OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))

The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations

In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

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Step 3: Third Party Technical Review

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.

- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 4: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor.

Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 5: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.

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- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 6: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

2. Changes to annotations or classification of materials.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

3. Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee makes a determination on the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.
- The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review.· All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.
[Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf](https://www.acquisition.gov/far/current/pdf/FAR.pdf)

4. Definitions

Technical Review - A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Technical Advisory Panel (TAP) - Group of third party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition to remove a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - Priority 1, above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

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Priority 2: A petition to remove a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a Priority 2, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

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Priority 3: A petition to add a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as Priority 3.

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Priority 4: A petition to reconsider adding a material that had previously been rejected by a Board vote would be given the lowest priority - Priority 4, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

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VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

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"No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5

~~years of such exemption or prohibition being adopted and the Secretary has NOSB members with diverse backgrounds are recruited to provide balance to the Board. While individual NOSB members represent the segments of the population from which they were selected, they also represent the greater good of the population as a whole.~~

~~• Conflict of Interest~~

~~The NOSB recognizes that members have been specifically appointed to the Board to provide advice and counsel to the Secretary concerning policies related to the development of organic standards and the creation and amendment of the National List. NOSB members have been appointed because they have professional expertise which enables them to advise the Secretary. This professional expertise may, at times, present an inherent conflict of interest. To prevent overt advocacy for direct financial gain and the appearance of self interest or the appearance of wrongful activity, the NOSB has adopted the following conflict of interest policy.~~

~~*Be it resolved by the National Organic Standards Board:*~~

~~*Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote.*~~

~~*That members of the Board shall refrain from promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall include private discussion with members of the Board advocating the value of the material, public discussion and/or written advocacy.*~~

~~*A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from a party who manufacture distributes or holds exclusive title to a formula for a material or product, process or practice.*~~

~~SECTION II~~

~~This section provides a description of the composition the NOSB. It also provides a list of expectations from members and presents guidelines for conducting business.~~

~~The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on~~

the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial **Sunset List Summary** for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews**, which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

○ At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances

Note: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider

changing an annotation or re-classifying a material, a subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. BOARD MEMBER JOB DESCRIPTIONS MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification.

The National Organic Standards Board (NOSB) fulfills three important roles

- The Board serves as the primary linkage to the organic community. In that regard, the Board must advise the NOP on the implementation of OFPA.
- The Board must approve all materials which appear on the National List.
- The Board maintains the responsibility to protect and defend the integrity of organic standards.

Composition of the Board 6518 (b)

The Board shall be composed of 15 members, of which:

- (1) four shall be individuals who own or operate an organic farming operation;
- (2) two shall be individuals who own or operate an organic handling operation;
- (3) one shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- (4) three shall be individuals with expertise in areas of environmental protection and resource conservation;
- (5) three shall be individuals who represent public interest or consumer interest groups;
- (6) one shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- (7) one shall be an individual who is a certifying agent as identified under section 2116 of OFPA. {§2119(b)}

Additionally, the position of Executive Director of the NOSB was added in 2005 to facilitate contact between NOP and NOSB

BOARD MEMBER STANDARDS

Participate in meetings — Members must make a commitment to attend meetings

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~~of the Board. Examples of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.~~

- ~~• **Serve on committees, as assigned**—Each member must be willing to serve on committees as assigned by the Chair, and to participate in the work of those committees.~~
- ~~• **Be informed about the decisions to be made**—Board members are expected to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board.~~
- ~~• **Fully disclose any conflict of interest positions**—Members having any commercial or immediate family interest that poses a potential or perceived conflict of interest must disclose that conflict to the Board and abide by any decision of the Board in dealing with the situation.~~

B. CONDUCTING BUSINESS

NOSB public meetings in brief:

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

Quorum—: As specified in OFPA, a majority of the members of the ~~Board shall constitute a quorum for the purpose of conducting business. [§2119(h)]~~ A majority of the members of a Committee, including the Executive Committee, NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases of a medical situation preventing attendance in person, a virtual presence is permitted.

Decisive votes—: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the ~~board~~NOSB at which a quorum is present shall be decisive of any motion ~~[§2119(i)].~~ Following Robert's Rules of Order, all (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast— in case of decisive votes. Similarly, all ~~Board~~NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

SECTION III

~~This section focuses on the responsibilities of the NOSB officers, as well as providing the procedures for electing officers, components of the Executive Committee and conducting meetings.~~

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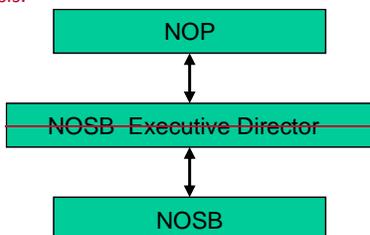
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ROLE OF THE EXECUTIVE DIRECTOR

The Executive Director (ED) of the NOSB is the operational liaison to the National Organic Program. The ED is an employee of the U.S. Department of Agriculture and works with the NOP on behalf of the Board on a standing basis.



The most important function of the ED is to facilitate the operation of the Board, while helping to maintain and strengthen its independence. Other specific functions of the ED are:

- Assist in the implementation of policies, goals, objectives, strategic plans, committee work plans, and recommendations set by the NOSB and NOP.
- Draft initial NOSB meeting agendas with NOSB Chair based on committee work plans for NOSB and NOP discussion, then finalizes agenda.
- Coordinate Board and committee meetings, and manage information reporting and communications between Board and NOP.
- Arrange, facilitate, and document in the form of written minutes the NOSB Committee conference calls necessary to achieve the most efficient workings of the Board. Minutes are distributed to committees for confirmation of accuracy and approval. Committee minutes must fully capture the discussion, reflect the diversity of opinions expressed during meetings in order that transparency exist and content remain useful for committee members, board members and our stakeholder public.
- Provide training and information to NOSB and task forces on compliance with all pertinent Acts and regulations (e.g., FACA, OFPA, NOP), including their role in advising the Secretary.
- **ESTABLISHES AND MONITORS BOARD ADHERENCE TO TIMELINES WHICH ENSURE NOP HAS SUFFICIENT TIME TO PUBLISH RELATED FEDERAL REGISTER NOTICES AND BOARD/COMMITTEE RECOMMENDATIONS THAT MEET DEADLINES FOR public comment.**
- Manage Board calendar and tracking databases in a manner that facilitates clarity of activities to the Board and the NOP.
- Work as liaison with NOP staff, TAP & technical review contractors and other government agencies (e.g., EPA, FDA, AAFCO).
- **ENSURE BOARD MEMBERS HAVE ALL MATERIALS AND INFORMATION NECESSARY TO PROVIDE INFORMED, STRUCTURED AND TIMELY RECOMMENDATIONS TO THE NOP FOR PROPOSED AMENDMENTS AND GUIDANCE DOCUMENTS TO NOP REGULATION 7 CFR 205. THIS INCLUDES THE PROVISION OF PETITIONS, TAP AND TECHNICAL REVIEWS, AND HISTORIC DISCUSSIONS OF SUBSTANCES PROPOSED FOR INCLUSION ON THE NATIONAL LIST, AS WELL HISTORIC DISCUSSIONS AND RECOMMENDATIONS REGARDING ISSUES.**

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- ~~Maintain executive committee meeting minutes and committee meeting minutes, committee records, reports, transcripts, appendices, working papers, drafts, studies, agendas and other documents which were made available to or prepared for or by the NOSB or its committees, and make such documents available for public inspection and copying at the Agency, electronically via the World Wide Web; and/or, upon written request in printed form.~~
- ~~Prepare and clear Federal Register Meeting Notice and News Release, ensuring publication 45 days prior to meeting.~~
- ~~Ensure proposed additions to the National List, or other recommendations, are posted on the NOSB website for 45 days prior to an NOSB meeting to allow for public comment.~~
- ~~Provide accurate, clear pre-meeting information to public regarding questions on recommendations.~~
- ~~Ensure NOSB members have timely access to public comments.~~
- ~~Schedule public comment according to issues, and accommodates commenters' travel schedules, where possible.~~
- ~~Ensure that Board members and NOP staff at NOSB meetings have access to relevant documents related to petitions, materials due to sunset, technical reviews, etc. The format could be electronic (CD version) or hard copy.~~
- ~~Track recommendations, changes, and votes during meeting to ensure accurate meeting transcripts.~~
- ~~Assist the NOSB Officers as needed, including scheduling and participating in Officer calls, and assisting the Secretary during Board meetings in managing public comments, summary of minutes, committee votes, election of officers, Board meeting breaks. Also stays apprised and assist as needed in committee meetings scheduled before, during and after Board meetings.~~

OFFICER RESPONSIBILITIES

Three principal officers — Chair, Vice Chair and Secretary — guide the Board.

Chair

The Chair is responsible to assure the integrity of the Board process, including effectiveness of meetings and the board's adherence to its own rules. The Chair shall:

- ~~Schedule meetings of the Board and the Executive Committee;~~
- ~~Draft meeting agendas in consultation with committee chairs and NOP staff;~~

CONVENE AND PRESIDE AT MEETINGS;

- ~~Review committee work plans;~~
- ~~Review meeting minutes for accuracy, and~~
- ~~Assist with the annual election of NOSB officers.~~

Vice Chair

The Vice Chair shall act in the absence of the Chair. The Vice Chair shall serve as a member of the Policy Development Committee, and work collaboratively with the PDC's members on the maintenance and upkeep of the Policy and Procedures Manual.

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Secretary

The Secretary will work with the NOP Executive Director (ED) to assist in maintaining the integrity of all legal and governing documents of the Board. It is the Secretary's responsibility to help the ED:

- Make sure official NOSB transcripts are posted for the public;
- Record all committee votes at NOSB meetings and circulate to the NOSB for approval;
- Review all additions to the Federal Register to report any discrepancies between Board recommendations and those published in the Federal Register;
- Transfer custody of the Board's vote records to the Secretary's successor, and
- Assist with the annual election of NOSB officers.

The Secretary may delegate tasks to others, but retains responsibility for the official record.

Administrative Team

The Administrative Team consists of the Chair, Vice Chair, Secretary and Executive Director. This group may meet on a weekly basis or as needed by teleconference or correspond by email in order to coordinate the overall logistics and operations of the board, the officer responsibilities noted above, and the overall support provided to the Board by the Executive Director.

A. ELECTION OF OFFICERS

A. NOMINATION

- **ALL INTERESTED NOSB MEMBERS ARE ELIGIBLE FOR CONSIDERATION FOR ANY OFFICER POSITION.**
- **CANDIDATES MAY BE SELF-NOMINATED OR NOMINATED BY ANOTHER MEMBER OF THE BOARD.**
- **SHOULD THE CHAIR, VICE CHAIR, OR SECRETARY RESIGN OR FAIL TO SERVE THE FULL TERM, THE EXECUTIVE COMMITTEE SHALL APPOINT AN INTERIM OFFICER.**
- **THE INTERIM OFFICER SHALL SERVE IN THE CAPACITY UNTIL THE NEXT REGULARLY SCHEDULED MEETING OF THE BOARD, DURING WHICH AN ELECTION WILL BE HELD TO FILL THE REMAINDER OF THE TERM.**
- **MEMBERS INTERESTED IN SERVING MORE THAN ONE CONSECUTIVE TERM IN AN OFFICER POSITION CAN IF THE BOARD IS IN FAVOR; HOWEVER IT IS RECOMMENDED THAT AN OFFICER NOT SERVE FOR MORE THAN TWO CONSECUTIVE TERMS.**

B. VOTING SCHEDULE

- **OFFICERS SHALL BE ELECTED FOR TERMS OF ONE YEAR BY MAJORITY VOTE AT THE ANNUAL FALL MEETING OF THE BOARD.**

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- ~~NEWLY APPOINTED OFFICERS WILL ASSUME THEIR POSITIONS AT THE CONCLUSION OF THE FALL BOARD MEETING PURSUANT TO THE ELECTION.~~
- ~~ACTING BOARD OFFICERS WILL ASSIST THE NEW OFFICERS TO TRANSITION INTO THEIR NEW ROLE.~~

~~C. ELIGIBILITY TO VOTE~~

- ~~ONLY NOSB BOARD MEMBERS PRESENT ARE ELIGIBLE TO VOTE FOR NOMINATED OFFICERS.~~
- ~~ABSENT NOSB MEMBERS WILL NOT BE ELIGIBLE TO VOTE.~~
- ~~BOARD MEMBERS SHALL BE ENTITLED TO CAST ONE VOTE PER NOMINATION.~~

~~D. COUNTING OF VOTES~~

- ~~VOTING WILL BE BY BALLOT IMMEDIATELY FOLLOWING NOMINATIONS FOR EACH OFFICE.~~

~~Ballots for officers will be cast in the following order:~~

- ~~Chair~~
- ~~VICE-CHAIR~~
- ~~SECRETARY~~

- ~~THE BALLOTS WILL BE COUNTED FOR ONE OFFICE AND THE ACTING CHAIR WILL ANNOUNCE THE TALLY BEFORE THE NEXT OFFICE IS OPENED FOR NOMINATIONS~~
- ~~THE ACTING SECRETARY WILL PREPARE AND DISTRIBUTE THE BALLOTS AND WILL GATHER THE VOTES BY SECRET BALLOT.~~
- ~~THE ACTING CHAIR WILL TALLY THE VOTES AFTER EACH OFFICER NOMINATION AND THE ACTING SECRETARY WILL VERIFY THE VOTE RESULTS.~~
- ~~THE CANDIDATE RECEIVING THE LARGEST NUMBER OF VOTES WILL BE ELECTED.~~
- ~~IN THE EVENT OF A TIE THERE WILL BE A REVOTE UNTIL A NOMINEE OBTAINS MAJORITY. ALL NOMINEES WILL BE INCLUDED IN THE REVOTE OR MAY BE GIVEN THE OPPORTUNITY THE WITHDRAW AT THEIR DISCRETION.~~
- ~~MEMBER VOTE COUNTS WILL REMAIN CONFIDENTIAL. OTHER NOSB MEMBERS WILL NOT BE ALLOWED TO DETERMINE HOW THE MEMBERS VOTED.~~
- ~~VOTES WILL BE DISPOSED OF BY THE CHAIR OR SECRETARY.~~

Calculation of Decisive Votes

<u># Votes Cast</u>	<u># Recusals and Abstentions</u>	<u>2/3 Majority*</u>
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<u>14</u>	<u>1</u>	<u>10</u>
<u>13</u>	<u>2</u>	<u>9</u>
<u>12</u>	<u>3</u>	<u>8</u>
<u>11</u>	<u>4</u>	<u>8</u>
<u>10</u>	<u>5</u>	<u>7</u>
<u>9</u>	<u>6</u>	<u>6</u>
<u>8</u>	<u>7</u>	<u>6</u>

C. PARLIAMENTARY PROCEDURES

The NOSB adopted the use of Robert’s Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

*** Substantive vs. non-substantive amendments.**

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal

~~The **ACTING SECRETARY WILL RECORD NEWLY ELECTED OFFICERS INTO THE NOSB MEETING SUMMARY** EXTENT TO WHICH THE EFFECTS of MINUTES.~~

~~**EXECUTIVE COMMITTEE**~~

- ~~The Executive Committee~~the recommendation differ from the effects of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of the standing committees. The Executive Committee, with participation of the NOP, shall meet monthly, as needed, or as called by the Chair, and shall conduct business on behalf of the Board. Only the full Board may take decisive action on guidance and other policy recommendations from

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~~committees, including the status of materials proposed for addition or deletion on the National List. The Executive Committee will provide guidance and feedback to Committees on their proposed work plans.~~proposal

~~MEETINGS~~

~~All Board meetings, conference calls, and bulletin board assembled for the purpose of making recommendations to the NOP are subject to FACA (see appendix B for FACA facts). In particular, these must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples are: assemblies for completing work, planning retreats, training and sharing information. At this time, full Board conference calls or full Board assembly via electronic bulletin board are not permitted. The date and location of periodic full in person Board Meetings (normally twice a year), will to the extent possible, be set by consensus of the Board in consultation with the NOP.~~

~~SECTION IV~~

~~BOARD COMMITTEES~~

~~Committees play an important role in administering the Board's responsibilities. Committees exist to provide greater depth and clarity in the Board's responsibility to make informed decisions. For example, at the request of the Secretary seeking advice on a matter related to the NOP, the full Board may request that a committee conduct research and analysis or draft proposed recommendations to be considered by the full Board. Except for the Executive Committee, no committees are authorized to act in place of the Board. Committees are empowered to analyze information and bring draft recommendations to the Board for action.~~

~~Committee chairs are appointed by the Board Chair. The current standing committees are:~~

- ~~• Certification, Accreditation, and Compliance~~
- ~~• Crops~~
- ~~• Handling~~
- ~~• Livestock~~
- ~~• Materials~~
- ~~• Policy Development~~

~~The Livestock Committee, the Crops Committee and the Handling Committee will each have co-chairs. One co chair will guide all committee discussion and will oversee the committee's work plan. The other co chair will be responsible for the committee's consideration of materials and will serve as the liaison to the Materials Committee.~~

- ~~1. Committee recommendations are finalized by the NOSB according to the following process:~~
- ~~2. Committee drafts the recommendation.~~
- ~~3. Draft recommendation is posted for public comment.~~
- ~~4. Public comments are considered by committee when making recommendation to the Board.~~
- ~~5. Board takes action on the recommendation~~

Board actions may include adoption of the recommendation as presented by the committee, amending and then adopting the recommendation, rejecting the recommendation, or referring the recommendation back to committee for further development.

COMMITTEE MEETINGS

Committees may hold meetings via telephone conference calls. Two weeks' notice should be provided in scheduling such calls. The date and time set for the call is a product of committee dialog regarding the most conducive schedule. This dialog may occur on a previous conference call or through E-mail. All E-mail requests for meeting times should allow 48 hours to respond.

Emergency calls may be scheduled with less notice only after each member is contacted to reach a consensus on time and date of ~~the meeting~~. If the members do not respond to E-mail requests, the chair or their designee must contact the member by phone.

STANDING COMMITTEES

~~Certification, Accreditation, and Compliance Committee (CACC)~~ The Certification, Accreditation, and Compliance Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of certification, accreditation and compliance sections of the organic regulations [7CFR Part 205] and OFPA. The CACC occasionally works with other committees to develop joint recommendations where certification and compliance issues are involved.

~~Crops Committee (CC)~~ The Crops Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the crop production section of the organic regulations as contained in [7CFR Part 205] and OFPA. The CC reviews petitions, substances scheduled to sunset, technical advisory panel reports, and public comments concerning materials used for crop production which have been requested for addition to or removal from the National List. The CC occasionally works with other committees to develop joint recommendations where crop issues are involved.

~~Handling Committee (HC)~~ The Handling Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the handling and labeling sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The HC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for processing and handling which have been requested for addition to or removal from the National List. The HC occasionally works with other committees to develop joint recommendations where handling issues are involved.

~~Livestock Committee (LC)~~ The Livestock Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the livestock and livestock feed sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The LC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for livestock production which have been requested for addition to or removal from the National List. The LC occasionally works with other committees to develop joint

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recommendations where livestock issues are involved.

~~**Materials Committee (MC)** The Materials Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The MC works with the NOP, NOSB Committees and TAP Contractors in managing the Materials Review Process including tracking petitions, sufficiency reports, materials scheduled to sunset and sunset review process. In addition to a chair appointed by the Board Chair, the MC shall include in its membership one of the co chairs from each of the Livestock, Crops, and Handling committees. Other members may be appointed as needed. The MC occasionally works with other committees to develop joint recommendations where materials are involved.~~

~~**Policy Development Committee (PDC)** The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual (in collaboration with the NOSB Vice Chair) and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.~~

~~**A. TASK FORCES**~~

~~As determined by the Board or Executive Committee, task forces shall be appointed to explore specific issues and present draft recommendations to the Board or to a committee. Task forces may include non-Board members of the public. Each task force shall include at least one member of the NOSB. Minutes shall be taken of task force meetings. Each task force shall submit a final report to the Board. Each task force shall be disbanded when its work has concluded or when the Board determines the task force is no longer necessary.~~

~~**Procedure for submitting final recommendations to NOP**~~

~~Within 30 days after the completion of the NOSB meeting all final~~

~~**AD-HOC COMMITTEES**~~

~~At the discretion of the NOSB Chairperson, with approval of the Executive Committee, an ad hoc NOSB committee may be formed to develop policy and guidance on specific issues that involve multiple standing committee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc committees may be comprised only of current NOSB members, and could either be a combination of two or more standing committees to form a "joint" committee, or could be a totally new committee comprised of selected NOSB members from various standing committees. Ad hoc committees can be dissolved at the recommendation of the NOSB chairperson with the approval of the executive committee. The position of the ad hoc committee chairperson is a non-voting member of the executive committee.~~

~~**SECTION V**~~

~~This section defines the responsibilities of the different committee chairs and respective vice chairs. It also provides indications on writing committee recommendations and presenting such~~

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~~recommendations for vote at NOSB meetings. Lastly, this section covers general and specific collaboration procedures between NOSB and NOP.~~

~~DUTIES OF COMMITTEE CHAIRS~~

~~Committee chairs are responsible for the following duties:~~

- ~~• Schedule committee meetings as needed.~~
- ~~• Draft committee meeting agendas and work plans in consultation with committee members, the Executive Committee, and NOP staff.~~
- ~~• Convene and preside committee meetings.~~
- ~~• Ensure committee meeting minutes are recorded.~~
- ~~• Review committee meeting minutes for accuracy.~~
- ~~• Report actions of the committee to the Board.~~
- ~~• Name a committee vice chair.~~
- ~~• Serve as mentor/trainer for new committee chair during transition periods.~~

~~Committee chairs shall not act unilaterally, especially concerning issues which involve statutory responsibilities of the Board.~~

~~DUTIES OF COMMITTEE VICE-CHAIRS~~

~~Committee vice chairs are responsible for the following duties:~~

- ~~• Provide support in developing and completing committee work plans.~~
- ~~• Assist in reviewing of committee meeting minutes for accuracy.~~
- ~~• Represent the committee chair in the absence of the chair.~~
- ~~• Vice Chairs of the Crops, Livestock and Handling Committees will serve on the Materials Committee as liaison for reviewing all petitioned substances.~~

~~Committee vice chairs shall not act unilaterally, especially concerning issues which involve statutory responsibilities of the Board.~~

~~PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS, VICE-CHAIRS, AND MEMBERS~~

~~Committee Chairs, Vice-Chairs and members shall be appointed to serve annually by the Chair of the Board. The annual committee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending on the following January 23). Newly appointed Chairs, Vice-Chairs and committee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice-Chair, and members.~~

In order to avoid disruption in the quality and volume of work produced by the NOSB, the appointment of committee chairs will follow these procedures during the following transition times:

AFTER ELECTION OF NOSB OFFICERS AT FALL NOSB MEETING:

APPOINTMENT OF COMMITTEE CHAIRS

THE BOARD CHAIR SHOULD APPOINT COMMITTEE CHAIRS FROM MEMBERS WITH AT LEAST ONE YEAR OF NOSB EXPERIENCE, IDEALLY, IT IS RECOMMENDED THAT A NEW COMMITTEE CHAIR SHOULD HAVE EXPERIENCE AS COMMITTEE VICE-CHAIR.

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Appointment of Committee Vice-Chairs

A Committee Vice-Chair shall be appointed by the Committee Chair and should be someone who has expressed to the Chair of the Committee interest in eventually serving as Committee Chair.

Time Frame for Appointments

Committee Chairs shall be appointed as Incoming Chairs in not more than 30 days after the newly elected NOSB Chair takes office (or continues in office), and incoming Vice-Chairs shall be appointed by Committee Chairs in no more than two weeks after that.

Exchange of Committee Files

Upon appointment, new and outgoing Committee Chairs should have a formal meeting to exchange all files related to the committee's work and to complete the first committee work plan under the new committee leadership.

Review of Committee Files

New Committee Chairs should review all work plan items and active files involving committee work.

Mentorship Period

The Incoming Chair and Vice-Chair of each committee shall participate in an orientation and mentorship period with the outgoing Chair and Vice-Chair of their committee until being seated in their positions at the beginning of the new term on January 24.

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After the Appointment of the New NOSB Members (prior to January 24):

New Committee Member Appointments

New incoming committee members shall be appointed by the Board Chair, in consultation with the outgoing and incoming committee Chairs, no more than two weeks after the appointment of the new NOSB members by the Secretary, with the Chair seeking and taking into account the expressed member interest, expertise, background, as well as new board composition.

Communication with Newly Appointed Members

Once appointed, incoming committee members shall be included in all emails pertaining to the committee assignments.

Attendance at Committee Meetings and Fall NOSB Meeting

New incoming members of the committee should participate in observer status in

committee meetings upon their appointment, and should be encouraged to attend the Fall Board meeting.

- ~~New Member Mentorship~~

~~The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in committee and board deliberations, shall ask incoming Board members to identify a mentor from existing Board members as soon after their appointment as possible, but no later than two weeks, or, if the Board member prefers or the Board member takes no action, the Board Chair shall assign a mentor in same time frame.~~

~~Between Board Appointments and Fall Board Meeting:~~

- ~~Changing Committee Appointments~~

~~If a Board member would like to change committees, either adding to or stepping down from his/her assignments, a request shall be made to the Board Chair. If the request does not alter the preferred number of committee members in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair states in writing that such change will interfere with the functioning of the committee. The Chair's determination should be made in consultation with Committee Chairs and the Executive Committee.~~

- ~~Filling Vacancy of Committee Chair and/or Vice Chair~~

~~In the case of a vacancy in the positions of Committee Chair, the Committee Vice-Chair shall assume the Committee Chair position and the new Committee Chair shall appoint a new Vice-Chair in accordance with the consultation procedures cited above.~~

PROCEDURES FOR COMPLETING COMMITTEE RECOMMENDATIONS

Developing committee recommendations follows these broad steps:

- ~~1. THE COMMITTEE PREPARES A RECOMMENDATION OR DISCUSSION DOCUMENT AS AGREED TO IN THE COMMITTEE WORK PLAN (SEE P. 32 PPM).~~**
- ~~2. THE RECOMMENDATION OR DISCUSSIONS DOCUMENT IS POSTED FOR PUBLIC COMMENT.~~**
- ~~3. DURING THE BOARD MEETING, THE COMMITTEE PRESENTS ITS RECOMMENDATION FOR DISCUSSION BY THE FULL BOARD.~~**
- ~~4. AT ANY POINT IN THE PROCESS PRIOR TO THE BOARD'S VOTE ON THE STATUS OF THE RECOMMENDATION, THE PRESENTING COMMITTEE MAY CONVENE AND VOTE TO WITHDRAW ITS RECOMMENDATION, BASED ON APPROVAL OF THIS ACTION BY THE MAJORITY OF THE MEMBERS OF THE COMMITTEE.~~**

5. ONCE PRESENTED, THE BOARD VOTES ON THE COMMITTEE RECOMMENDATION.

In order to be considered a voting item, all recommendations must be submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting. This time is needed in order to allow the Program to publish a meeting notice and allow for public comment. using the following procedure:

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The Board may take Each proposal lead prepares the following actions for each committee documents:

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- o A recommendation: cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)

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1. Adopt the recommendation as presented by the committee;
2. Amend and adopt the amended recommendation;
3. Reject the recommendation; or
4. Refer the recommendation back to the committee for further development.

-
-
-
- Writing Committee Recommendations

This section provides an outline to be used by committees in writing a recommendation document. These guidelines not only allow consistency in the content of NOSB recommendations, but should also provide the NOSB, and the public, a fast manner to weigh the advantages and disadvantages of a proposal.

Recommendations not related to material petitions or sunset reviews, should include the following sections:

I. Introduction:

This section consists of a brief summary of the recommendation, its main issues and its relevance to the organic community. This section should also mention the goals and intent of the proposed recommendation.

II. Background:

This section should present the issues that justify the development of the recommendation as well as any relevant work done by the NOSB in the past.

III. Relevant areas in the Rule:

~~This section should mention any areas of the Rule or OFPA which provide the basis for the recommendation.~~

~~IV. Discussion:~~

~~This section should be used to expand on the intent of the recommendation. It is also a place to emphasize the SWOT of the recommendation (strength, weaknesses, opportunities and threats). No recommendation is 100% perfect and this section can serve to clarify the tradeoffs and advantages of a recommendation. Thus, it is advisable to mention all major alternatives reviewed by the committee. If appropriate, different stakeholders groups should be identified indicating how each group's needs are met or affected.~~

~~V. Recommendation:~~

~~This is the core, or deliverable, of the recommendation.~~

~~VI. Committee Vote:~~

~~This section should present the names of the members who moved and second the motion to approve the recommendation. As a norm, a motion should always be presented in the affirmative. In the case of recommendations for petitions to add materials to the National List, two votes should be taken and recorded, the first for a synthetic or non synthetic material classification, and the second to list or not list the material. The record should list the number of synthetic and non synthetic votes, yes and no votes for listing, and the number of abstentions and absences.~~

Minority opinion:

~~If applicable, the dissenting opinion(s) of committee or task force members shall be reported. A member of a committee can present a minority report to the committee recommendation. Such document should include reasons for opposing a proposed recommendation and cite where the opposition points are in the recommendation. In addition, the minority report could, provide alternative approaches or solutions from those given in the recommendation, or recommend an amendment to the recommendation. The minority opinion will be included as a separate document at the end of the recommendation.~~

~~Recommendations related to material petitions or sunset reviews, should include the following sections:~~

- ~~I. **List:** This section identifies the placing of the material under review within the National List. Any annotations related to the material should be included.~~
- ~~II. **Committee Summary:** This section should present a brief background of the material under review highlighting its uses and past NOSB decisions. It should include a short description of any current research done by the committee (e.g., review of technical reports, individual investigation, etc.) and should provide a description of the main arguments supporting the committee's final decision. This section should mention any areas of the Rule or OFPA which provide the basis for the recommendation.~~
- ~~III. **Committee Recommendation:** The committee recommendation should be stated clearly here including any corresponding annotation.~~
- ~~IV. **Committee Vote:** This section should present the names of the members who moved and second the motion to approve the recommendation and vote count. As a norm, a motion for a petitioned material or sunset review should always be presented in the affirmative.~~

Minority opinion:

~~Presenting Committee Recommendations at NOSB Meetings~~

~~NOSB committees and task forces will follow the outline presented below in order to present draft policy and/or material recommendations for consideration by the Board:~~

- ~~I. **Introduction:** A brief summary of the issue or statement of the problem.~~
- ~~II. **Background:** An explanation with sufficient detail and rationale to support a proposed recommendation, including reasons why the recommendation should be adopted, historical context, and the regulatory framework pertinent to the issue.~~
- ~~III. **Recommendation:** The concise text of the recommended action.~~
- ~~IV. **Committee vote:** The vote of the committee or task force shall be reported. In the case of recommendations for petitions to add materials to the National list, two votes will be recorded, one for synthetic or non-synthetic material classification, and the other for listing or not.~~

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V. **Minority opinion:** If applicable, the dissenting opinion(s) of committee or task force members shall be reported.

NOSB-NOP COLLABORATION

~~The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the Act. In 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution to accomplish this and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture.~~

~~The mutual goals to advance the integrity of organic products, principles and products can best be accomplished through team work and cooperation between the NOSB and the NOP and is implemented regularly through two way feedback by the NOSB Executive Director and periodically at the Executive Committee's monthly calls. Especially at these calls, NOSB committee work plans and priorities are discussed and NOP requests and opinions are aired.~~

~~An effective collaboration process between the NOP and the NOSB should ensure that NOP receives NOSB input and feedback, and vice versa. The process can be complicated due to several factors like the following:~~

- ~~• The NOSB is a FACA advisory committee, and as such, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).~~
- ~~• The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. However, the NOSB has unique statutory authority related to the determination of materials as approved or prohibited substances for inclusion on the National List.~~
- ~~• The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, or initiate policies on its own accord.~~

~~Several collaboration approaches may be required depending on the type of issue faced by the Board. Below are descriptions of the most common situations faced by the NOSB. In all cases, the end product should be a recommendation by the Board to the NOP and each recommendation should be accompanied by a cover sheet illustrated in figure 1.~~

1. Materials proposed to be added to or removed from the National List.

~~The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances, or to add, remove, or modify annotations restricting the use of such listed materials.~~

2. Recommendation for modification of existing standards or new standards.

~~The NOSB will use the decision making procedures outlined in Section VIII to justify modifying existing standards or proposing new standards. The NOP may request that the NOSB develop~~

recommendations for new or existing standards. The request should be in writing and should include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal situation, and desired timeframe for receiving the recommendation. ~~The request will be posted on the NOP web site.~~

- o ~~Providing advice~~ The proposal that was voted on ~~NOP policy~~ at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and ~~interpretation~~ completeness, sign and date them, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of ~~standards~~. ~~An examples~~ people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Before Public Meetings:

~~3.~~ **Written comment:** All members of the public are ~~NOSB providing encouraged to submit~~ public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read ~~comments on specific actions by the NOP, such as the yeast and compost policies~~ in advance, eliminate or decrease the need for paper copies to be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

4. Compliance and Enforcement.

~~The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. As timely and appropriate, the NOP reports to NOSB on the status of enforcement actions and also posts the status on the NOP web site.~~

5. Management Review.

NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB has a role to play in terms of seeing that corrective actions with OIG are completed.

In all the above situations, FACA procedures must be carefully followed to provide transparency and necessary public input.

The primary means of collaboration will be through NOP participation in Executive Committee (EC) and Standing Committee calls. The NOP Deputy Administrator or designee will participate in all EC calls. The NOSB Executive Director (ED) will participate in all NOSB calls as described in the ED duties in the PPM. Upon request and mutual agreement, the Deputy Administrator will participate in Standing Committee calls. In addition, each Standing Committee will be assigned an NOP staff person to provide additional technical, legal, and logistical support.

Work plans for action items are developed for each upcoming public board meeting. This is the

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~~mode for developing recommendations and discussion documents. Work plan procedures are described in detail in Section VIII, page 32. The proposed work plans are presented and discussed at each public board meeting, but may be revised based on comments and Board priorities and resources.~~

~~NOP publicly made requests at board meetings are important considerations in the development of Committee work plan. These NOP requests to NOSB will be followed up in writing stating the problem to be addressed, background, statutory authority and the time frame for response. The proposed Committee Work plans will be reviewed at the next EC call following the Board meeting, with participation by the NOP Deputy Administrator. This participation in the development of work plans is vital for effective NOSB/NOP collaboration. Due to change in circumstances, these work plans may need to be revised prior to the posting of the final agenda of the upcoming Board meeting. Committee work plan changes will be done in consultation and full knowledge of the EC and NOP.~~

Figure 1: Form Used to Submit NOSB Final Recommendations to the NOP
(Non-Materials Recommendations)

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: _____

Subject: _____

Chair: _____

The NOSB hereby recommends to the NOP the following:

Rulemaking Action _____

Guidance Statement _____

Other _____

Statement of the Recommendation (Including Recount of Vote):

Rationale Supporting Recommendation (including consistency with
OFPA and NOP):

Committee Vote:

Moved: _____ Second: _____

Yes: ___ No: ___ Abstain: ___ Absent: ___ Recusal: ___

SECTION VI

MISCELLANEOUS POLICIES

~~NOSB Policy for Presenters Invited by Committees~~

- ~~• Need for presentation established within the appropriate committee by the committee chairperson.~~
- ~~• The committee chairperson should notify the NOSB Chair with a request to issue an invitation at least 45 days prior to meeting. Exceptions are at the discretion of the NOSB Chair.~~
- ~~• Presenter(s) must be invited by committee chair and/or NOSB Chair and approved by the NOSB Chair.~~
- ~~• Reason(s) for presentation, subject area and bio/resume of presenter(s) to be circulated via email to entire board at least 2 weeks prior to meeting.~~
- ~~• Invited presenter(s) must provide objective information.~~
- ~~• Presenter(s) cannot be a petitioner on the topic under discussion.~~
- ~~• Presenter(s) must disclose any actual or perceived conflict of interest including information concerning who provided funding for the presentation.~~

~~NOSB Policy for Surveys Conducted on Behalf of NOSB Committees~~

- ~~1. All surveys, including electronic surveys, conducted in the name of any NOSB Committee, must be approved by the NOSB Executive Committee before they are submitted for approval to USDA, which must submit for approval to the Office of Management and Budget (OMB); and~~
- ~~2. A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.~~

Public Comment at NOSB

Oral Comments

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give

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the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

Comments at In-Person Public Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. ~~However, the NOSB will attempt to accommodate all persons requesting public comment time.~~ Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP, working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. ~~Advance~~Written submissions allow NOSB members the opportunity to read comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.
- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- ~~• Persons must give their names and affiliations for the record at the beginning of their public comment.~~
- ~~• Proxy speakers are not permitted.~~
- Public ~~comment requests~~comments may be scheduled according to topic.
- Individuals providing public comment ~~will~~shall refrain from making any personal attacks ~~and from~~or remarks that ~~otherwise might~~ impugn the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.
- ~~• Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a~~

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~~comprehensible understanding of the speaker's concerns.~~

~~Adopted October 17 2012; 15 yes, 0 no, 0 absent, 0 abstain, 0 recuse~~

Policy for Public Communication between NOSB Meetings-

(Adopted April 11, 2013)

The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position
- An NOSB member may self-nominate or may be nominated by another member of the NOSB
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Subcommittee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term
- Members may serve more than one term in any officer position.

Voting schedule

- Officers shall be elected for one-year terms by majority vote at the fall NOSB meeting.
- Newly elected officers will assume their positions at the conclusion of the fall NOSB meeting, and assume the responsibilities thereof at that time
- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

Counting of Votes

- Voting will be by secret ballot immediately following nominations for each office
- Ballots for officers will be cast in the following order:
 1. Chair
 2. Vice Chair
 3. Secretary
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote
- The Secretary will tally the votes after each officer nomination and the Chair will verify the results
- The candidate receiving the greatest number of votes will be elected
- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote or may be given the opportunity to withdraw at their discretion
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.

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G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.
- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.
- Speakers must be approved and invited by the NOP.

If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.
Speakers are expected to disclose any financial interests that he or she has that can be reasonably assumed to influence his or her presentation content.

2. Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Subcommittee before they are submitted for approval to USDA, and
- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

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APPENDICES Adopted April 11 2013; 15 yes, 0 no, 0 absent, 0 abstain, 0 recuse
SECTION VII

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X.

A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

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(NOSB Recommendation Adopted October 17, 2001)

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1.1.4.1—Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

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1.2

1.2 An organic production system is designed to:

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1.2.1 Optimize soil biological activity;

1.2.2 Maintain long-term fertility;

1.2.3 Minimize soil erosion;

1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;

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1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;

1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;

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1.2.7 Minimize pollution of soil, water, and air; and

1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

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1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

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1.3.1 Providing good quality organically grown feed;

1.3.2 Maintaining appropriate stocking rates;

1.3.3 Designing husbandry systems adapted to the species' needs;

1.3.4 Promoting animal health and welfare while minimizing stress; and

1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

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1.4 Organic handling practices are based on the following principles:

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1.4.1 Organic processors and handlers implement organic good manufacturing and handling

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- practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
- 1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
 - 1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;
 - 1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and
 - 1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.
- 1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
 - 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
 - 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
 - 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
 - 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
 - 1.10 —Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
 - 1.11 —Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (~~geo/gmo's~~GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.
 - 1.12 —Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

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2. **NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING**
(NOSB Recommendation Adopted April 29, 2004)

A significant task responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

1. Does the substance promote plant and animal health by enhancing the soil's physical, chemical, or biological properties?
2. Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
3. Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
4. Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
5. Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
6. Does the substance allow for an increase in the long-term viability of organic farm operations?
7. Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
8. If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
9. Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
10. Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
11. Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
12. Does use of the substance have a positive impact on biodiversity?

Adopted April 29, 2004 – 13 yes, 0 no, 1 absent

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SECTION VIII

3. PROCEDURES OF THE NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

Duty of Care

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

Duty of Loyalty

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In dispatching their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.
Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

Duty of Obedience

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing.

COMMITTEE WORK PLANS

At the end of every NOSB meeting, each committee chair is required to present the committee's work plan. Given the nature, and number, of the issues the Board handles, it is important for a committee to follow a structured procedure for assigning priorities in the work plan. The following provides a guideline on how to develop a committee work plan. The committee chair, working with the committee, should follow three general steps in producing a work plan: 1) List all issues before the committee; 2) Prioritize each issue; 3) set a calendar; and 4) Obtain feedback from the Executive

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Committee and the Program.

To this effect, Board members must:

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)

Adhere to the responsibilities of the Board.

~~Step 1- Identifying all issues~~

The committee work plan rises out of these main situations:

- ~~Items committed, or assigned to a committee, by the Board during an official session.~~
- ~~Items that are reviewed by a committee on a regular basis such as materials sunset review or petitions submitted by members of the public.~~
- ~~Requests or suggestions from the National Organic Program such as clarifications on a particular issue or guidance on enforcement.~~
- ~~Proposals stemming from the committee members' contact with the organic community.~~

~~In many cases not all issues should be the responsibility of the committee. Selecting what the committee should be reviewing can be done based on the following criteria:~~

- ~~Relevance to the organic community (Is this an important issues? vs. Is this an interesting issue?)~~
- ~~Criticality regarding mandate (is the issue within the committee's or the NOSB's realm?)~~
- ~~Feasibility in terms of the Rule (can a proposal by the committee be realistically enforced by the NOP?)~~

~~Step 2- Prioritizing the issues~~

~~After listing the issues to review, the committee should prioritize its work plan items according to the following criteria:~~

- ~~Preference given to petitioned materials~~
- ~~Relevance to the organic community, public at large and the environment~~
- ~~Size of the population affected by the issue~~
- ~~Timeline since the issue/petition was submitted~~

~~The criteria are presented in order of importance and should be used to rank or prioritize each issue accordingly. For example, a petitioned material has priority over an issue that has been waiting to be reviewed for an extended period of time.~~

~~Step 3- Setting a calendar for reviews~~

~~Once the issues are prioritized, the committee chair should define a calendar for discussion of each issue. The calendar should allow committee members to understand specific deadlines and should reflect the posting/publication target dates mandated by the Program and the Federal Regulation.~~

~~Step 4- Incorporating Input from the Executive Committee~~

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The committee chair must present the finalized work plan at the first Executive Committee conference call following a normal NOSB meeting. This event is not only an opportunity for the EC to provide guidance to the committee chair, but it is also an opportunity to obtain input from the NOP regarding the feasibility of implementing the committee's recommendation.

MATERIALS REVIEW PROCESS

This section presents the procedures followed by the NOSB to evaluate petitions. First, the NOP material review process is presented. Second, a review of the NOSB process for selecting and reviewing the work of technical advisory panels is provided followed by a description needed in a formal petition. Third, the process for NOSB material review is provided. This section concludes by providing a graphical description of the sunset review process.

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List. A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

Definitions:

~~Technical Advisory Panel (TAP) - Group of third party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.~~

~~Technical Review - A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.~~

~~Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility~~

~~During this phase the NOP will:~~

- ~~• Notify the petitioner via letter and/or electronic mail of receipt of the petition. Determine whether the petition is complete~~
- ~~• Determine if the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.~~
- ~~• Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA); the Food and Drug Administration (FDA); or other appropriate federal agency if applicable;~~
- ~~• Identify and secure any confidential business information (CBI) designated by the petitioner;~~
- ~~• Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.~~
- ~~• Upon determination of completeness and eligibility, the following actions will be taken:~~

~~• PUBLISH THE PETITION ON NOP WEBSITE, AND~~

- ~~• Notify the National Organic Standards Board (NOSB) materials committee chairperson and the chairperson of the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock, Handling or other pertinent~~

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committees). This notification will be sent via letter and/or electronic mail and inform the chairs that the petition is complete, provide OFPA review and EPA/FDA determination checklist, and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report.

-Phase 2: Determine if a Third Party Technical Review is Required

During this phase:

- ~~The NOSB materials committee, working with other applicable NOSB committees, has 60 days to submit any questions to the NOP. The questions requested by the committee should include items that need specific background information, recommended technical expertise, and be based on the OFPA criteria.~~

- ~~Per the NOP materials review process, the NOSB should review the petition and using the NOP checklists for the material determine the following:~~

- ~~1) If the material is deemed appropriate for consideration on the National List (pending criteria). If the answer is no to this question, an explanation is required.~~
- ~~2) If the answer to question #1 is yes, the NOSB committee assigned for the review (as identified by the Materials Committee Chair) must decide if
 - ~~a) there is sufficient information in the petition,~~
 - ~~b) the committee can reasonably research any pending technical information, or~~
 - ~~c) there is the need to secure a technical review from a third party expert (see section titled Procedures for Handling Technical Reviews)~~~~
- ~~3) If the answer to question #1 is no, the Materials Committee Chair will inform the NOP that the petition is incomplete and will include an explanation. If the reviewing committee concludes there is a need for a third party technical review, the Materials Committee Chair will proceed to make the request to the Program.~~

- ~~Notify the petitioner, via letter and/or electronic mail, that the petition is incomplete or ineligible; or~~

-Phase 3: Evaluation by a Third Party Expert

During this phase the NOP will:

- ~~Notify the third party expert of the petition's determination of completeness and eligibility. This third party will have technical expertise relevant to the petition and the notification will constitute official notice of the need for a technical review.~~

During this phase the Third Party Expert will:

- ~~Conduct activities necessary to provide responses to evaluation questions contained in the Statement of Work (SOW) and any additional questions identified by the NOSB as described above;~~

- ~~Use the TR template to prepare and distribute to the NOP a draft technical report (TR) in electronic format.~~

-Phase 4: Sufficiency Determination

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During this phase the NOP will:

- Submit a copy of the draft TR for review to the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling);
- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - ~~IS TECHNICALLY OBJECTIVE AND FREE FROM OPINIONS OR CONJECTURE;~~
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

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During this phase the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:

- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - Is technically objective and free from opinions or conjecture;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

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- Notify the NOP in letter and/or electronic mail the acceptance of the TR within 60 days of receiving the TR. If the TR is not accepted by the NOSB materials and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling), the committees must provide to the NOP in letter and/or electronic mail the specific areas of the TR that were concluded to be insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient.
- Upon concurrence by the NOP that the TR is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the TR that are insufficient, the

~~rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient. The time frame required for the completion of the changes will be determined through mutual agreement between the contractor and the NOP.~~

~~-Phase 5: Action by NOSB Materials Chair and the Committee that the Substance Is Being Petitioned for Addition or Prohibition from the National List (Crops, Livestock or Handling)~~

~~During this phase the NOSB materials Chair and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:~~

- ~~• Convene at a mutually convenient time to review, discuss and recommend an action on the petitioned substance. The committee may convene as the TAP by electronic mail or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The NOSB materials committee or delegated committee must convene and recommend an action on the petitioned substance no later than 60 days before a scheduled meeting of the full NOSB.~~

~~-Phase 6: Action by Full NOSB~~

~~During this phase the NOP will:~~

- ~~• Publish the recommendation of the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) on the NOP website and request a minimum of 60 days of written public comment on the recommendation prior to the public NOSB business meeting.~~
- ~~• Set as an agenda item for the next meeting of the NOSB time sufficient to discuss and make a recommendation by the full NOSB on the petitioned substance.~~

~~PROCEDURES FOR HANDLING TECHNICAL REVIEWS~~

~~The NOSB's role involves reviewing specific materials; however, a petition could involve a wide range of topics. Although members of the Board represent several areas of the organic community and hold advanced degrees in different scientific areas, they might lack the expertise, or time, required to address the data needs of a petition. In such cases the Board has the option of requesting the assistance of third-party experts and expecting from these experts a written technical review or report.~~

~~Third party experts can consist of the following:~~

- ~~1. Employees of the USDA such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed.~~
- ~~2. Consultants or contractors.~~

A committee should follow these steps in deciding the need for third-party expert:

1. Define if the committee has the expertise needed to address the questions related to the petition, mainly:
 - a. Impact on the environment
 - b. Impact to human health
 - c. Sustainability and compatibility with organic principles.
2. If the committee does not have the expertise or resources (e.g., time), the Committee chair should make a request to the Chair of the Materials Committee for a third-party expert specifying:
 - a. The third-party expert's required background and level of expertise
 - b. Existence of potential sources of conflict that could result in biased reviews.
3. When requesting the assistance of a third-party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but not limited to:
 - a. All uses of the petitioned material beyond what the petitioner has requested
 - b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
 - c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
 - d. All possible manufacturing methods for a petitioned material.
 - e. Potential effects on public health and biodiversity
 - f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long term effects on sustainability.
4. If required, the committee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third-party expert.

These are basic principles that should be considered when dealing with a third-party expert:

1. A committee cannot proceed with a recommendation on a material if it is determined that there is limited valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
2. The decision to request third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.
3. Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the committee reviewing the material. In some cases the Materials Committee can take the initiative to request a third party expert. The logic is that a material review is an issue assigned to a committee and it is up to the committee to decide on the need for a third party expert.
4. The decision to define the expertise needed in the third party expert is the responsibility of the committee reviewing the material or issue.

5. To incorporate a diversity of opinions and to minimize the risk of bias, a committee should aim to work with a range of technical experts (individuals, or institutions).

HANDLING WITHDRAWALS OF PETITIONS BY THE PETITIONER.

When a petition involving a material is withdrawn by the petitioner, the Board should suspend its review and recommendation procedure. In the case of a petition not involving a material, Board members have the option of completing its review and providing a recommendation or guidance.

In the case a petition previously withdrawn is resubmitted, the Board should review it in the order it is received. This means that a withdrawn petition should be considered a completely new request and falls to the end of the queue of materials pending review.

The petitioner can withdraw a petition at any moment during the process of review by the Board, public comment, or prior to the Board's voting on the petition.

A petitioner should have the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research) only. It is the hope of the Board that petitioners will not abuse this privilege with the intent of finding agreeable members in subsequent submissions.

TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES

Statement of Work

Request for Proposals to Perform Technical Advisory Panel Evaluation of Substances Petitioned for Inclusion on or Removal from the National Organic Program's National List of Allowed and Prohibited Substances.

Agency Need

See Statement of Work, 1.0 Background.

1. Background

The Organic Foods Production Act of 1990 (OFPA), as amended, requires the Secretary of Agriculture (Secretary) to establish a National List of Allowed and Prohibited Substances (National List). This list identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, by organic production and handling operations. The OFPA authorizes the National Organic Standards Board (NOSB) to develop and forward to the Secretary a recommended Proposed National List, and subsequent proposed amendments to it. The OFPA provides that persons may petition the NOSB to evaluate a substance for inclusion on or removal from the National List.

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on December 21, 2000, as part of the National Organic Program (NOP) final rule, 65 Fed. Reg. 80548-80684, (2000). Based on information supplied to the NOSB by trade associations, certification organizations and other organic industry sources, there are many substances currently used in organic production and handling that have not been evaluated by the NOSB for inclusion on the National List. Evaluations of these substances must be expedited to prevent the possible disruption of well-established and accepted production, handling, and processing systems.

~~Section 2119 of the OFPA (7 U.S.C. 6518 (k)(3)) provides that the NOSB shall convene Technical Advisory Panels (TAP) to provide scientific evaluation of substances for inclusion on the National List. TAP evaluations assist the NOSB in evaluating substances being considered for addition to or removal from the National List. The NOP, on behalf of the NOSB, establishes contracts to conduct the TAP evaluations.~~

~~2. Mission of USDA/AMS/NOP~~

~~The mission of NOP is to establish national standards governing the marketing of certain agricultural products as organically produced. The NOP is assisted by the NOSB, which provides policy advice in carrying out the program, including advising the Secretary on substances for inclusion on or removal from the National List.~~

~~The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include TAP evaluations, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and public comment. The NOSB submits its recommendations, along with the results of the required evaluation and technical advisory panel evaluation for each substance, to the Secretary for consideration in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).~~

~~3. Specific Task~~

~~The contractor(s) shall furnish technical advisory panel evaluations for crop production, livestock production, and processing substances submitted to the NOSB in response to petition notices, such as was published in the Federal Register on July 13, 2000, as well as other substances requiring evaluation as determined by the NOP.~~

~~For crop and livestock production substances, the contractor(s) shall use the criteria in Section 2119 of the OFPA (7 U.S.C. 6518 (m)(1-7)). The criteria are:~~

- ~~• The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems;~~
- ~~• The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence in the environment;~~
- ~~• The probability of environmental contamination during manufacture, use, misuse or disposal of the substance;~~
- ~~• Its effects on human health;~~
- ~~• The effects of the substance on biological and chemical interactions in the agroecosystem;~~
- ~~• The alternatives to using the substance; and,~~
- ~~• The compatibility of the substance with a system of sustainable agriculture.~~

~~For processing substances, the contractor(s) shall use the criteria approved at the February 10, 1999, NOSB meeting. The criteria are:~~

- ~~Processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;~~
- ~~Manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA;~~
- ~~The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations;~~
- ~~The primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing, except in the latter case as required by law;~~
- ~~It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances;~~
- ~~Its use is compatible with the principles of organic handling; and,~~
- ~~There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.~~

~~4. Minimum Skills and Experience Requirements~~

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

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~~5. Place of Performance~~

~~Contractor(s) shall perform all task related activity within the United States of America at specific locations determined by contractor(s). During the contract period, the contractor(s) shall travel at contractor(s)'s expense to NOSB meetings for the purpose of disseminating substance review findings to the NOSB and general public.~~

~~6. Government Furnished Equipment and Facility~~

~~None, except that the NOP shall provide Contractor(s), on a non-routine basis, with substance review petitions, ancillary documents or other applicable information in possession of NOP.~~

~~7. Compensation~~

~~The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s) shall be compensated at a firm fixed price rate not to exceed \$4,000.00 per substance reviewed. Total compensation shall not exceed \$100,000.00.~~

~~8. Period of Performance~~

~~September 30, 2001 – September 30, 2002 (262 working days)(Holiday time off is at contractor(s)' discretion.)~~

9. Scope of Performance

~~Phase 1: Data Gathering and Compilation (120 days)~~

~~Phase I is not to exceed 120 days for any one substance. During this phase the contractor(s) provider shall perform the following activities:~~

- ~~• Characterize [the] substance(s) and identify uses and applications;~~
- ~~• Determine whether [the] substance(s) are synthetic or non-synthetic (See 7.S.C. 6502 (21) for definition of synthetic);~~
- ~~• Determine [the] substance(s) chemical or biological composition and possible impact on human/animal health and the environment;~~
- ~~• Identify [the] substance(s) relevant toxicological studies, including ensuring substance does not contain residues of heavy metals or other environmental contaminants in excess of Food and Drug Administration Action Level or Environmental Protection Agency tolerances;~~
- ~~• Determine [the] substance(s) persistence in the environment;~~
- ~~• Determine [the] substance(s) effect on soil structure and ecology;~~
- ~~• Identify alternatives to the use of the substance(s);~~
- ~~• Determine [the] substance(s) historical use in organic production, processing and handling; and~~
- ~~• Determine [the] substance(s) status under OFPA and with other government agencies.~~

~~Additionally, within 45 days of commencement of Phase I, the contractor(s) must notify the NOP in writing of any substance(s) not appropriate for National List evaluation. Other substances for evaluation may be substituted upon agreement between the NOP, the NOSB, and the contractor(s).~~

~~Phase 2: Evaluation against Criteria (100 days)~~

~~Phase II is not to exceed 100 days for any one substance. The contractor(s) shall engage no less than three evaluators for each substance. No current member of the NOSB may serve as an evaluator. Evaluators may use data from all relevant sources. Evaluators shall make recommendations to the contractor(s) as to the substance's status as synthetic or non-synthetic and whether, in either case, the substance should be added to or removed from the National List.~~

~~Phase 3: Recommendation (42 days)~~

~~Phase III is not to exceed 42 days for any one substance. Contractor(s) shall provide the NOP with a recommendation regarding each substance's suitability for inclusion on or removal from the National List. All data and analyses collected in Phase I and II will be forwarded to the NOP upon the completion of Phase III in accordance with the reporting requirements stated below.~~

Evaluation Factors for Award

~~The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s)~~

selection will be based on evaluation of proposals in accordance with the responses received to the criteria outlined in Section 4.0, Minimum Skills and Experience Requirements and Section 9.0, Scope of Tasks. Award will be made to that offeror whose combination of technical experience and cost represents the best value to the Government and is most advantageous (cost, and other factors considered), and which is within the available NOP resources.

The NOP also reserves the right to reject any or all proposals received and/or request clarification or modification of proposals. The NOP reserves the right to determine a competitive range for negotiation based upon the technical and cost acceptability of proposals. In addition, the NOP reserves the right to award a contract without discussions.

Cost evaluation will include an analysis of the total cost and cost elements (if applicable) to perform the required work. The total costs supplied by the offeror shall constitute the total firm fixed unit price for that service or deliverable.

Proposals that are unrealistic in terms of technical commitment, or unreasonably low or high in costs, will be deemed reflective of an inherent lack of technical competence or as indicative of a failure to comprehend the complexity involved in the contract requirements. Such may be grounds for rejection of the proposal.

Other Evaluation Factors

Technical proposals will be initially evaluated with respect to six (6) major factors for determination of the competitive range. Technical factors are listed in descending order of importance. The technical proposal is of greater importance than the cost proposal; when technical proposals are relatively equal in technical merit, cost will increase in importance.

Technical Factors:

Factor 1 Overall Technical Approach; Proposed Methodology; Demonstrated Understanding of the Scope of Work and the Requirements

Factor 2 Previous Demonstrated Experience and Past Performance

Factor 3 Quality Control

Factor 4 Capability and Experience of Key Personnel

Factor 5 Project Management and Support Capability

Factor 6 Reasonableness of Cost

Reporting Requirements

Progress reports are due to the NOP each 60 days after the contract award date. A final report is due within 60 days of the end of the contract period. The contractor(s) shall forward five copies of the bi-monthly progress reports and the final report and all deliverables to the NOP in Washington DC. Documents should be addressed to: Richard H. Mathews, Program Manager, National Organic Program, USDA AMS TM NOP, 1400 Independence Avenue, S.W., Room 4008 So., Ag Stop 0268, Washington, D.C. 20250-0200, Attention: Substance Evaluations.

The narrative in the progress reports should refer back to the stated objectives and timeline of the

~~original contract proposal. Beneath each objective, the objective's current status should be reported. Any substantive diversion from a stated objective, or any deviation from the proposed timeline should be explained. Only the activities required under the contract should be reported. At a minimum, the progress reports should also include the following:~~

- ~~1. A short summary of the accomplishments for the reporting period;~~
- ~~2. Progress on completing individual project tasks;~~
- ~~3. The planned and actual schedules for task completion;~~
- ~~4. Projected accomplishments for the next reporting period; and,~~
- ~~5. Data on financial expenditures by task category.~~

~~Any deliverables required under the contract should be submitted upon completion and addressed to: NOP Program Director, National Organic Program, USDA AMS TM-NOP, 1400 Independence Avenue, S.W., Room 4004 So., Ag Stop 0268, Washington, D.C. 20250-0268, Attention: Substance Evaluations.~~

~~INFORMATION TO BE INCLUDED IN A PETITION~~

~~Any person may petition to add a substance to or remove a substance from the National List of Allowed and Prohibited Substances by submitting the information and following the procedures identified below.~~

~~ITEM A~~

~~The petitioner should identify which of the following categories the substance is being petitioned for inclusion on or removal from the National List:~~

- ~~1. Synthetic substance's allowed for use in organic crop production;~~
- ~~2. Nonsynthetic substances prohibited for use in organic crop production;~~
- ~~3. Synthetic substances allowed for use in organic livestock production;~~
- ~~4. Nonsynthetic substances prohibited for use in organic livestock production;~~
- ~~5. Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)"; or~~
- ~~6. Nonorganic agricultural substances not commercially available in organic form.~~

~~ITEM B~~

~~The petitioner must submit the following information:~~

- ~~1. The substance's common name.~~
- ~~2. The manufacturer's name, address, and telephone number.~~
- ~~3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant.~~
- ~~4. A list of the crop, livestock, or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.~~

- ~~5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.~~
- ~~6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.~~
- ~~7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.~~
- ~~8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.~~
- ~~9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.~~
- ~~10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.~~
- ~~11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.~~
- ~~12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:~~

~~*A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)*~~

- ~~• Explain why the synthetic substance is necessary for the production or handling of an organic product.~~
- ~~• Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.~~
- ~~• Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.~~

~~*B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)*~~

- ~~• Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.~~
- ~~• Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.~~

~~*C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604*~~

- ~~• Explain why the non-synthetic substance should not be permitted in the~~

production of an organic product.

- Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

- Explain why the non-synthetic substance should be permitted in the production of an organic product.
- Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic or synthetic substances on the National List or alternative cultural methods.

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance Onto the National List, § 205.605(a)

- Explain why the substance is necessary for use in organic handling.
- Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
- Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Non-Synthetic, Non-Agricultural Substance From the National List, § 205.605(a)

- Explain why the substance is no longer necessary for use in organic handling.
- Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606

- Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria:

- (1) Regions of production, including factors such as climate and number of regions;
- (2) Number of suppliers and amount produced;
- (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;
- (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and
- (5) Other issues which may present a challenge to a consistent supply.

H. Removal of a Non-Organically Produced Agricultural Substance From the National List, § 205.606

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:

- (1) Region of production, including factors such as climate and number of regions;
- (2) Number of suppliers and amount produced;
- (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
- (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
- (5) Any other issues which may present a challenge to a consistent supply.

13. ~~A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:~~

- a. ~~Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.~~
- b. ~~"Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI.~~

This information must be

- (1) commercially valuable,
- (2) used in the applicant's business, and
- (3) maintained in secrecy.

- c. ~~Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."~~
- d. ~~The CBI deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI deleted copy is paginated the same as the CBI copy. (The CBI deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI deleted copy.~~
- e. ~~Each page with CBI deletions should be marked "CBI deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI deleted."~~
- f. ~~If several pages are CBI deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI deleted.")~~
- g. ~~All published references that appear in the CBI copy should be included in the reference list of the CBI deleted copy. Published information usually cannot be claimed as confidential.~~

~~National List substance evaluations conducted by the NOSB will involve a public and open process. No confidential information will be available for public inspection.~~

~~The NOP Program Director may request additional information from the petitioner following receipt of the petition.~~

PRIORITY OF PETITIONS GUIDELINE

Prioritization

National List materials petitions received and deemed sufficient by the NOP / NOSB will be prioritized by the Materials Committee Chair for consideration as follows:

1. Petitions to Remove a Material From the National List:

a. A petition to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority **Priority 1**, above all other petitions in the queue of the reviewing committee (Crops, Handling, or Livestock).

~~b. A petition to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2**, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing committee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.~~

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2. Petitions to Add a Material Adhere to the National List:

a. A petition to **add** a material to the National List will be considered by the reviewing committee (Crops, Handling, or Livestock) requirements specified in the chronological order it is received, and will be designated as **Priority 3**.

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3. Petitions to Reconsider a Material for Addition to the National List:

a. A petition to **reconsider** adding a material that had previously been rejected by a board vote would be given the lowest priority **Priority 4**, and would go to the bottom of the committee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions for listing a substance that had been previously rejected by the board must contain substantive new information to warrant reconsideration.

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~~This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing committee, such as, but not limited to, a delay in the delivery of a Technical Review for a petitioned substance, the committee chair must exercise his or her judgment in the possible reassignment of priorities and workload to make best use of resources to advance petition recommendations.~~

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• NOSB **COMMITTEE RECOMMENDATION** Policy and Procedures Manual
 Form NOPLIST1- Committee Transmittal to NOSB

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For NOSB Meeting: _____	Substance: _____																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/> Petition is for: _____ _____ _____ on the National List § 205. _____																									
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) — Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment _____ Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																									
2. Essential & Availability Criteria _____ Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																									
3. Compatibility & Consistency _____ Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																									
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) _____ Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																									
B. Substance Fails Criteria Category: _____ Comments: _____ _____																									
C. Proposed Annotation (if any): _____ _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion): _____																									
Classification of the material: Synthetic _____ Non-synthetic _____ Absent: _____ Abstain _____																									
Motion by: _____ Seconded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____																									
Recommended Committee Action & Vote _____ _____																									
Motion by: _____ Seconded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Crops</td> <td style="width: 20px;"></td> <td style="padding: 2px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 2px;">Allowed³</td> <td style="width: 20px;"></td> </tr> <tr> <td style="padding: 2px;">Livestock</td> <td></td> <td style="padding: 2px;">Non-Synthetic</td> <td></td> <td style="padding: 2px;">Prohibited²</td> <td></td> </tr> <tr> <td style="padding: 2px;">Handling</td> <td></td> <td style="padding: 2px;">Synthetic</td> <td></td> <td style="padding: 2px;">Rejected²</td> <td></td> </tr> <tr> <td style="padding: 2px;">No restriction</td> <td></td> <td style="padding: 2px;">Commercially Un-Available as Organic²</td> <td></td> <td style="padding: 2px;">Deferred⁴</td> <td></td> </tr> </table>	Crops		Agricultural		Allowed ³		Livestock		Non-Synthetic		Prohibited ²		Handling		Synthetic		Rejected ²		No restriction		Commercially Un-Available as Organic ²		Deferred ⁴		1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____ _____ 2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____ _____ Describe why a prohibited substance: _____ _____ 3) Substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected: _____ _____ 4) Substance was recommended to be deferred because _____ _____ if follow up needed, who will follow up _____
Crops		Agricultural		Allowed ³																					
Livestock		Non-Synthetic		Prohibited ²																					
Handling		Synthetic		Rejected ²																					
No restriction		Commercially Un-Available as Organic ²		Deferred ⁴																					

E- Approved by Committee Chair to transmit to NOSB:

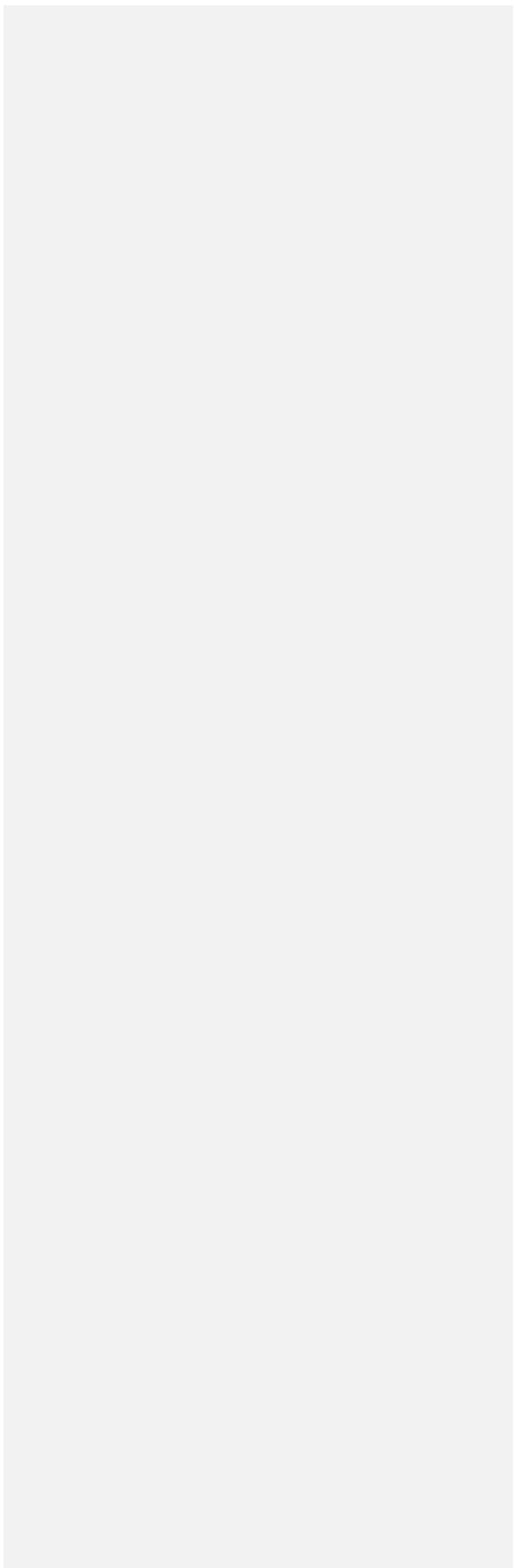
-Committee Chair _____ Date

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [205.600 b.2]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [6518 m.3]				
3. Is the substance harmful to the environment and biodiversity? [6517c(1)(A)(i);6517(c)(2)(A)]				
4. Does the substance contain List 1, 2, or 3 inerts? [6517 c (1) (B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[6518 m.2]				
10. Is there any harmful effect on human health? [6517 c (1)(A) (i) ; 6517 c(2)(A)]; 6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.2]				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [205.600 b.5]				

[†]if the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.



Category 2. Is the Substance Essential for Organic Production?— Substance _____

Question	Yes	No	N/A [‡]	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]				
2. Is there an organic substitute? [§205.600 b.1]				
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(iii)]				
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
6. Is there any alternative substances? [§6518 m.6]				
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

[‡] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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

Substance _____

Question	Yes	No	N/A [‡]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(iii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]				
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

[‡] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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

Substance _____

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non organic form of the material /substance is necessary 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?				
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?				
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?				
5. Does the industry information provided on material / substance non availability as organic, include (but not limited to) the following:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
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;				
d. Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

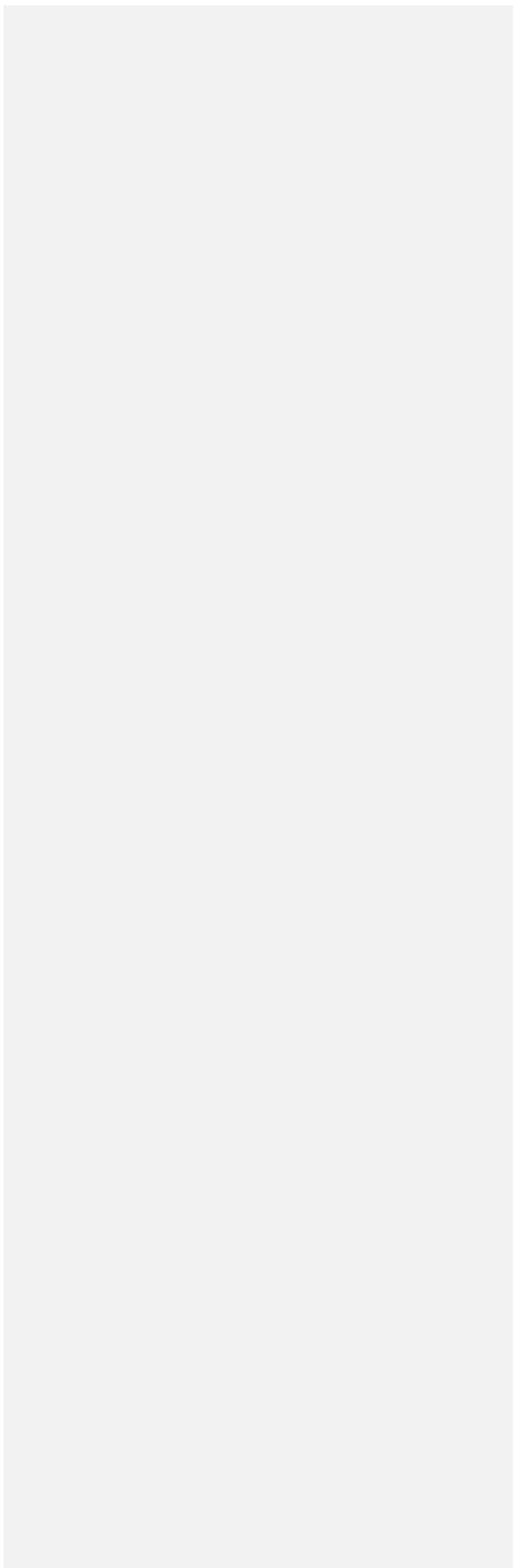
NOSB RECOMMENDED DECISION FORM

Form-NOP/IST2-- Full Board Transmittal to NOP

For NOSB Meeting: _____	Substance: _____																												
A. Evaluation Criteria (Documentation attached; committee recommendation attached) Criteria Satisfied?																													
1. Impact on humans and environment	Yes No (see B below)																												
2. Availability criteria	Yes No (see B below)																												
3. Compatibility & consistency	Yes No (see B below)																												
B. Substance fails criteria? Criteria category: _____ Comments: _____	C. Proposed Annotation: _____ _____ Basis for annotation: To meet criteria above: ____ Criteria: _____ Other regulatory criteria: ____ Citation: _____																												
Final Board Action & Vote: Motion by: _____ Second: _____																													
Vote:	<table border="1" style="width:100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width:15%;"></td> <td style="width:15%;">Agricultural</td> <td style="width:15%;"></td> <td style="width:15%;">Nonagricultural</td> <td style="width:15%;"></td> <td style="width:15%;">Crops</td> <td style="width:15%;"></td> </tr> <tr> <td>Yes: _____</td> <td>Synthetic</td> <td></td> <td>Not-synthetic</td> <td></td> <td>Livestock</td> <td></td> </tr> <tr> <td>No: _____</td> <td>Allowed¹</td> <td></td> <td>Prohibited²</td> <td></td> <td>Handling</td> <td></td> </tr> <tr> <td>Abstain: _____</td> <td>No-restriction</td> <td></td> <td>Deferred⁴</td> <td></td> <td>Rejected³</td> <td></td> </tr> </table>		Agricultural		Nonagricultural		Crops		Yes: _____	Synthetic		Not-synthetic		Livestock		No: _____	Allowed ¹		Prohibited ²		Handling		Abstain: _____	No-restriction		Deferred ⁴		Rejected ³	
	Agricultural		Nonagricultural		Crops																								
Yes: _____	Synthetic		Not-synthetic		Livestock																								
No: _____	Allowed ¹		Prohibited ²		Handling																								
Abstain: _____	No-restriction		Deferred ⁴		Rejected ³																								
1) Substance voted to be added as "allowed" on National List Annotation: _____																													
2) Substance to be added to "prohibited" paragraph of National List Describe why a prohibited substance: _____																													
3) Substance was rejected by vote for amending National List Describe why material was rejected: _____																													
4) Substance was recommended to be deferred Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____																													
E. Approved by NOSB Chair to transmit to NOP: _____ _____, NOSB Chair _____ Date																													
F. NOP Action: _____ Include in FR to amend National List: Return to NOSB Reason: _____ _____ _____, NOP Director _____ Date																													

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PROCEDURES FOR THE MATERIALS REVIEW PROCESS FOR NOSB MEMBERS

- ~~1. Upon receipt of the TAP reviews each member should read the report prepared by the contractor, along with the submitted petition, additional information and recommendations of the contracted panel of experts.~~
- ~~2. Questions or clarification of the review may be answered by further review of the literature provided by the TAP contractor or by the Chair of the committee contacting the contractor directly. Questions regarding the process can be directed to the Chair of the Materials Committee.~~
- ~~3. The materials are either directed to the processing, crops or livestock committee(s) depending on the specified use(s) of the material as stated in the petition. NOSB members assigned to those committees shall conduct a thorough review of the material and vote on whether it is synthetic or nonsynthetic, and then if it should be allowed or prohibited for specific use as either a crop, livestock or processing material. Materials may be followed by an annotation which restricts their use. Recommended annotations applicable to the material must be voted on by committee.~~
- ~~4. Committee draft recommendations will be submitted to the NOP at least thirty (30) days prior to the next NOSB meeting where the material will be considered.~~
- ~~5. The Chair of each committee will present the Board with the committee's written votes and recommendations during the Materials Review process at the NOSB meeting. The recommendation should come in the form of a motion which must be seconded by an NOSB member to move forward. The process will follow Robert's Rules of Order in which the Chair would open the motion for discussion. The Chair shall ask if any Board members have conflicts of interest. After discussion board members will vote on the motion.~~
- ~~6. NOP staff will record the votes of the each NOSB member and announce whether or not the motion passed.~~
- ~~7. If the motion fails the Board Chair asks for a new motion and the procedure is repeated until a final motion is passed by a 2/3 majority.~~

SUNSET REVIEW PROCESS

~~Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance (nor is it used to change an existing annotation) or new uses of a listed substance. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited. (Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance must be renewed as listed. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.)~~

Since the sunset review process is an assessment of National List substances to ensure their continued compliance with regulatory standards, the NOSB may determine that new restrictions in the form of annotations are necessary given changes in use patterns and scientific understanding. An annotation to expand the use of a substance does not fall within the purview of the sunset process and must only be considered through the petition process.

~~The Organic Foods Production Act of 1990 (OFPA) authorized a National List of Allowed and Prohibited Substances (Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:~~

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~~"No exemption or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has reviewed such exemption or prohibition."~~

~~The National List that was implemented in October 21, 2002 contained over 200 substances. The first sunset review of listed materials was completed in October, 2007. Decisions made through the Sunset review must be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.~~

Steps followed in Sunset Process

~~Not all listed materials reach sunset status at the same time, but the review process includes these steps:~~

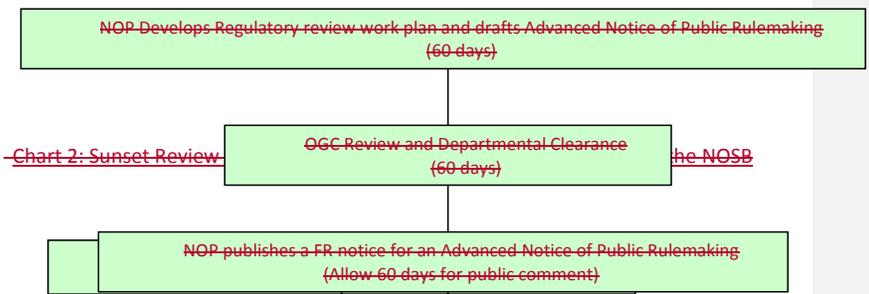
- ~~1.— A public notice is placed in the Federal register (Advance Notice of Proposed Rule Making or ANPR of the pending sunset of the listed materials. The public has 60 days after the publication date to provide written comment (see Chart 1 below). The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.~~
- ~~2.— Public comments are collected and forward to the NOSB (see Chart 2).~~
- ~~3.— The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material's removal, renewal, or renewal with the addition of an annotation. The review is conducted based on "Force of Evidence" as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.~~
- ~~4.— The reviewing NOSB committee provides its recommendation to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - ~~(i). Simple motion to remove, add, or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).~~
 - ~~(ii). Simple motion to renew the existing listing.~~~~

5.— At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee's recommendation.

6.— The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.

The NOP will review public comment and draft the final rule. The final rule will proceed through interagency (i.e. OGC, OMB, and departmental) and congressional review, and upon receiving clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.

~~Chart 1: Sunset Review — NOP Posts an ANPR~~



~~Chart 2: Sunset Review~~

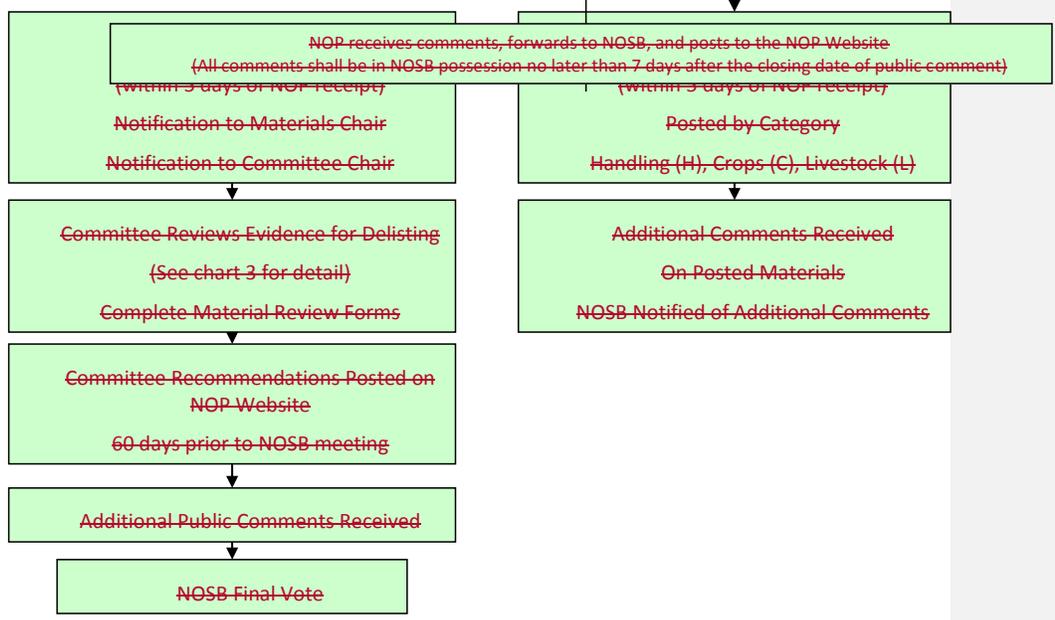
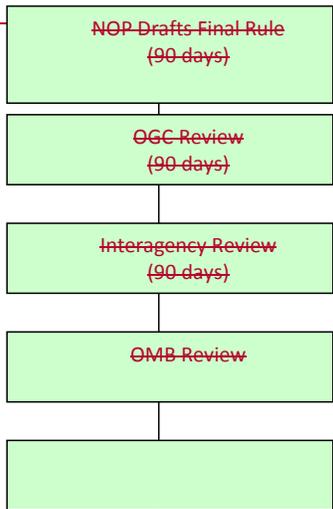
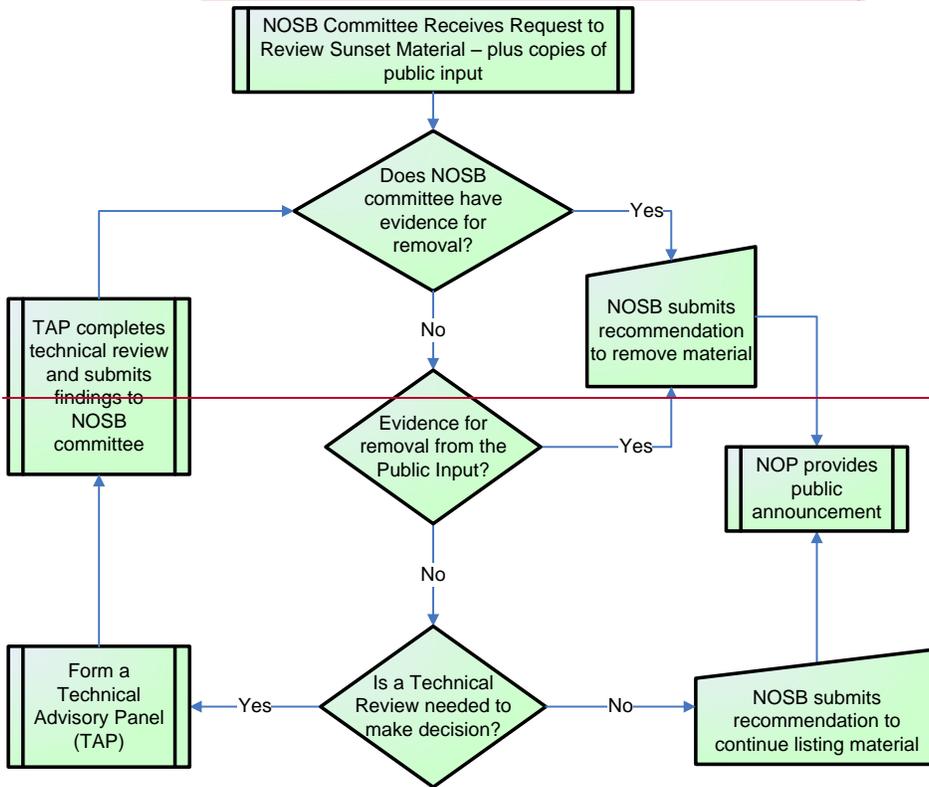


Chart 3: Sunset Review – NOSB Committee Reviews Evidence for Delisting



HANDLING TECHNICAL ERRORS AFTER AN ITEM HAS BEEN PLACED IN THE FEDERAL REGISTER

In order to minimize confusion in the organic community, the Board needs to monitor and correct discrepancies between items which have been voted on and their subsequent insertion in the Federal Register. Some examples of the different types of technical corrections needed are:

Annotations different than what was originally recommended by NOSB and changed by the Program in order to fit the demands of other federal regulatory bodies (ex: livestock medications withholding times).

An unforeseen consequence of a recommendation voted by the Board could require additional annotations in order to fit the needs of the organic industry. The absence, for example, of an explicit description of what methods of extraction are allowed for specific materials could result in the unwanted use of materials extracted using prohibited extraction processes.

The Board should follow these steps to monitor and correct technical discrepancies:

(1) The Secretary of the Board, with the assistance of the NOSB Executive Director, shall review all additions to the Federal Register and report to the Board any discrepancies between Board recommendation and those published in the Federal Register.

(2) When the Program incorporates changes to a recommendation voted and presented by the Board, the Program is expected to communicate these changes prior to final action by the Program to the Board Chair, Vice Chair and Secretary. The Board Chair, Vice Chair and Secretary will report such activity to the Board and then work with the Program in order to assist the Program in stating the exact reasons for such deviations in the preamble to the Rule change posted.

(3) In the cases of unintended consequences with a published recommendation, the Chair of the Board, with the approval of the Executive Committee, will assign committee to resolve the issue.

APPENDICES AND RESOURCES

Appendix A – DECISION MAKING PROCEDURES FOR THE NOP

1. Define the Problem

- a. What is the problem?
- b. Identify where we are now.
 - i. State the present condition in no more than two sentences.
- c. Identify where we want to be.
 - i. State the future objective in no more than two sentences.

2. Analyze the Problem

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- a. Why is there a problem?
- b. Is the evidence of the problem supported by credible and compelling facts or data?
 - i. What are the facts or data used to draw an affirmative conclusion?
- c. Who does this problem affect?
- d. What is the problem's effect?
- e. In what time frame must the problem be resolved?
- f. If the problem deserves immediate attention, what other priorities must be adjusted to accommodate this problem?
- g. If the problem deserves immediate attention, what are the consequences of a delay?

3. Develop Possible Solutions

- a. Propose ideas for possible solutions
- b. Evaluate ideas for possible solutions
 - i. List pros for each possible solution
 - ii. List cons for each possible solution
- c. Select a Solution
 - i. Is the recommended solution legal?
 - ii. Is the recommended solution practical?
 - iii. Is the recommended solution supported by credible and compelling facts or data?
 - 1. What are the facts or data used to draw an affirmative conclusion?
 - iv. How does the recommended solution solve the problem?
 - v. How does the recommended solution meet the time frame identified in 2(b)?
- d. Review recommended solution for unintended consequences.

4. Develop Action Plan

- a. Develop Action Steps
 - i. Identify action steps to bridge the gap between present condition and future objective using the recommended solution.
- b. Approve Action Plan
- c. Implement Action Plan

Final - 5/9/2003

B. Appendix B-2 - FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information,

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~~such as~~ member orientation and training, and NOSB ~~committee~~Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.

- Designated Federal OfficialsOfficers must approve all meetings and agendas, and attend meetings. The ~~NOP Program Director~~Advisory Board Specialist is the NOSB's Designated Federal OfficialOfficer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
 - Post a provisional agenda~~;~~ on its web site~~;~~ no later than 90 days before the meeting is scheduled to begin~~;~~
 - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin~~;~~ and
 - Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin~~;~~

• ~~Detailed minutes will be kept and must contain:~~

- ~~a. Date and location of the meeting;~~
- ~~b. A record of the persons present;~~
- ~~c. A complete and accurate description of matters discussed and conclusions reached, and~~
- ~~d. Any advice or recommendations provided by the committee.~~

- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.

- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage:
<http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeId=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=13170><http://www.gsa.gov/portal/content/100916>

Appendix C – DUTIES OF THE DESIGNATED FEDERAL OFFICER

~~The Designated Federal Officer assigned to the National Organic Standards Board and its committees, under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing~~

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regulations (41 CFR Part 101-6.10), is the National Organic Program's Program Director. The Program Director:

1. Must approve or call the meeting of the NOSB;
2. Must approve the agenda;
3. Must attend the meetings;
4. Shall adjourn the meetings when such adjournment is in the public interest; and
5. Chairs the meeting when directed by the Secretary of Agriculture or the Secretary's designee.

~~Appendix D – PARLIAMENTARY PROCEDURE AT A GLANCE~~

TO DO THIS	YOU SAY THIS	May you interrupt speaker?	Must you be seconded?	Is the motion debatable?	Vote required
Adjourn the meeting	I move that we adjourn	no	yes	no	majority
Recess the meeting	I move that we recess until...	no	yes	no	majority
Complain about noise, room temperature, etc.	Question of privilege	yes	no	no	no vote
Suspend further consideration of something	I move that the motion be laid on the table	no	yes	no	majority
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we postpone this matter until...	no	yes	yes	majority
Have something studied further	I move to refer the motion to the committee	no	yes	yes	majority
Amend a motion	I move to amend...	no	yes	yes	majority
Introduce business (a primary motion)	I move that...	no	yes	yes	majority
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decides
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to	I call for a division	no	no	no	no vote

verify a voice vote					
Object to the consideration of some undiplomatic matter	I object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	no	yes	no	majority
Reconsider something already disposed of	I move to reconsider...	yes	yes	yes	majority
Consider something vote out of its scheduled order	I move we suspend the rules and consider...	no	yes	no	2/3 vote
Vote on a ruling by the chair	I appeal the decision of the chair	yes	yes	yes	majority
Table a motion take matter from table	I move to take from the table	No	Yes	No	majority
Rescind motions Cancel previous action	I move to rescind	No	Yes	Yes	2/3 vote

Appendix E – BASIC CHEMISTRY

~~The science of chemistry deals with the structure of matter – material things – and the changes that matter undergoes. Matter can exist in any size, shape, or color. It is solid, liquid, or gas, living or nonliving. Chemistry seeks to identify the simplest parts of matter; how they are separated and purified; how they are put together; how they are rearranged to produce new forms of matter; and what energy is absorbed or released when such rearrangements are made (Matta and Wilbraham, 1986). A distinction should be made between chemical and physical changes. The OFPA and NOS definition of synthetic specifically mentions chemical change but not physical change. A physical property is a quality or condition of a substance that can be observed or measured without changing the substance's composition. It can be specified without reference to any other substance. Other physical properties of matter include color, solubility, mass, odor, hardness, density, electrical conductivity, magnetism, melting point and boiling point. Physical properties help chemists identify substances (Matta and Wilbraham, 1986). When contractors are hired to technical review of substances for the NOSB and USDA/NOP, they typically list the physical properties of the substances in their review because this is the common way in which substances are described.~~

~~Physical changes may result when the temperature of a substance changes. Raising the temperature of a solid may turn it into a liquid (i.e., ice turns into water). A conversion without causing a change in the composition of the substance is called a physical change (Matta and Wilbraham, 1986). When ice undergoes the physical change of melting, this change does not change the nature of water. The physical properties are the same for water that has been frozen and melted as for water that has been converted into steam and then condensed (Matta and Wilbraham, 1986). Historically, the organic industry and the NOSB have acknowledged that physical changes do not render a substance synthetic.~~

However, there are some substances that have been identified where high temperatures during manufacturing do engender a chemical change in the substance. An example is mined minerals. Historically, the industry and NOSB has recognized that burning or excessive heating of mined mineral is considered to render them synthetic. Formerly, NOSB defined mined minerals as any naturally occurring non-living substance derived from the earth or water. A mined mineral cannot have undergone molecular change through heating, acidification, basification or fortification with synthetic materials (NOSB Final Recommendation Addendum Number 25, Definitions and Interpretations, Austin, Texas, 1995). Therefore, heat can alter the physical properties of a substance and for other substances act as a catalyst in chemical reactions or change.

In a chemical reaction, the starting substance or substances, referred to as reactants, are changed into new substances or products. Chemists use an arrow as a shorthand form of the phrase "are changed into"; reactants → products (Matta and Wilbraham, 1986). An example to distinguish between physical and chemical changes is illustrated when sulfur (a solid) is added to iron filings (a solid). They may be separated unchanged from a mixture of the two substances mixed together. This separation is an example of a physical change. If the mixture of these two substances is heated, a chemical change takes place and the sulfur and iron are changed into a nonmagnetic substance, iron sulfide: Iron + Sulfur → Iron Sulfide (Matta and Wilbraham, 1986). A substance's composition and behavior in chemical reactions—its chemical reactivity—comprise its chemical properties.

What is a substance?

In chemistry, a pure **substance** is a homogenous material that has a definite chemical composition throughout. There are two kinds of pure substances. One kind can be decomposed into two or more different substances by simple chemical change; these are called **compounds**. There are many millions of compounds.

An example of a compound is pure table salt, which can be decomposed into sodium and chlorine by an appropriate process. Many of the substances on the National Lists of Synthetic substances allowed for use in organic crop and livestock production (Sections 205.601 and 205.603) are compounds. Examples include: isopropanol, chlorine dioxide, ammonium carbonate, lime sulfur and copper sulfate.

The second kind of pure substances are called **elements**, which cannot be decomposed by chemical change. There are 90 natural elements; examples are gold, copper, oxygen, sulfur and hydrogen. Elements cannot be separated into simpler substances by chemical reactions. An example of an element on the National List is sulfur (elemental) for crop production (205.601(e)(3)) (Boikess and Edelson, 1978).

Mixtures consist of a physical blend of two or more substances in which the combined substances retain their identity. Most materials found in nature are mixtures. Mixtures can be either homogeneous (same composition throughout) or heterogeneous (has non-uniform composition). A **solution** is a type of a mixture where there is a homogeneous combination of different substances. The difference between a heterogeneous mixture and a solution is that any sample of a solution has the same composition, while the composition of a mixture is not the same throughout. Solutions may be gaseous, liquid or solid. Examples of mixtures on the National List are aquatic plants and fish emulsions. The various compounds and elements that make up these products are within the

plant, animal or mineral. When a particular component of the plant is desired for use in an agricultural input it typically has to be extracted and in many cases undergo additional chemical reactions to make it into a substance that is functional when combined with other substances.

A distinction should be drawn between a mixture and a compound. **The elements making up a compound cannot be recovered without a chemical change.** The substances making up a mixture or solution can. Some mixtures can be separated into their various components by simple physical methods. An example is a gray colored mixture produced by stirring together powdered yellow sulfur and black iron filings. The individual particles of sulfur and iron can be readily distinguished from one another under a microscope. The mixture is easy to separate because the iron filings can be removed from the mixture with a magnet leaving sulfur behind. Both the sulfur and the iron are unchanged in composition (example from Matta and Wilbraham, 1986).

The substances making up a mixture or a solution need not be elements. For example, one can prepare a solution by dissolving salt, a compound, in water another compound. In addition, the substances making up a mixture or a solution can be combined in varying proportions. The elements in a compound have fixed proportions (paragraph found in Boikess and Edelson, 1978). Main groups of compounds can be classified based on similar chemical properties. The following are descriptions of each group (Boikess and Edelson, 1978).

Salts: a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group (NH_4^+) instead of a metal are also classified as salts. Some salts are NaCl, KCl, KMnO_4 and NH_4Cl . A salt is an ionic solid at room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as Na^+ , K^+ , Ca^{2+} or Mn^{3+} and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as Cl^- or NH_3^- . A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When NaCl dissolves in water, the correct formula is $\text{Na}^+ + \text{Cl}^-$. This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

Acids: a compound that is a source of H^+ ions. An acid is usually a compound of hydrogen and a nonmetal or a negative polyatomic group. Unlike salts, acids usually are not aggregates of ions. An acid may be a gas (hydrochloric), liquid (sulfuric) or a solid (oxalic). Like salts, acids tend to form ions when they dissolve in water. When a substance separates into ions it is said to dissociate. Some acids dissociate completely and are called strong acids. Most acids dissociate only partially when dissolved in water. These are called weak acids, they are weak electrolytes.

Bases: a compound that is a source of OH^- ions in water solution. A compound of a cation and the OH^- anion is a base. Bases resemble salts in many ways. They are ionic solids that dissociate into ions when dissolved in water. Bases that contain a cation and OH^- are generally dissociate completely in water and are classified as strong bases. Some strong bases are NaOH (sodium hydroxide) and KOH (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce OH^- ions by reaction with water. An example is ammonia (NH_3) which reacts with water to produce hydroxide ions.

Nonelectrolytes: Compounds containing only nonmetals usually exist as discrete molecules, rather

than collections of ions. These compounds do not dissociate into ions when they dissolve in water. Many organic compounds are nonelectrolytes and they will not dissolve appreciably in water i.e. oil. Some will dissolve in water, although they will not dissociate into ions i.e. sugar, and ethyl alcohol.

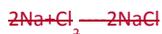
Oxides: is a binary compound of any element with oxygen, when the oxygen has an oxidation number of -2 . Almost every element forms at least one oxide. The properties of oxides vary widely depending on the element they may resemble a salt, acid, base or non-electrolyte.

What constitutes a chemical change?

The chemical properties of a substance are those that describe the way in which it can undergo change, either alone or in interactions with other substances, to form different materials. Such changes are called chemical reactions. The chemical properties that are characteristic of any substance can be described iron combines readily with oxygen to form the compound called rust (Boikess and Edelson, 1978).

The following are common types of chemical reactions that describe what is happening when different substances and compounds interact (Boikess and Edelson, 1978).

1.—Addition or combination reaction: Two substances combine to form one:



2.—Decomposition reactions: One compound breaks into two or more compounds or elements.—



3.—Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa. $\text{AB} + \text{CD} \rightarrow \text{AD} + \text{CB}$

a.—1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both H^+ and OH^- ions. The OH^- anion combines with the positive portion of the compound that is hydrolyzed. This positive portion may be a cation or an atom with a positive oxidation number. The H^+ cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.

b.—Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

Since many materials used in organic agriculture are derived from plants and animals it is important to mention chemical reactions that occur in by products of these organisms. In living organisms, enzymes play the role in catalyzing a specific reaction or type of reactions.

Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide

bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

1. Heat—most become denatured when heated above 50-60 degrees C.
2. Large changes in pH—adding concentrated acid or alkali to a protein in a aqueous solution causes changes in the charged character of ionizable side chains and interferes with salt linkages.
3. Detergents—treating a protein with sodium dodecylsulfate (SDS), a detergent, causes the native conformation to unfold and exposes the nonpolar protein side chains to the aqueous environment. These side chains are then stabilized by hydrophobic interaction with hydrocarbon chains of the detergent.
4. Organic Solvents—such as alcohols, acetone or ether.
5. Mechanical treatment. Most globular proteins denatured in aqueous solution if they are stirred or shaken vigorously.
6. Urea and guanidine hydrochloride—These substances can cause disruption of protein hydrogen bonding and hydrophobic interactions.

Denaturation can be partial or complete. It can also be reversible or irreversible. Irreversible denaturation causes a fundamental change in the protein, in particular destroying any physiological (biological) activity. In the case of reversible denaturation, the change may only be temporary (Brown, 1988).

References:

- Boikess, R.S. and Edelson, E. Chemical Principles. Harper and Row, New York, 1978.
Brown, W.H. Introduction to Organic Chemistry. Brooks/Cole Publishing Company, California, 1988.
Matta, Michael, and Wilbraham, A.C. General, Organic and Biological Chemistry. Benjamin/Cummings Publishing Company, California, 1986.

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**National Organic Standards Board
Policy Development Subcommittee
Discussion Document: Sunset Review Efficient Work Load Reorganization
February 23, 2016**

INTRODUCTION:

At present, the National Organic Standards Board (NOSB) conducts sunset reviews of materials according to the same schedule that the materials were added to the National List. Since the majority of materials on the National List were first included when the organic regulations were published in 2002, the number of materials reviewed each year by the NOSB is radically disproportionate. The peak of required reviews in 2/7 review cycle¹ (2022/2027) with 187 material listings (estimated) and corresponds to the date that most materials were added on the National List with the promulgation of the final rule in 2002. In contrast the 4/9 cycle (2019/2024) has only 1 material set for review. The sum of all years other than the 2/7 cycle is 31 (estimated). Reviewing 187 materials in one year and 27 materials over 4 years is an inefficient use of resources and board time.

BACKGROUND:

The National List identifies synthetic substances that may be used in organic production and nonsynthetic (natural) substances that may not be used. It also includes non-organic substances that may be used in or on processed organic products.

As provided for by the “sunset provision” of the Organic Foods Production Act, (OFPA) “No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition...within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition (7 U.S.C. 6517(e)).”

The National Organic Standards Board (NOSB) reviews materials on the National List on a schedule that ensures each material is reviewed prior to the end of this five-year period. By giving each material its due consideration, the NOSB can offer recommendations to the Secretary (via USDA National Organic Program) as to whether materials should be removed from the National List. The review of each material can be significant, as it involves research

¹ A Note of terminology used to talk about sunset review cycles. Sunset review cycles occur every five years on a predictable pattern. To facilitate brevity in this document the review cycle will be termed by the last year digits – so an item on the current 2018 sunset review would be part of the 3/8 sunset review cycle.

Terminology used	Current Sunset Cycle	Next Sunset Review year
0/5 cycle	2020 (reviewed in 2018)	2025 (reviewed in 2023)
1/6 cycle	2021 (reviewed in 2019)	2026 (reviewed in 2024)
2/7 cycle	2022 (reviewed in 2020)	2027 (reviewed in 2025)
3/8 cycle	2018 (reviewed in 2016)	2023 (reviewed in 2021)
4/9 cycle	2019 (reviewed in 2017)	2024 (reviewed in 2022)

(including completion of technical reports by a third party, upon NOSB's request), debate among the NOSB, public comment periods, and public meetings. Public comment includes considerable time and resources by a wide array of stakeholders, including thousands of pages of detailed written reports for every material, and these must be prepared in a very short period of time. The NOP currently allows for approximately two years for each material to complete the sunset review cycle, and materials that "sunset" in 2018 are being considered in 2016 by the NOSB.

The advantages of a more even distribution of this work include:

- More balanced attention for individual materials, regardless of the date added to the National List
- Predictable and balanced materials workload for NOSB
- Reduced strain on NOP in supporting the NOSB's reviews during peak years, including coordination and review of technical reports and rulemaking actions
- Greater efficiencies in time and staff resources at NOP
- More reasonable number of items for the public to comment on in the limited time provided under the regulations.

Advancing the review of materials is the only way to resolve the distribution problem. Without any change, the disproportionate number of materials that sunset in 2017 will again come up for review in 2022. Since the review workload is lighter in all other years of the five year cycle than 2017, the NOSB could achieve an even load most quickly by advancing review as soon as possible after the 2017 materials have completed the renewal process.

RELEVANT AREAS OF THE RULE:

"No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition...within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition (7 U.S.C. 6517(e))."

DISCUSSION:

The following items were considered in the proposal to reorganize the 2/7 review.

3/8 cycle excluded – Items will not be moved from the 2/7 to the 3/8 because of timing - items would need to be included in 2016 review occurring concurrent to this discussion document. Additionally, items should be "reviewed" after the program has "renewed" items on the national list. This renewal step will take place no later than 3/17/2017 when the first 2017 material reached 5 years from its last renewal. Since reviews occur 2 years prior to sunset review date 2018 materials need to be reviewed prior to 3/17/2017.

Only materials on the 2/7 cycle subject to early review- Only items from the 2/7 cycle are being evaluated for an early review. Items on other cycle will remain where they are even if earlier review would lead to a more efficient review. Since materials may be added or removed from the list in any year, a perfectly even work load is unrealistic.

Materials voted for removal during 2016 and 2017 Sunset Review Excluded. Items voted for removal under the 2016 and 2017 sunset review are excluded from this process and accounting

of materials since these materials should be removed from the National List prior to implementation of these proposals.

Material Removals – Farmers, livestock operations and handling operations need to operate under a predictable business environment. These business are planning operations and researching new alternative materials on a 5 year cycles. Items reviewed early under the reorganization plan should be allowed to sunset on their original timeline in 2022. To do this, the NOSB will modify their sunset review documents to specify a 2022 removal and work in collaboration with the program to delay rulemaking until 2022.

Workload – Workload should be roughly even amongst the 5 years. Materials should be split by sub- committee to even the workload of each subcommittee. Since materials may be added or removed from the list in any year, a perfectly even work load is unrealistic.

Impartial and Efficient - The process of reorganization should be as impartial and non-political as possible while also being efficient. The most impartial reorganization reviews materials sequentially based on their listing on the national list. The most efficient reviews would group like items and groupings (i.e. all soil amendments) into the same year so the full list of materials could be considered. However, this can only be done in a limited way since only items of the 2/7 cycle are being reorganized. There are a number of options that balance impartiality and efficiency with different weights.

Method for Reorganization:

The following proposals are being considered for reorganization. The NOSB is seeking comment from the public on the preferred plan for reorganizing the sunset review process. Items voted to be removed in the 2016 and 2017 review are not included on the lists below. One of the proposals, “Current State” is to make no changes to the present sunset review process.

PROPOSALS CONSIDERED:

Attachment A shows the National list substances and the proposed next sunset review year under the various proposals.

Current State/Control:

- for reference – no change

Subcommittee	2018	2019	2020	2021	2022	Grand Total
CS	7	1	4	2	52	66
HS	10		2	5	94	111
LS					41	41
Grand Total	17	1	6	7	187	218

Option A: Straight division sequentially by reference number

- 3/8 cycle excluded
- 205.601, 205.602, 205.603, 205.604, materials on the 2/7 cycle are reorganized to the 4/9, 0/5, 1/6, 2/7 cycle sequential starting at 205.601 (a). Items on 205.605(a) 205.605(b) and 205.606 items are alphabetize within their own list and reorganized sequential amongst the same 4 review cycles.

Subcommittee	2018	2019	2020	2021	2022	Grand Total
CS	7	14	17	15	13	66
HS	10	23	26	29	23	111
LS		11	10	10	10	41
Grand Total	17	48	53	54	46	218

Option B: Like grouping referred together, groupings combined to make even numbers

- 3/8 cycle excluded
- Items are grouped by similar items within lists. Items on 205.601 are reorganized by subsection (i.e. part (a), (b), (c), etc.). Items on 205.602 are considered in the same cycle. Items on 205.603 are broken up by type (i.e. parasiticides, sanitizers, etc.). Items on 205.604 are considered together. Items are grouped by 205.605(a), 205.605 (b) 1st ½ of 205.606 (when alphabetized) and 2nd ½ of 205.606 (when alphabetized) are put into each cycle.

Subcommittee	2018	2019	2020	2021	2022	Grand Total
CS	7	15	19	13	12	66
HS	10	23	37	21	20	111
LS		12	10	11	8	41
Grand Total	17	50	66	45	40	218

RECOMMENDED PROPOSAL:

Option C: Same items grouped together, divided by reference

- 3/8 cycle excluded
- Like items, regardless of listing section are grouped together by item (i.e. chlorine materials on 205.601, 205.603 and 205.605 are all grouped together) and reorganized to the year where they first appear on the list starting at 205.601(a).
- 205.601, 205.602, 205.603, 205.604, materials on the 2/7 cycle are reorganized to the 4/9, 0/5, 1/6, 2/7 cycle sequential starting at 205.601(a). Items on 205.605(a) 205.605(b) and 205.606 items are alphabetize within their own list and reorganized sequential amongst the same 4 review cycles.

Subcommittee	2018	2019	2020	2021	2022	Grand Total
CS	7	15	16	15	13	66
HS	10	27	27	27	20	111
LS		11	10	10	10	41
Grand Total	17	53	53	52	43	218

The PDS recommends option C as the best proposal to move forward with. The PDS believes this proposal achieves efficiency by grouping like items for review, allowing for TR's to be coordinated across subcommittees and for reviews to take into account all facets of allowed usages across the organic industry. At the same time, the reorganization is impartial and blind to bias by using sequential reordering.

REQUEST FOR PUBLIC COMMENT:

We are seeking comment from the public on the following:

- 1) Which of the four options would be most advantageous for a reorganization of sunset review?
- 2) If Option C is preferred are there other items that should be grouped together? (Later materials on the 2/7 reviews cycle will be reordered as a result of any changes earlier in the list).

Vote in Subcommittee

Motion to accept the sunset timeline reorganization discussion document

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Attachment A

National List Section	Substance	Sunset/ Expiration Date	SC	Next Sunset Review Year under proposal:			RECOMMEN DATION: Option C	Notes
				Contr ol	Optio n A	Optio n B		
205.601(a)	Calcium hypochlorite	6/27/2017	CS	2022	2019	2020	2019	
205.601(a)	Chlorine dioxide	6/27/2017	CS	2022	2020	2020	2019	
205.601(a)	Copper sulfate	11/3/2018	CS	2018	2018	2018	2018	
205.601(a)	Ethanol	6/27/2017	CS	2022	2021	2020	2020	
205.601(a)	Hydrogen peroxide	6/27/2017	CS	2022	2022	2020	2021	
205.601(a)	Isopropanol	6/27/2017	CS	2022	2019	2020	2022	
205.601(a)	Ozone	11/3/2018	CS	2018	2018	2018	2018	
205.601(a)	Peracetic acid	5/29/2018	CS	2018	2018	2018	2018	
205.601(a)	Soap-based algicide/demosser s	6/27/2017	CS	2022	2020	2020	2019	
205.601(a)	Sodium carbonate peroxyhydrate	6/22/2020	CS	2020	2020	2020	2020	
205.601(a)	Sodium hypochlorite	6/27/2017	CS	2022	2021	2020	2019	
205.601(b)	Herbicides, soap-based	6/27/2017	CS	2022	2022	2019	2020	

205.601(b)	Newspaper or other recycled paper	6/27/2017	CS	2022	2019	2019	2021	
205.601(b)	Plastic mulch and covers (petroleum-based other than polyvinylchloride (PVC))	6/27/2017	CS	2022	2020	2019	2022	
205.601(b)	Biodegradable biobased mulch film	10/30/2019	CS	2019	2019	2019	2019	
205.601(c)	Newspaper or other recycled paper	6/27/2017	CS	2022	2021	2019	2021	
205.601(d)	Soaps, ammonium	6/27/2017	CS	2022	2022	2021	2019	
205.601(e)	Ammonium carbonate	6/27/2017	CS	2022	2019	2021	2020	
205.601(e)	Aqueous potassium silicate	6/22/2020	CS	2020	2020	2020	2020	
205.601(e)	Boric acid	6/27/2017	CS	2022	2020	2021	2021	
205.601(e)	Copper sulfate	11/3/2018	CS	2018	2018	2018	2018	
205.601(e)	Elemental sulfur	6/27/2017	CS	2022	2021	2021	2022	
205.601(e)	Lime sulfur	6/27/2017	CS	2022	2022	2021	2019	
205.601(e)	Oils, horticultural	6/27/2017	CS	2022	2019	2021	2020	
205.601(e)	Soaps, insecticidal	6/27/2017	CS	2022	2020	2021	2021	
205.601(e)	Sticky traps/barriers	6/27/2017	CS	2022	2021	2021	2022	
205.601(e)	Sucrose octanoate esters	6/27/2017	CS	2022	2022	2021	2019	
205.601(f)	Pheromones	6/27/2017	CS	2022	2019	2021	2020	
205.601(g)	Vitamin D3	6/27/2017	CS	2022	2020	2019	2021	
205.601(h)	Ferric phosphate	9/12/2016	CS	2021	2021	2021	2021	
205.601(i)	Aqueous potassium silicate	6/22/2020	CS	2020	2020	2020	2020	
205.601(i)	Copper sulfate	6/27/2017	CS	2022	2021	2020	2022	
205.601(i)	Coppers, fixed	6/27/2017	CS	2022	2022	2020	2019	
205.601(i)	Elemental sulfur	6/27/2017	CS	2022	2019	2020	2022	
205.601(i)	Hydrated lime	6/27/2017	CS	2022	2020	2020	2020	
205.601(i)	Hydrogen peroxide	6/27/2017	CS	2022	2021	2020	2021	
205.601(i)	Lime sulfur	6/27/2017	CS	2022	2022	2020	2019	
205.601(i)	Oils, horticultural	6/27/2017	CS	2022	2019	2020	2020	
205.601(i)	Peracetic acid	5/29/2018	CS	2018	2018	2018	2018	
205.601(i)	Potassium bicarbonate	6/27/2017	CS	2022	2020	2020	2021	
205.601(j)	Aquatic plant	6/27/2017	CS	2022	2021	2022	2022	

	extracts							
205.601(j)	Elemental sulfur	6/27/2017	CS	2022	2022	2022	2022	
205.601(j)	Humic acids	6/27/2017	CS	2022	2019	2022	2019	
205.601(j)	Lignin sulfonate	6/27/2017	CS	-	-	-	-	Removed 2017
205.601(j)	Liquid fish products	6/27/2017	CS	2022	2020	2022	2020	
205.601(j)	Magnesium sulfate	6/27/2017	CS	2022	2021	2022	2021	
205.601(j)	Soluble boron products	6/27/2017	CS	2022	2022	2022	2022	
205.601(j)	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt	6/27/2017	CS	2022	2019	2022	2019	
205.601(j)	Sulfurous acid	6/22/2020	CS	2020	2020	2020	2020	
205.601(j)	Vitamin B1	6/27/2017	CS	2022	2020	2022	2020	
205.601(j)	Vitamin C	6/27/2017	CS	2022	2021	2022	2021	
205.601(j)	Vitamin E	6/27/2017	CS	2022	2022	2022	2022	
205.601(k)	Ethylene	6/27/2017	CS	2022	2019	2022	2019	
205.601(l)	Lignin sulfonate	6/27/2017	CS	2022	2020	2019	2020	
205.601(l)	Sodium silicate	6/27/2017	CS	2022	2021	2019	2021	
205.601(m)	EPA List 3 - Inerts of Unknown Toxicity	11/3/2018	CS	2018	2018	2018	2018	
205.601(m)	EPA List 4 - Inerts of Minimal Concern	6/27/2017	CS	2022	2022	2021	2022	
205.601(n)	Hydrogen chloride	9/12/2016	CS	2021	2021	2021	2021	
205.601(o)	Microcrystalline cheesewax	3/15/2017	CS	2022	2019	2022	2019	
205.602(a)	Ash from manure burning	6/27/2017	CS	2022	2020	2019	2020	
205.602(b)	Arsenic	6/27/2017	CS	2022	2021	2019	2021	
205.602(c)	Calcium chloride	11/3/2018	CS	2018	2018	2018	2018	
205.602(d)	Lead salts	6/27/2017	CS	2022	2022	2019	2022	
205.602(e)	Potassium chloride	6/27/2017	CS	2022	2019	2019	2019	
205.602(f)	Sodium fluoaluminatate	6/27/2017	CS	2022	2020	2019	2020	
205.602(g)	Sodium nitrate	10/21/2012	CS	-	-	-	-	Invalid Listing
205.602(h)	Strychnine	6/27/2017	CS	2022	2021	2019	2021	

205.602(i)	Tobacco dust (nicotine sulfate)	6/27/2017	CS	2022	2022	2019	2022	
205.603(a)	Aspirin	6/27/2017	LS	2022	2019	2021	2019	
205.603(a)	Atropine	6/27/2017	LS	2022	2020	2021	2020	
205.603(a)	Butorphanol	6/27/2017	LS	2022	2021	2021	2021	
205.603(a)	Calcium hypochlorite	6/27/2017	LS	2022	2022	2019	2019	
205.603(a)	Chlorhexidine	6/27/2017	LS	2022	2019	2019	2022	
205.603(a)	Chlorine dioxide	6/27/2017	LS	2022	2020	2019	2019	
205.603(a)	Electrolytes	6/27/2017	LS	2022	2021	2020	2019	
205.603(a)	Ethanol	6/27/2017	LS	2022	2022	2019	2020	
205.603(a)	Fenbendazole	5/16/2017	LS	2022	2019	2022	2020	
205.603(a)	Flunixin	6/27/2017	LS	2022	2020	2021	2021	
205.603(a)	Furosemide	6/27/2017	LS	-	-	-	-	Removed 2017
205.603(a)	Glucose	6/27/2017	LS	2022	2021	2020	2022	
205.603(a)	Glycerine	6/27/2017	LS	2022	2022	2020	2019	
205.603(a)	Hydrogen peroxide	6/27/2017	LS	2022	2019	2019	2021	
205.603(a)	Iodine	6/27/2017	LS	2022	2020	2019	2020	
205.603(a)	Isopropanol	6/27/2017	LS	2022	2021	2019	2022	
205.603(a)	Ivermectin	6/27/2017	LS	2022	2022	2022	2021	
205.603(a)	Magnesium hydroxide	6/27/2017	LS	2022	2019	2021	2022	
205.603(a)	Magnesium sulfate	6/27/2017	LS	2022	2020	2020	2021	
205.603(a)	Moxidectin	5/16/2017	LS	2022	2021	2022	2019	
205.603(a)	Oxytocin	6/27/2017	LS	2022	2022	2021	2020	
205.603(a)	Peracetic acid	6/27/2017	LS	2022	2019	2019	2021	
205.603(a)	Phosphoric acid	6/27/2017	LS	2022	2020	2019	2022	
205.603(a)	Poloxalene	6/27/2017	LS	2022	2021	2021	2019	
205.603(a)	Sodium hypochlorite	6/27/2017	LS	2022	2022	2019	2019	
205.603(a)	Tolazoline	6/27/2017	LS	2022	2019	2021	2020	
205.603(a)	Vaccines	6/27/2017	LS	2022	2020	2020	2021	
205.603(a)	Xylazine	6/27/2017	LS	2022	2021	2021	2022	
205.603(b)	Copper sulfate	6/27/2017	LS	2022	2022	2020	2022	
205.603(b)	Formic Acid	8/3/2017	LS	2022	2019	2020	2019	
205.603(b)	Hydrated lime	6/27/2017	LS	2022	2020	2020	2020	
205.603(b)	Iodine	6/27/2017	LS	2022	2021	2019	2020	
205.603(b)	Lidocaine	6/27/2017	LS	2022	2022	2021	2020	
205.603(b)	Mineral oil	6/27/2017	LS	2022	2019	2020	2021	
205.603(b)	Procaine	6/27/2017	LS	2022	2020	2021	2022	
205.603(b)	Sucrose octanoate esters	6/27/2017	LS	2022	2021	2020	2019	

205.603(d)	Methionine	10/2/2017	LS	2022	2022	2022	2019	
205.603(d)	Trace minerals	6/27/2017	LS	2022	2019	2022	2020	
205.603(d)	Vitamins	6/27/2017	LS	2022	2020	2022	2021	
205.603(e)	EPA List 4 - Inerts of Minimal Concern	6/27/2017	LS	2022	2021	2022	2022	
205.603(f)	Excipients	6/27/2017	LS	2022	2022	2022	2022	
205.604(a)	Strychnine	6/27/2017	LS	2022	2019	2019	2021	
205.605(a)	Agar-agar	11/3/2018	HS	2018	2018	2018	2018	
205.605(a)	Alginate acid	6/27/2017	HS	2022	2020	2019	2019	
205.605(a)	Animal enzymes	11/3/2018	HS	2018	2018	2018	2018	
205.605(a)	Attapulgate	8/3/2017	HS	2022	2021	2019	2020	
205.605(a)	Bentonite	6/27/2017	HS	2022	2022	2019	2021	
205.605(a)	Calcium carbonate	6/27/2017	HS	2022	2019	2019	2022	
205.605(a)	Calcium chloride	6/27/2017	HS	2022	2020	2019	2019	
205.605(a)	Calcium sulfate	11/3/2018	HS	2018	2018	2018	2018	
205.605(a)	Carnauba wax	6/27/2017	HS	2022	2021	2019	2020	
205.605(a)	Carrageenan	11/3/2018	HS	2018	2018	2018	2018	
205.605(a)	Citric acid	6/27/2017	HS	2022	2022	2019	2021	
205.605(a)	Dairy cultures	6/27/2017	HS	2022	2019	2019	2019	
205.605(a)	Diatomaceous earth	6/27/2017	HS	2022	2020	2019	2020	
205.605(a)	Egg white lysozyme	9/12/2016	HS	-	-	-	-	Removed 2016
205.605(a)	Enzymes	6/27/2017	HS	2022	2021	2019	2019	
205.605(a)	Flavors	6/27/2017	HS	2022	2022	2019	2021	
205.605(a)	Gellan gum	6/22/2020	HS	2020	2020	2020	2020	
205.605(a)	Glucono delta-lactone	11/3/2018	HS	2018	2018	2018	2018	
205.605(a)	Kaolin	6/27/2017	HS	2022	2019	2019	2022	
205.605(a)	Lactic acid	6/27/2017	HS	2022	2020	2019	2019	
205.605(a)	L-Malic acid	9/12/2016	HS	2021	2021	2021	2021	
205.605(a)	Magnesium sulfate	6/27/2017	HS	2022	2021	2019	2021	
205.605(a)	Microorganisms	9/12/2016	HS	2021	2021	2021	2021	
205.605(a)	Nitrogen	6/27/2017	HS	2022	2022	2019	2020	
205.605(a)	Oxygen	6/27/2017	HS	2022	2019	2019	2021	
205.605(a)	Perlite	6/27/2017	HS	2022	2020	2019	2022	
205.605(a)	Potassium chloride	6/27/2017	HS	2022	2021	2019	2019	
205.605(a)	Potassium iodide	6/27/2017	HS	2022	2022	2019	2020	
205.605(a)	Sodium bicarbonate	6/27/2017	HS	2022	2019	2019	2019	
205.605(a)	Sodium carbonate	6/27/2017	HS	2022	2020	2019	2020	
205.605(a)	Tartaric acid	11/3/2018	HS	2018	2018	2018	2018	

205.605(a)	Wood resin	6/27/2017	HS	2022	2021	2019	2021	
205.605(a)	Yeast	10/21/2017	HS	2022	2022	2019	2022	
205.605(b)	Acidified sodium chlorite	3/15/2017	HS	2022	2019	2020	2019	
205.605(b)	Activated charcoal	9/12/2016	HS	2021	2021	2021	2021	
205.605(b)	Alginates	6/27/2017	HS	2022	2020	2020	2020	
205.605(b)	Ammonium bicarbonate	6/27/2017	HS	2022	2021	2020	2021	
205.605(b)	Ammonium carbonate	6/27/2017	HS	2022	2022	2020	2020	
205.605(b)	Ascorbic acid	6/27/2017	HS	2022	2019	2020	2022	
205.605(b)	Calcium citrate	6/27/2017	HS	2022	2020	2020	2019	
205.605(b)	Calcium hydroxide	6/27/2017	HS	2022	2021	2020	2020	
205.605(b)	Calcium hypochlorite	6/27/2017	HS	2022	2022	2020	2019	
205.605(b)	Calcium phosphate dibasic	6/27/2017	HS	2022	2019	2020	2020	
205.605(b)	Calcium phosphate monobasic	6/27/2017	HS	2022	2020	2020	2020	
205.605(b)	Calcium phosphate tribasic	6/27/2017	HS	2022	2021	2020	2020	
205.605(b)	Carbon dioxide	6/27/2017	HS	2022	2022	2020	2021	
205.605(b)	Cellulose	11/3/2018	HS	2018	2018	2018	2018	
205.605(b)	Chlorine dioxide	6/27/2017	HS	2022	2019	2020	2019	
205.605(b)	Cyclohexylamine	9/12/2016	HS	-	-	-	-	Removed 2016
205.605(b)	Diethylaminoethanol	9/12/2016	HS	-	-	-	-	Removed 2016
205.605(b)	Diglycerides	6/27/2017	HS	2022	2020	2020	2022	
205.605(b)	Ethylene	6/27/2017	HS	2022	2021	2020	2019	
205.605(b)	Ferrous sulfate	6/27/2017	HS	2022	2022	2020	2019	
205.605(b)	Glycerin	6/27/2017	HS	2022	2019	2020	2020	
205.605(b)	Hydrogen peroxide	6/27/2017	HS	2022	2020	2020	2021	
205.605(b)	Magnesium carbonate	6/27/2017	HS	-	-	-	-	Removed 2017
205.605(b)	Magnesium chloride	6/27/2017	HS	2022	2021	2020	2021	
205.605(b)	Magnesium stearate	6/27/2017	HS	2022	2022	2020	2022	
205.605(b)	Monoglycerides	6/27/2017	HS	2022	2019	2020	2019	
205.605(b)	Nutrient vitamins and minerals	10/21/2017	HS	2022	2020	2020	2020	

205.605(b)	Octadecylamine	9/12/2016	HS	-	-	-	-	Removed 2016
205.605(b)	Ozone	6/27/2017	HS	2022	2021	2020	2021	
205.605(b)	Peracetic acid	9/12/2016	HS	2021	2021	2021	2021	
205.605(b)	Phosphoric acid	6/27/2017	HS	2022	2022	2020	2022	
205.605(b)	Potassium acid tartrate	6/27/2017	HS	2022	2019	2020	2022	
205.605(b)	Potassium carbonate	6/27/2017	HS	2022	2020	2020	2019	
205.605(b)	Potassium citrate	6/27/2017	HS	2022	2021	2020	2020	
205.605(b)	Potassium hydroxide	5/29/2018	HS	2018	2018	2018	2018	
205.605(b)	Potassium phosphate	6/27/2017	HS	2022	2022	2020	2021	
205.605(b)	Silicon dioxide	11/3/2018	HS	2018	2018	2018	2018	
205.605(b)	Sodium acid pyrophosphate	9/12/2016	HS	2021	2021	2021	2021	
205.605(b)	Sodium citrate	6/27/2017	HS	2022	2019	2020	2022	
205.605(b)	Sodium hydroxide	6/27/2017	HS	2022	2020	2020	2019	
205.605(b)	Sodium hypochlorite	6/27/2017	HS	2022	2021	2020	2019	
205.605(b)	Sodium phosphates	6/27/2017	HS	2022	2022	2020	2020	
205.605(b)	Sulfur dioxide	6/27/2017	HS	2022	2019	2020	2021	
205.605(b)	Tetrasodium pyrophosphate	9/12/2016	HS	-	-	-	-	Removed 2016
205.605(b)	Tocopherols	6/27/2017	HS	2022	2020	2020	2022	
205.605(b)	Xanthan gum	6/27/2017	HS	2022	2021	2020	2019	
205.606	Arabic gum	6/27/2017	HS	2022	2022	2022	2020	
205.606	Beet juice extract color	6/27/2017	HS	2022	2019	2021	2021	
205.606	Beta-carotene extract color	5/29/2018	HS	2018	2018	2018	2018	
205.606	Black currant juice color	6/27/2017	HS	2022	2020	2021	2022	
205.606	Black/Purple carrot juice color	6/27/2017	HS	2022	2021	2021	2019	
205.606	Blueberry juice color	6/27/2017	HS	2022	2022	2021	2020	
205.606	Carob bean gum	6/27/2017	HS	2022	2019	2022	2021	
205.606	Carrot juice color	6/27/2017	HS	2022	2020	2021	2022	
205.606	Casings	6/27/2017	HS	2022	2021	2022	2019	
205.606	Celery powder	6/27/2017	HS	2022	2022	2022	2020	
205.606	Cherry juice color	6/27/2017	HS	2022	2019	2021	2021	
205.606	Chia (Salvia hispanica L.)	6/27/2017	HS	-	-	-	-	Removed 2017

205.606	Chokeberry— Aronia juice color	6/27/2017	HS	2022	2020	2021	2022	
205.606	Cornstarch (native)	6/27/2017	HS	2022	2021	2022	2019	
205.606	Dillweed oil	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Elderberry juice color	6/27/2017	HS	2022	2022	2021	2020	
205.606	Fish oil	6/27/2017	HS	2022	2019	2022	2021	
205.606	Fructooligosaccha rides	6/27/2017	HS	2022	2020	2022	2022	
205.606	Galangal, frozen	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Gelatin	6/27/2017	HS	2022	2021	2022	2019	
205.606	Grape juice color	6/27/2017	HS	2022	2022	2021	2020	
205.606	Grape skin extract color	6/27/2017	HS	2022	2019	2021	2021	
205.606	Guar gum	6/27/2017	HS	2022	2020	2022	2022	
205.606	Inulin- oligofructose enriched	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Kelp	6/27/2017	HS	2022	2021	2022	2019	
205.606	Konjac flour	6/27/2017	HS	2022	2022	2022	2020	
205.606	Lecithin—de-oiled	3/15/2017	HS	2022	2019	2022	2021	
205.606	Lemongrass- frozen	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Locust bean gum	6/27/2017	HS	2022	2020	2022	2022	
205.606	Orange pulp, dried	3/15/2017	HS	2022	2021	2022	2019	
205.606	Orange shellac- unbleached	6/27/2017	HS	2022	2022	2022	2020	
205.606	Paprika color	6/27/2017	HS	2022	2019	2021	2021	
205.606	Pectin (non- amidated forms only)	6/27/2017	HS	2022	2020	2022	2022	
205.606	Peppers (Chipotle chile)	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Pumpkin juice color	6/27/2017	HS	2022	2021	2021	2019	
205.606	Purple potato juice	6/27/2017	HS	2022	2022	2022	2020	
205.606	Red cabbage extract color	6/27/2017	HS	2022	2019	2021	2021	
205.606	Red radish extract color	6/27/2017	HS	2022	2020	2021	2022	
205.606	Saffron extract color	6/27/2017	HS	2022	2021	2021	2019	
205.606	Seaweed, Pacific	3/15/2017	HS	2022	2022	2022	2020	

	kombu							
205.606	Sweet potato starch	6/27/2017	HS	2022	2019	2022	2021	
205.606	Tragacanth gum	6/22/2020	HS	2020	2020	2020	2020	
205.606	Turkish bay leaves	6/27/2017	HS	-	-	-	-	Removed 2017
205.606	Turmeric extract color	6/27/2017	HS	2022	2020	2021	2022	
205.606	Wakame seaweed (Undaria pinnatifida)	6/27/2017	HS	2022	2021	2022	2019	
205.606	Whey protein concentrate	6/27/2017	HS	-	-	-	-	Removed 2017

Sunset 2018 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), §205.605(b), §205.606
April 2016

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 that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2018. 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 the fall 2016 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2016 public meeting. These comments should be provided through www.regulations.gov by April 14, 2016 as explained in the meeting notice published in the Federal Register.

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 substances currently on the National List were added to the list based on evidence available to the NOSB at the time. 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 §205.606.

For nonorganic agricultural substances on section §205.606, the NOSB 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 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 April 14, 2016 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2018 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), §205.605(b), §205.606
April 2016

Reference: 7 CFR 205.605(a) Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

(Linked below)

[Agar-agar](#)

[Animal enzymes](#)

[Calcium sulfate-mined](#)

[Carrageenan](#)

[Glucono delta-lactone](#)

[Tartaric acid](#)

Reference: 7 CFR 205.605(b) Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

[Cellulose](#)

[Potassium hydroxide](#)

[Silicon dioxide](#)

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(2) [Beta-carotene extract color](#)

Agar-agar

Reference: §205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Agar-agar has been used as a food additive for over 350 years. Current uses in food include: stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. It can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. Useful characteristic of agar-agar include that it can withstand high temperatures, and since it is practically tasteless and doesn't require the addition of cations to form gels, it doesn't interfere with taste profiles. It can be used in foods in combination with other thickening or gelling agents. It is classified as GRAS.

Manufacture:

Agar-agar is derived from red algae. The main species harvested are *Gelidium* and *Gracilaria*, the second of which can be cultivated. After harvesting, the algae are cleaned with water, dried in the sun, pressed into bales and shipped to processors for agar-agar extraction. Prior to extraction the *Gracilaria* species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution) followed by rinsing with water and sometimes a weak acid to neutralize the alkali. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides. This chemical change produces agar-agar with increased gel strength. Without this pretreatment, the gels extracted from *Gracilaria* species would be too weak for most food applications. (TR 2011, 165-176)

After pretreatment, the algae are placed in tanks for the extraction, via hot water pressure, and then filtration. The last step is to remove water from the gel either through a freeze thaw process or by mechanical pressure. The gels are then dried with hot air resulting in a finished product of flakes, strips, or powder.

Based on this manufacturing information, the Handling Subcommittee acknowledges that a reclassification of agar-agar might be needed in the future once the NOP finalizes the Guidance for Material Classification.

International:

Agar-Agar is permitted for use in organic production by CODEX, the Commission of the European Communities, IFOAM, and Canada.

Discussion:

The 2011 TR did not find the substance to be harmful to human health, additionally the report stated that no excessive levels of heavy metals or other contaminants have been reported in agar-agar. In regards to whether the substance may be harmful to the environment or biodiversity, the TR stated there is limited evidence to suggest that the harvesting of agarophytes (algae used to make agar-agar) may be harmful to biodiversity. Additionally, harvesting wild agarophytes may also reduce biodiversity on nearby beaches. The TR concludes through that no studies were found to indicate whether or the not the harvesting of agarophytes in particular is harmful to the biodiversity or nearby beaches or in the

algae beds themselves (TR 2011 296-312).

The NOSB is in the process of reviewing the use of all marine plants currently on the National List, for which a limited technical report will be requested. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

Additional information requested by NOSB:

The 2011 TR provides possible agricultural alternatives to agar-agar in food applications, including: (1) gelling agents, such as pectin (high methoxy), gelatin, unmodified starches, and konjac flour; and (2) thickeners, emulsifiers, and stabilizers, such as vegetable gums (Arabic, locust/carob bean, guar), unmodified starches, tragacanth gum, konjac flour.

1. Have there been any new developments with alternatives to agar-agar?
2. Why is agar-agar used instead of alternatives? What are the unique characteristics that make it essential to organic handling?

Animal enzymes

Reference: §205.605(a) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Technical Report: [2000 TAP](#), [2011 TR](#), [2015 TR](#)

Petition(s): NA

Past NOSB Actions: [11/2000 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Subcommittee Review

Use: Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-142)

Animal enzymes, such as rennet, are used as a coagulant to curdle milk, to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect. For example, the amount of animal-derived rennet used to clot milk is 0.036 percent. (TR 2011 727-728)

Manufacture:

Traditionally the fourth stomach or other organs of goat kids or calves are dried, cleaned, and then sliced into pieces, before being stored in either whey or saltwater. Vinegar or wine can be added to lower the pH. After allowing the solution to sit for a few days, it is filtered repeatedly. A small amount of boric acid is added to the filtrate. In industrial production the stomach is minced and the pH adjusted by adding hydrochloric acid and sodium phosphate. (TR 2011 444-458)

International: The use of enzymes is permitted in organic processing in Canada, EU, IFOAM and in CODEX.

Ancillary substances: Explained in the Enzymes Technical Evaluation Report – Limited Scope, (NOP 2015):

“Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014).”

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.

To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

An additional ancillary substance proposal will be reviewed at a later date.

Discussion:

Evaluation question #9 in the 2011 TR does not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

Evaluation question #10 in the 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals (Tucker and Woods, 1995). FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (FDA, 1995). (TR 2011 752-758).

There are no true alternatives to animal enzymes. Enzymes can only be substituted with another enzyme with the same function. One alternative to animal derived rennet for the production of cheese is genetically engineered chymosin, which is incompatible with organic food handling due to excluded methods.

The 2000 TAP review for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Additional information requested by NOSB

1. Are any animal derived enzymes currently being produced from organic livestock? If yes, on what scale?
2. In the 2011 TR on Animal Enzymes, manufacture of the substance is focused on rennet. Please submit information if the manufacture of other types of animal enzymes differ from rennet.

Calcium sulfate-mined

Reference: §205.605(a)

Technical Report: [1996 TAP](#), [2001 TAP](#)

Petition(s): [2000](#)

Past NOSB Actions: [09/1996 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

- Used as a coagulant in tofu manufacturing. Calcium sulfate is essential to soft and silky tofu types.
- Yeast food and dough conditioner, water conditioner
- Firming agent (in canned foods)
- Gelling ingredient
- Used in baking powder
- Sequestrants, filler, carrier, pH buffer, abrasive agent
- Cosmetics and toothpaste

Manufacture:

Calcium Sulfate can be obtained from natural sources or synthetic sources. The listing restricts calcium sulfate to mined sources and mined gypsum is the primary source. After mining crude gypsum is ground and separated. It is normally sold as pure but may contain impurities of calcium carbonate and natural occurring silica. Calcium sulfate is GRAS.

International: IFOAM – restricted “For soybean products, confectionery and in bakers’ yeast” but not restricted to mined sources. CODEX – restricted to “Cakes & biscuits/soy bean products/bakers yeast. Carrier,” but it is not restricted to mined sources. Japan – restricted to “Limited to be used as coagulating agent or used for the confectionary, the processed beans products or bread yeast,” but it is not restricted to mined sources. Canada – restricted to “as a carrier for cakes and biscuits; for soybean products; and for bakers’ yeast” with the restriction, “Sulfates produced using sulfuric acid are prohibited.” EU - restricted to “use as a coagulation agent and carrier only” but is not restricted to mined sources. Mexico – restricted to “Acidifiers, acidity, anti-caking agent, antifoam, filler and coagulant,” but is not restricted to mined sources.

Ancillary substances: None reported in 2001 TAP

Discussion:

Information from the petition and 2001 TAP review maintain that this material is consistent with OFPA criteria. Unless new information is provided from the public about impacts to the environment or human health this material should be renewed.

Additional information requested by NOSB:

None

Carrageenan

Reference: §205.605(a)

Technical Report: [1995 TAP](#), [2011 TR](#); [2016 Limited Scope TR](#)

Petition(s): NA

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987 –misspelled as ‘carageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Carrageenan (CAS # 9000-07-1) is a generic term referring to a family of linear polysaccharides (i.e., complex carbohydrate chains) that are extracted from species of red seaweeds (Class *Rhodophyceae*). It is an FDA-approved direct food additive with an average molecular weight of 200-800 kDa, and may be referred to as “undegraded” or “native” carrageenan in the literature. The actual molecular weight of food-grade carrageenan represents a spectrum of molecular weights that are naturally present in live seaweed.

Carrageenan can function as a bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, or thickener. It can promote gel formation and thicken, stabilize and improve palatability and appearance of foods. It is typically used at a rate ranging from 0.03% to 0.75%, and its most common uses are in dairy products, non-dairy “milk” analogs, meats, and drink mixes. It has been used in food processing for more than 600 years.

During the last Sunset Review in 2012, the NOSB discovered that there was a lot of controversy surrounding this ingredient, both among the scientific community and the public. The scientific community disagreed over the research methodology used in studies and meta reviews that were not always consistent with how carrageenan behaves when ingested in food. Several public interest organizations were taking sides with one scientific group's approach over the others because of concerns that carrageenan caused inflammation or worse. The NOSB could not thoroughly investigate these issues within the very short period of time between the sunset announcement and the vote to renew. The members of the 2012 Handling Subcommittee did promise the public to do a more thorough analysis at the time of the next sunset review.

Therefore the Handling Subcommittee commissioned a Limited Scope Technical Report (TR, see link above) to supplement the one that was done in 2011. This report focused on the effects of the substance on human health: Evaluation Question #10. Very specific questions were posed about the research methodology regarding the molecular weights of carrageenan, the relative value of *in vivo* vs. *in vitro* studies, and the newest studies since the last TR was done in 2011.

The TR came back with the following statement, “Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature.” (lines 173 - 174). And this, “ However, since different animal species, different animals within the same species, and different human intestinal cell lines have produced different experimental results, it is reasonable to expect that humans may also experience varying degrees of sensitivity to carrageenan in the diet.” (lines 177 - 180)

Members of the Handling Subcommittee have not decided on whether to propose removing

carrageenan from the National List. We are troubled that the research showing inflammation and glucose intolerance is all from one research team and has not been replicated. We hope that in the next few months before we vote more conclusive research replication or rebuttal will help inform our decision.

It is also worth noting that in the time since the last review the World Health Organization JECFA committee re-evaluated carrageenan for use in infant formula and changed their opinion on restricting its use to have an unrestricted status. (See TR for citation).

This is the first meeting of the two meetings at which carrageenan will be considered under the new sunset review process. All stakeholders can now read the new TR and try your best to mount arguments for one side or the other. It does come down to a core question of philosophy about the organic regulations: if humans have varying degrees of sensitivity to carrageenan in the diet, is that enough reason to prohibit it in all organic foods? Humans are also sensitive to gluten, dairy, legumes, and many other foods; is that a reason to keep them out?

Additional information requested by NOSB

1. After the last review in 2012 we know some companies pledged to remove carrageenan from their products. Has this been successful and what alternatives have been used? Are there any products for which it has not been successful, and why?
2. Are there any stakeholders who rely on this material? If so for what uses and why have alternatives not been successful?
3. Is "sensitivity" to a food ingredient enough of a reason to prohibit a substance in organic products if it is clearly listed as an ingredient on a food label?

Glucono delta-lactone

Reference: §205.605(a) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Technical Report: [2002 TAP](#); [2016 TR](#)

Petition(s): [2002](#)

Past NOSB Actions: [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use: Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly in the production of silken tofu. In tofu production GDL serves as a coagulant. GDL can also be used as a curing agent, leavening agent, pH control agent and sequestrant.

Manufacture: There are a variety of ways a GDL can be produced. The most common form has gluconic acid production is called the Blom process in which gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium hydroxide or calcium carbonate is added to this to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via acid base reactions and fermentation (2016

Technical Review pgs. 10-11). Other processes to make GDL involve oxidation with bromine water (disallowed by the annotation on the National List) and oxidation with purified enzymes.

International: GDL is not listed on the permitted substances lists of Canada, EU, Japan, Codex, or IFOAM.

Ancillary Substances: GDL is >99% pure and has no ancillary substances present. GDL is often sold in formulation with other additives specifically designed for the application – these substances should be reviewed separately as they are not ancillary substances.

Discussion: The original petition and primary use of GDL is for the coagulation of tofu. Several coagulants for tofu exist including magnesium chloride, calcium chloride, calcium sulfate and magnesium sulfate. Acids such as citric or lactic acid can be used as well. Each of these substances produces a different type of tofu texture and flavor, resulting in distinctly different products. Calcium salts produce firm tofu, sulfate salts produce soft tofu, and GDL produces silken tofu. Citrus and Lactic acids produce acidified tofu, which is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

The 2016 Technical Review examined human health and environmental impacts of GDL use and production but found low to no risk. The review did raise the question of classification, given the substance is produced via fermentation and acid-base reactions similar to that of citric acid (also listed on 205.605(a) nonsynthetic). The technical review also raised concerns about the potential for GMO enzymes to be used in the production of GDL via the oxidation with enzymes production method, which is not the most common form of production.

Additional information requested by NOSB

1. Is GDL being used in applications other than tofu production for organic processed foods?
2. If GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salts sufficient to produce all forms of tofu?
3. Should GDL produced from enzymes be prohibited or further restricted due to concerns around GMOs?

Tartaric acid

Reference: §205.605(a) Tartaric acid - made from grape wine.

Technical Report: [2011 TR](#)

Petition(s): [2011 Petition to remove from 205.605\(b\) - made from malic acid](#)

Past NOSB Actions: [NOSB meeting review 11/1995](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Uses:

Tartaric acid is a natural organic acid that is in many plants especially grapes, bananas, and tamarinds. Tartaric acid can be used to create several different salts, including tartar emetic (antimony potassium tartrate), cream of tartar (potassium hydrogen tartrate), and Rochelle salt (potassium sodium tartrate). The primary uses of tartaric acid are associated with its salts.

Tartaric acid and its salts have a very wide variety of uses. These include use as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. It has been used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks.

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to 'rise' without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties. Cream of tartar is used to make cake frosting and candies

International:

The use of tartaric acid (C₄H₆O₆; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredient classified as a food additive in beverages. Use of the synthetic form is allowed only if the nonsynthetic form of tartaric acid is not commercially available. Tartaric acid derived from nonsynthetic sources is also permitted for use as a processing aid in beverages (the Canadian General Standards Board, 2011).

The European Economic Community (EEC) permits the use of tartaric acid as a food additive in organic food if derived from a plant source, which is presumably grapes (EEC 889/2008, 2008).

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, and stabilizer. Tartaric acid from a plant source (i.e. nonsynthetic L(+) tartaric acid) is permitted for use as a food additive in organic food production (although exclusions of the GFSMA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

Additional information requested by NOSB

1. The Handling Subcommittee requests public comment on the use of Tartaric Acid and its essentiality in organic processing.

Cellulose

Reference: §205.605(b) Cellulose - for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Use:

Cellulose (CAS # 9004-34-6 alpha cellulose) is available in several different forms with each having varying functional qualities used for multiple purposes in organic handling. There are two specific forms of cellulose currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing. Uses in organic handling include: as a processing aid for filtration of juices; as an anti-caking agent ingredient for use in shredded cheese; and as a processing aid in the form of peelable hot dog and sausage casings. Some of these uses in organic handling have been around since even before the creation of OFPA, with cellulose being allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture:

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth (EMBL, 2015)(TER 2-11-2016). Most commercially available cellulose (powdered) is produced from wood pulp (40-50% cellulose) or other plant sources (such as: corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc.) through a delignification process that results in a chemically changed synthetic end product (Franz and Blaschek 1990; French et al. 1993). The original process for making regenerated cellulose is called the viscose method. It converts cellulose fibers into regenerated fibers and films and with some minor changes is still in use today (this process was invented in the 1890's). The new Technical Evaluation Report (February 11, 2016) mentions several other sources of cellulose such as: from recycled paper and cardboard (US EPA 2015b) and microbially produced cellulose made from the fermentation of sugars with bacteria and microalgae. Cellulose is also currently being looked at in research studies in nanotechnology, according to information provided in the new TR (Hubbe et al. 2008) (Martirosyan and Schneider 2014).

International: Cellulose is permitted by most organic standards outside of the U.S. for at least some uses and applications in organic processing or handling.

- **Canada** – Allowed as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings (CAN/CGSB 2015).
- **European Economic Community** (EEC) Council Regulation EC No. 834/2007 and 889/2008 – Cellulose is authorized for use in the wine sector only for use as an inert filtering aid (EU Commission 2008).
- **IFOAM** –in Appendix 4, Table 1 “List of approved additives and processing/post-harvest handling aids” as a processing and post-harvest handling aid with no annotation (IFOAM 2014).

Discussion:

During the previous Sunset Review cycle there were no sources of either nonsynthetic or organic cellulose identified. During the current cycle we will be asking organic handlers and other stakeholders to help provide answers to that question. There are numerous uses for cellulose in food handling, but

not all uses are allowed in organic food production/handling. The current annotation for cellulose in organic handling under §205.605(b) allows it to be used only as: a filtering aid, as a component of processed meat casings, or as an anti-caking agent. This is a material that was in use by organic handlers in organic food production even prior to the formation of the National Organic Program and the creation of the National List.

The new TR states that food-grade cellulose filters composed of either 100% or food grade 99%+ cellulose without ancillary ingredients are commercially available (ErtolAlsop 2015; Purifiber 2015; International Fiber Corporation 2015). There are other ingredients that sometimes may be added to reduce labor costs or increase the functional efficiency of cellulose for certain processes. While the TR (February 11, 2016) also mentions that these ancillary substances or ingredients may be added for other uses along with cellulose, it does make it very clear that for all of these uses there are well defined sources of commercially available cellulose that do not include these ancillary ingredients (International Fiber Corporation 2015).

The new TR does raise a couple of concerns regarding potential for environmental impact; specifically, depending on the source of the cellulose, there could be some concerns associated with the logging of the trees for wood, and some natural ecosystems have been replaced with fast-growing species of pulp trees (Roberts 2007). Recycling and the use of alternative crops will help to mitigate the impact. Some concerns have also been raised about cellulose waste generated from food processing, but these are a subject of current research to look at conversion of these wastes into useful products. (Das and Singh 2004). Also, recycling and the use of alternative crops will help to mitigate the impact of cellulose manufacturing on biodiversity (Roberts 2007).

The TR also mentions that studies on both animal models and human subjects found cellulose to be non-toxic (LSRO 1973). Although cellulose is not explicitly listed as GRAS in 21 CFR 184, the Select Committee on GRAS Substances concluded that “[t]here is no evidence in the available information on pure and generated cellulose, including micro-crystalline cellulose, that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are at levels that are current, or might reasonably be expected in the future” (SCOGS 2015).

During the October 16, 2001 NOSB Fall meeting the original discussion around listing cellulose for use in organic handling first took place regarding whether or not it should be added to the National List. At that time, it was determined that there were two sources of cellulose approved for use: regenerative casings, and powdered cellulose for use as anti-caking or as a filter aid. Part of the discussion during that time was considering adding the word “powdered” as part of the annotation. It was ultimately decided not to include the more restrictive addition as part of the original annotation for cellulose. During the last Sunset Review cycle at the Spring 2012 NOSB meeting it was discussed and voted on by the board to add the word “powdered” as part of the annotation. When the NOP did the 2013 Sunset Docket they were not able to make the change to the cellulose annotation voted on by the NOSB due to the lack of time needed to add changes, inform the public, and the need to determine/estimate the impact that this more restrictive annotation might have on organic stakeholders currently using this material. So it remains un-clarified at this time if the word “powdered” should be added to the annotation as a means by which to limit the type of cellulose allowed for these particular uses or not. Also, at the Spring 2012 NOSB meeting certifiers and handlers provided information to confirm that the microcrystalline form was not used in organic handling and that, per conversations with the NOP, it was also determined that this form of cellulose was not allowed for use in organic handling.

Additional information requested by NOSB

1. Have there been any new sources for either a nonsynthetic or an organic form of cellulose

identified during this current Sunset Cycle? If so please provide the NOSB with information on this source.

2. Are there any new or potential uses not covered by the current annotation that should be brought to the NOSB's attention? If so please explain.
3. Have there been any possible alternatives to any of the allowed uses for cellulose identified during this current Sunset Cycle, and if so please provide the NOSB with their names and how they compare to the use of cellulose for the specific use.
4. What impact would the inclusion of the word "powdered" as part of the annotation have on your handling process? Should the NOSB consider bringing forth a separate proposal to make this change to the cellulose annotation?
5. Could you help us to identify any ancillary substances that might be used with cellulose in organic handling or processing? The new Technical Evaluation Report mentions several potential ones for both powdered and the inedible form used in regenerative casings. Are any of these currently being used in organic handling and processing?

Potassium hydroxide

Reference: §205.605(b) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): 2001 petition, [2011](#) Amend annotation

Past NOSB Actions: [10/1995 meeting minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: Added to the National list 12/21/2000 ([65 FR 80548](#)); National List amended 11/03/2003 ([68 FR 62215](#)); National List amended 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Uses:

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener and poultry scald agent. It is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as GRAS for humans (21 CFR 184.1631), which are allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. In fruit and vegetable peeling, potassium hydroxide serves to weaken the glycolytic bonds of pectin, which is responsible for skin adhesion. Weakening these bonds allows the peeling of fruit and vegetable skins by water spray or other mechanical methods. According to the TR, Peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution—about 10%—and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to neutralize the pH of the fruit.

International:

- Canada - Canadian General Standards Board Permitted Substances List –Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (CAN/CGSB 2011 Table 6.6).
- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and

Marketing of Organically Produced Foods (GL 32-1999) – Allowed for pH adjustment for sugar processing (FAO/WHO Joint Standards Programme 1999, Table 4).

- European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 – Caustic potash is on Annex VII, “Products for cleaning and disinfection” (EU Commission 2008). However, it does not appear in Annex VIII, “Certain products and substances for use in production of processed organic food, yeast and yeast products.”
- Japan Agricultural Standard (JAS) for Organic Production—“Limited to be used for processing sugar as pH adjustment agent” (Japan MAFF 2000).
- IFOAM – Organics International (IFOAM) – Not found.

History:

In 1995, the NOSB approved the addition of potassium hydroxide to 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read — “prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.” The 2001 TAP review for that expansion noted that: “The stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances.” The 2001 TAP review also noted that the environmental effects which had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step. Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Committee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercially processing methods used for peaches, the NOSB full board favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Additional information requested by NOSB

1. The Handling Subcommittee requests public comment on the use of potassium hydroxide and its essentiality in organic processing.

Silicon dioxide

Reference: §205.605(a) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

Technical Report: [1996 TAP](#), [2010 TR](#)

Petition(s): [2010 petition to remove](#)

Past NOSB Actions: [09/1996 minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: Added to NL 12/21/2000 ([65 FR 80548](#)); National list amended 05/28/2013 (effective 11/03/2013) ([78 FR 31815](#))

Sunset Date: 11/03/2018

Use:

Synthetic amorphous silicon dioxide is used as a food additive for various functions including:

- An anticaking agent in foods
- A stabilizer in beer production, and filtrated out of the beer prior to final processing
- An adsorbent in tableted foods
- A carrier
- A defoaming agent

Manufacture:

Silicon dioxide can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment. According to FDA regulations, silicon dioxide (as a food additive) should be manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

Silicon dioxide can be produced as a nanomaterial, but for use in organics the material would have to be petitioned to be placed on the National List. As stated in NOP Policy Memorandum from March 2015:

As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been: 1) petitioned for use; 2) reviewed and recommended by the NOSB; and 3) added to the National List through notice and comment rulemaking.

Currently there is no silicon dioxide produced with nanotechnology on the National List.

International: Silicon dioxide is permitted in organic handling by Canada, European Union, IFOAM, and Japan. In the EU its use is restricted to an anticaking agent for herbs and spices, of plant origin. In Japan its use is limited to processed foods of plant origin as gel or colloidal solution.

Ancillary substances: None reported in 2010 TR

History:

In 2010 a petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of a commercially produced rice based certified organic alternative to silicon dioxide. In 2011, the NOSB did not pass the petition. New data was presented in the petition claiming that a reformulation of the rice based alternative could now be substituted for silicon dioxide at nearly 1:1 rations, but the Handling Subcommittee felt the data was limited, not published from a third party source, and did not conclusively demonstrate its applicability in all products and processes.

The subcommittee did however wish to acknowledge the availability of a natural alternative and even though they did not vote to remove silicon dioxide in its entirety they did pass (Yes: 11, No: 3) a recommendation to amend the annotation of silicon dioxide to:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetics allowed—Silicon dioxide—providing sufficient evidence showing nonsynthetic alternatives are not commercially available for a specific product/process is presented.

Resulting in its current listing as:

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available

The subcommittee in their 2010 recommendation also publically noted that additional information and clarification of processors' needs regarding silicon dioxide would be needed for future deliberations by the NOSB.

Discussion:

The 2010 TR did not find the manufacture or use of silicon dioxide to be harmful to people or the environment. The question that the subcommittee has is if silicone dioxide should remain on the list due to 205.600:

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes.

Additional information requested by NOSB

1. Are there instances where due to lack of availability of organic alternatives, you must use silicon dioxide?
2. Are there instances where the organic alternative does not perform the needed function and therefore you must use silicon dioxide? If so, what are those functions? And what has been the undesired result when silicon dioxide was tried?

Colors: Beta-carotene extract

Reference: §205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(2) Beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7).

Technical Report: [2011 TR](#)

Petition(s): [2007](#), [2009](#)

Past NOSB Actions: [04/2007 recommendation](#), [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 06/27/2007 ([72 FR 35137](#)); National List amended 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Discussion:

Beta-carotene was petitioned by color manufacturers in 2007. No TAP was requested. The NOSB Handling Subcommittee rejected the petition to add this material to 205.606 stating: "the petitioner did not provide credible information regarding the lack of supply of organic raw material, and the ability to process them as organic". (Vote: 4:1)

However, at the March 2007 NOSB meeting the material was approved.

The Interim Final Rule (FR 35141) includes the following: "Though a significant number of comments were received, very few comments submitted were from processors or handlers. Comments from this segment of the industry would be helpful in developing a final rule. A number of comments expressed

concern regarding the information and criteria used for determining the fragility of the organic ingredient supply or organic availability of the proposed 38 nonorganic agricultural ingredients.”

The Interim Final Rule also includes the following: “As a result of the district court's final order and judgment in *Harvey v. Johanns* and requests for an extension of the public comment period on AMS-TM-07-0062, AMS is issuing this interim final rule to: (1) Permit the use of the 38 ingredients during the extended comment and final rulemaking periods to minimize the impact to the organic industry; and (2) extend the comment period (60 days) to receive additional comments regarding the addition of the 38 non-organic agricultural ingredients to § 205.606. Effective Date Effective June 9, 2007, these 38 substances were prohibited for use in processed products labeled as ‘organic.’ Continued loss of the use of these products would disrupt the trade of food products currently being labeled as ‘organic.’ Therefore, the continued use of these products as ingredients in foods labeled as ‘organic’ is necessary to prevent possible significant business disruption for organic producers and handlers. Accordingly, pursuant to 5 U.S.C. 553, it is found, and determined, upon good cause, that it is impracticable, unnecessary, and contrary to the public interest to give further notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this interim final rule until 30 days after publication in the Federal Register.”

In 2009, another manufacturer petitioned to add an amendment to the listing: “...Derived from carrots or algae”. The petitioner stated: “Our research over the past few years shows that at this time the only source of beta-carotene that can be extracted using NOP compliant nonsynthetic methods is algae. The algae derived beta-carotene uses extraction methods of CO₂, ethanol or vegetable oil.”

A Technical Report was requested and received in July 2011.

The TR indicated that a common source of beta carotene color was derived from the micro-algae *Dunaliella salina* and *Dunaliella bardawil*. These species are cultivated in Australia, for example. The TR, lines 327-350, describes the intensive culture system of production in a high salt, nitrate rich medium.

The TR further states: “*Dunaliella* species are commonly observed in salt lakes in all parts of the world from tropical to temperate to polar regions where they often impart an orange-red color to the water. As in commercial cultivation of the production, β-carotene is accumulated as droplets in the algal chloroplast stroma, especially under the environmental conditions in high temperature, high salinity, high irradiance, and nutrient limitation (low nitrogen). Then, β-carotene may be obtained from algal biomass or dried powder by using hot edible oil extraction and supercritical carbon dioxide, see EQ #2. In addition, it is desirable to re-utilize the culture medium remains after harvesting (biomass removal). *Dunaliella* growth medium could be recycled biologically by treating the medium with bacteria that are naturally present in medium because of the high concentration of glycerol, amino acids, and other organic compounds (Ben-Amotz, 1995). In a review article conducted by Dufosse et al. (2005), they concluded that algal forms are the richest source of pigments and can be produced in a renewable manner, since they produce some unique pigments sustainably. The report also stated that the production of β-carotene from *Dunaliella* will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature. (TR 530-545).

The TR supported the petitioner’s research findings. Therefore the Handling Subcommittee voted 4: 0 with 3 absences to approve this amendment, and the NOSB in December 2011 voted 14: 0 to approve the amendment.

The NOSB in 2011 found that the material met all the OFPA Criteria, and in 2013 the Final Rule was published (78 FR 31815).

The NOSB is in the process of reviewing use of all marine plants which are presently on the National List, and will be requesting a limited Technical Report. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

Additional information requested by NOSB

1. Has there been any change in the ability of manufacturers to produce beta-carotene color from carrots using NOP compliant extraction methods?
2. Is this color necessary for organic processors?
3. Which species of algae are used and from where are they harvested?
4. If the typical species used are from the genus *Dunaliella* (as cited in the TR) is harvesting of these species of micro algae from the wild, certified wildcrafted, or cultivated?
5. When used as a color, is this material also a source of Vitamin A?

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Sodium Lactate and Potassium Lactate
February 23, 2016

Summary of Proposed Action: To add Sodium Lactate and Potassium Lactate to the National List at §205.605(b). NOP requested in a memorandum dated June 25, 2014 that the National Organic Standards Board review these materials. The original joint petition was submitted January 5, 2005, by Christopher Ely, Applegate Farms, on behalf of the manufacturers Purac America and Trumark Company.

History

On January 5, 2004 the NOP received a combined petition for two substances to be added to the National List for use in organic handling, these substances were Sodium Lactate and Potassium Lactate (the salts of lactic acid). Lactic acid is listed on the National List at §205.605(a) as an approved non-synthetic material for use in products labeled as “organic” or “made with organic (specified ingredients of food group(s)). Lactic acid appears in “Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic)”.

On January 22, 2004, the NOP notified the petitioner that their petition would not be necessary since the materials sodium and potassium lactate were composed of substances that were already included on the National List (sodium hydroxide, lactic acid, and/or potassium hydroxide). Eventually, this interpretation was deemed inconsistent with previous NOSB recommendations on the classification of materials and was causing some confusion within the organic industry regarding the status of the two materials (sodium lactate and potassium lactate) as well as other lactate salts (example: calcium lactate) (McEvoy 2014). Thus, the NOSB (Handling Subcommittee) took up the request for the consideration of sodium lactate and potassium lactate for inclusion to the National List, §205.605 (b) Synthetics Allowed.

The original 2004 petition was submitted for the following use: Both sodium lactate and potassium lactate are used in meat processing as a pathogen inhibitor that is added to meat as an ingredient for use in controlling *Listeria monocytogenes* in Ready-to-Eat Meat and poultry products. Both of these materials have been recognized by the USDA-FSIS (Food Safety and Inspection Service) as being two of the few known antimicrobials validated through scientific studies to inhibit the growth of *Listeria monocytogenes*, *E.coli*, *Salmonella*, and other pathogens. They also control *Clostridium Botulinum* (botulism) in meats as well. Sodium and potassium lactate can replace nitrates/nitrites in meat products and are generally recognized as safe (GRAS).

In the February 17th, 2015 Technical Evaluation Report it mentions that both sodium and potassium lactate are affirmed as GRAS. Sodium lactate is affirmed GRAS at 21 CFR 184.1768 and potassium lactate at 21 CFR 184.1639. However, the FDA does not authorize their use in infant foods and formulas.

Sodium lactate and potassium lactate come as a liquid and may be added to meat as an ingredient at the rate of 1% to 4.8% as prescribed by the USDA-FSIS regulations, depending on the product. Whether a handling operation uses sodium lactate or potassium lactate is at the discretion of the processor or by the requirements of the specific recipe – i.e. Low sodium products (Applegate Farms 2004).

Manufacture:

Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugarcane or sugar beets) or starch. This substrate is fermented by food grade microorganisms to form Lactic acid. Sodium hydroxide is produced by the electrolysis of a concentrated sodium chloride (table salt) solution. Potassium hydroxide (KOH) is a synthetic, inorganic compound

produced by an electrolysis process using only potassium chloride (approved for use in organic foods per §205.605(a)) and water.

Sodium and/or Potassium lactate are generally produced from natural (fermented) lactic acid, which is then reacted with either sodium hydroxide or potassium hydroxide, respectively (Houtsma 1996).

Lactates are naturally produced in the human body.

Discussion:

This proposal was referred back to the Handling Subcommittee at the fall 2015 NOSB meeting in Stowe, VT. The reason for doing so was to provide the subcommittee and board an opportunity to look into the other ways that these two materials were currently being used by organic handlers. This was based off of information provided to the full board during the public comment period.

The original petition asked that sodium and potassium lactate be added to the National List for use in meat processing as a pathogen inhibitor. While the petitioned request for these materials covered a very specific usage, it was not completely clear whether or not the petitioned use is currently the only way that these two materials are being utilized in organic handling. This is part of the confusion from the action taken in 2004 by the NOP's decision to not accept the need for the petitioner's request to have sodium lactate and potassium lactate added to the National List.

Information provided during the written public comment period prior to and at the fall NOSB meeting in Stowe, Vermont by several commenters mentioned other ways that these materials were being used. . Some of those additional uses are: use in organic meat flavors (e.g. chicken flavor, beef flavor) and use in organic processed meats (e.g. sausages, meatballs, etc.). These are a few of the uses mentioned by one certifier about how some of their clients currently use these materials. Also, in comments provided both in written comments submitted and in oral testimony by an international certified organic handler, they have used sodium lactate in the manufacturing of their organic herb and spice pastes for 5 years prior to the NOP memo. It has become an integral part of their production process. They have tried other materials but so far sodium lactate provides the functional part of what they need and ask for it to be allowed for not only antimicrobial control, but also as a pH regulator. Sodium lactate helps them to maintain a balanced pH of their product, which is a critical parameter for both safety and product quality (Chang et al, 2008; Nguefack et al, 2009; Canillac et al, 2004; Gurierrez et al, 2008) (9/30/2015 Public Comment document: Botanical Food Company pg4). Some comments provided that the inclusion of these two materials onto the National List would help to eliminate the confusion that currently exists.

There were some comments opposed to the listing of both materials, stating that they should not be allowed in organic processing further stating that they were intended for use as preservatives. It should also be noted that in the February 17th, 2015 Technical Evaluation Report, it states that: meat products that contain sodium or potassium lactate can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product and at what levels (USDA FSIS 2005).

There are alternatives mentioned in the TR and the original petition such as: natural antimicrobials and agricultural antimicrobials (such as cranberry, cherry, lime and vinegar powders) (both currently being researched), essential oils, lactic acids, and bacteriophages (microorganisms) to name a few.

There does not appear to be any human health concerns associated with either of these two materials according to the information provided in the Technical Evaluation Report. Both materials are considered to be GRAS by the FDA according to this same report. There was an environmental issue raised about

the amount of gypsum created in the manufacturing of lactic acid. This concern seems to have been mitigated by utilizing this by-product material (gypsum) as a soil additive (Gypsoil and ADM 2011) (Feb.17, 2015 TR) and by research being implemented to look at other ways to produce lactic acid. According to a report published by the EPA lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008) (Feb.17, 2015 TR).

In the Technical Evaluation Report from February 17, 2015 it does state that no additional ingredients (e.g., stabilizers, preservatives, carriers, anti-caking agents, or other materials) are added to the commercially available forms of these materials. Thus, there are no ancillary substances associated with either of these two materials. However, the TER does mention that sodium diacetate (below 2%) sometimes may be combined with either of these two materials to help lower the pH of the surface meat products and therefore decrease microbial growth. Sodium diacetate is GRAS, contains 60% sodium acetate and 40% acetic acid (Miller 2010) (Feb.17, 2015 TR). During the public discussion at the Stowe, Vermont NOSB meeting (Fall 2015) it was decided that sodium diacetate is an additional active ingredient sometimes used in conventional processing to enhance the microbial control measures and did not serve as an ancillary substance for this petitioned use as it applies to organic handling.

Both sodium lactate and potassium lactate have been allowed for use in organic handling since the January 22, 2004 decision was rendered by the National Organic Program (McEvoy 2014). This decision (to not have sodium and potassium lactate petitioned for inclusion to the National List) was originally based on the fact that all three of the materials used to produce sodium lactate and potassium lactate were already approved and on the National List. That decision was not consistent with previous NOSB Recommendations on classification of materials. The intent of this proposal is to correct that previous decision and go through the appropriate process (Petitioned Material Proposal) to see whether or not these two materials should in fact be added to the National List of Allowed Substances. It is the intent of the subcommittee and ultimately that of the entire National Organic Standards Board by moving forward with this proposal we can clear up the confusion, re-establish a concise and transparent process by which these two materials shall be reviewed and ultimately voted on.

Sodium Lactate

There are three mechanisms by which sodium lactate can have an antimicrobial affect. The first is by changing water activity (it lowers the water activity of meat and thereby slows microbial growth). The second occurs as sodium lactate passes through the cell membrane and lowers intracellular pH. The third takes place as sodium lactate affects cellular metabolism by inhibiting ATP generation (ATP-adenosine triphosphate, a nucleoside triphosphate which transports chemical energy within cells for metabolism (Biology Online 2010)). The lactic acid portion of sodium lactate has antimicrobial properties, as it can be incorporated into the microbial cell. The lactic acid then interferes or slows down the normal metabolic process that generates cell energy in the cell. (Miller 2010) (Feb.17, 2015 TR).

Potassium Lactate

Potassium lactate has a potassium ion rather than the sodium ion found in sodium lactate. It has been shown to decrease microbial growth and to limit the growth of some major meat pathogens with similar capabilities to those of sodium lactate. Potassium lactate can be used as a substitute for sodium lactate as a non-meat ingredient, with similar functionality, but does not have the salty taste (Miller 2010) (Feb.17, 2015 TR).

Again, the original petitioned use for these materials was for use in Ready-to-Eat Meat and poultry products as an ingredient to function as a pathogen inhibitor, especially for use in providing microbial control of *Listeria monocytogenes*.

Information provided from public comments for the fall 2015 NOSB meeting made it clear that while both forms (sodium and potassium) lactate are used, sodium lactate seemed to be the one more commonly used. The rationale between the differences in use is primarily due to whether or not the use was for a sodium or a low sodium product. Also, as stated information provided by public comment and subcommittee, research does show that these two substances are currently used in organic handling in a variety of ways for several different uses other than just the original petitioned use.

Recently the original petitioner (formerly Purac and now Corbion Purac) contacted the NOP stating that they had just become aware that these two substances were back up for discussion. They were asked to submit their comments during the up-coming open public comment period in writing or during oral testimony. This helps to address one of the concerns from the Handling Subcommittee that if these materials were important in organic handling, then why hadn't they heard from the petitioner or manufacturer. It was just brought to their attention.

Please provide the full NOSB your comments on this proposal and if you are an organic handler currently using either of these materials (or have used them prior to the NOP memo), if the proposed annotation would capture your current use pattern, assuming these two materials were added to the National List. Also, could you explain why these substances would be preferred over currently used alternative materials or practices?

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

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Subcommittee Action & Vote:

Classification Motion: Move to classify both sodium lactate and potassium lactate as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

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

Listing Motion: Move to list Sodium Lactate and Potassium Lactate at §205.605(b) of the National List with the following annotation: for use as an antimicrobial agent and pH regulator only.

Motion by: Harold V. Austin IV

Seconded by: Tom Chapman

Yes: 5 No: 0 Abstain: 1 Absent: 2 Recuse: 0

Proposed Annotation (if any): for use as an antimicrobial agent and pH regulator only.

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes: To regulate how each of these substances are to be allowed for use in organic handling or processing.

Approved by Harold Austin, Handling Subcommittee Chair, to transmit to NOSB February 23, 2016

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Oat Beta Glucan
January 19, 2016**

Summary of Proposed Action:

Oat beta glucan is being petitioned by manufacturer Tate & Lyle for addition at §205.606, as a natural component of oats, an agricultural commodity. According to the petition the substance is isolated through a simple process of grinding, enzyme treatment, water extraction and drying. No synthetic chemical additions or solvents are used in the manufacturing process being petitioned. The only additives used in producing oat beta glucan are water and enzymes. Specifically, the enzyme is food-grade alpha-amylase and non-GMO per GRAS self-determination. In addition to the beta glucan, dextrins and gluco-oligosaccharides are found in the final product, which is in powder form.

Due to oat beta glucan's high soluble fiber content, bland flavor and minimal impact at low use levels, its used to supplement fiber content in processed foods including biscuits, cakes, breads, cereals, bars, soups, and smoothies. Other common names for oat beta glucan include oat bran soluble fiber, oat fiber, oat soluble fiber, and oat bran fiber.

Overall, oat beta glucan appears to have no significant negative impacts on human health. There have been studies that show the positive effect of the substance on lowering cholesterol and modulating blood glucose.

The petition points out that oat beta glucan is used in handling, not crop production and thereby concludes that it has no effect on soil, crops, or livestock. The subcommittee however would like to point out that according to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

The petition points out that currently there is no source of organic oat beta glucan, despite organic oats and organics oat bran being widely available in the U.S. and Canada. Additionally the petition claims that in Nordic countries, where a large amount of oat beta glucan is manufactured, organic oats and organic oat bran quantities are limited. The petition goes on to state that if the demand for organic oat beta glucan was to increase, the Nordic manufacturing facilities could purchase organic oats and organic oat bran from the U.S. The petitioner thought this scenario was unlikely to happen soon due to the undetermined demand for oat beta glucan in organic form and that it would be more likely to happen if the use of non-organic beta glucan in organic foods was successful first.

The handling subcommittee would like to point out that the global market is the universe of supply, non-commercial availability is not dependent on upon geographical location. The subcommittee sees no reason why oat beta glucan could not be manufactured organically. In fact, the manufacturer Garuda International used to produce organic oat beta glucan but stopped doing so due to low demand.

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

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)

Criteria Satisfied?

- | | | |
|------------------------------|-----------------------------|------------------------------|
| X Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | X No | <input type="checkbox"/> N/A |
| X Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

Substance Fails Criteria Category: 2- Essentiality and Availability. **Comments:** The Subcommittee felt that there were alternatives currently available and alternative sources for which these petitioned needs could be met.

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify Oat Beta Glucan as agricultural

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 4 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Listing Motion: Move to list Oat Beta Glucan at §205.606 of the National List

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Approved by Harold V. Austin IV, Handling Subcommittee Chair, to transmit to NOSB January 19, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 1. Adverse impacts on humans or the environment? Oat beta glucan

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	x		Produced from non-organic oat, which according to the USDA pesticide data program, can contain 7 pesticide residues.
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); §6518(m)(4), 205.600(b)(3)]		x		
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		Not really sure, the appendix is not really legible. I don't know if those limits are okay or not.

Category 2. Is the Substance Essential for Organic Production? Oat beta glucan

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		
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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	x			Yes, natural because it uses enzymes.
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		Currently no. Former producer of organic oat beta glucan stopped producing due to low demand.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		x		
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x	x		Currently no, but could be made from organic oats
9. Are there any alternative substances? [§6518(m)(6)]	x	x		Yes, but petition claims they are unpalatable
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	No ancillaries reported in the petition
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Category 3. Is the substance compatible with organic handling practices? Oat beta glucan

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			
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	Not used in farming
4. Are the ancillary substances reviewed compatible with organic handling [?]			x	Not ancillary substances identified in petition
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		Primary use is to increase fiber
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 increase fiber

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)] Oat Beta Glucan

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			Page 4 of the petition
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	x		Page 12 of the petition, gives their justification.
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	x			Page 12 petition

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			Page 12 petition
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?				

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Hypochlorous Acid
February 16, 2016**

Summary of Proposed Action:

On May 29, 2015 the NOP received a petition to add hypochlorous acid (CAS #7790-92-3) to the National List at §205.601 - Synthetic substances allowed for use in organic crop production. This material is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products. The petition was forwarded to the Handling Subcommittee on June 3, 2015.

The petition was submitted by Botanical Food Company Pty Ltd. hypochlorous acid is being petitioned for use in the following areas:

1. On Farm
 - a. As a post-harvest sanitizer for raw herb and spice material <60 ppm
 - b. As an equipment and cold room sanitizer <200 ppm
2. In Processing plants
 - a. As a post-harvest, pre-process sanitizer for herbs and spices <200 ppm
 - b. As a microbial rinse for herbs and spices <60ppm
 - c. As an equipment and room sanitizer <200 ppm

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water (EW). The memo was issued as a response to requests asking for the National Organic Program to clarify whether EW was allowed as a sanitizer and antimicrobial agent for use in organic production and handling.

The NOP felt that the allowance of EW by a certifier or a material evaluation program were based on an incorrect interpretation of the allowance for chlorine materials on the National List of Allowed and Prohibited Substances at 7CFR §205.600-606. The NOP requested that certifiers ensure that the use of EW was not allowed in organic handling or production and that any party wishing for further consideration of EW for use in organic handling or production should submit a petition to get it added to the National List. Thus, the rationale for the petition currently before the Handling Subcommittee and the full NOSB is in response to the NOP policy memo.

Manufacture and Uses of the Substance:

Hypochlorous acid is produced by electrolysis of a dilute water-sodium chloride solution flowing through specialized equipment designed to separate alkaline and acidic products. This electrolytic process facilitates the conversion of chloride ions and water molecules into chlorine oxidants (chlorine gas, hypochlorous acid, and hypochlorite ion) within the anode chamber and sodium hydroxide in the cathode chamber of the production equipment. At an acidic to neutral pH, the predominant chemical species is hypochlorous acid (HOCl) with a high oxidation reduction potential (ORP) of $\geq 1,000$ mV.

Hypochlorous acid has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of hypochlorous acid against foodborne pathogens on raw agricultural products and food contact surfaces. Applications of hypochlorous acid as a disinfectant for reducing microbial contamination have been reported for fresh fruits and vegetables, poultry carcasses, shell eggs, cutting boards, and food processing surfaces.

According to the TR, some advantages of using hypochlorous acid water are: 1) It is as effective as any chlorine treatment; 2) it is not necessary to handle potentially dangerous chemicals, e.g. chlorine gas, chlorine dioxide, bleach; 3) the apparatus to produce hypochlorous acid is relatively inexpensive and easy to operate; 4) because only water and sodium chloride are used, hypochlorous acid production is environmentally friendly; and 5) the properties of the hypochlorous acid can be controlled at the preparation site.

Hypochlorous acid can be used as an ingredient in an antimicrobial pesticide formulation and may be applied to dairy processing equipment, and food processing equipment and utensils. The Food and Drug Administration (FDA) regulations (21 CFR Part 178) permit the use of sanitizing solutions containing sodium hypochlorite on food processing equipment and food contact surfaces. In addition to sanitizing food contact surfaces, cleaning solutions containing the active ingredient hypochlorous acid may be used for sanitizing raw fruits and vegetables during the washing or peeling process. The USDA's Food Safety and Inspection Service Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products", has approved the use of electrolytically generated hypochlorous acid as a food additive for use on meat and poultry products. It is allowed for use on red meat carcasses down to a quarter of a carcass, whole or eviscerated poultry carcasses, in water used in meat and poultry processing, in poultry chiller water, for reprocessing contaminated poultry carcasses, on giblets and salvaged parts, and on beef primal cuts of beef. Depending on the product sanitized from 5 to 50 ppm free available chlorine can be used.

Discussion:

From an environmental impact perspective, hypochlorous acid would appear to pose less of a risk for the environment than some of the alternatives as it is made from water and salt. There are no by-products to be disposed of since all of the materials are formulated and used in the final application process. Also, it would appear that hypochlorous acid would pose less of a risk to human health and/or worker health compared to some of the possible alternative products as well. According to the August 13, 2015 TR it states that hypochlorous acid at a pH 6.5-7.5 is safer to use than other disinfectants containing chlorine. The level of chlorine in hypochlorous acid is usually over ten thousand times less than that of common household bleach. The on-site production helps to alleviate the need to transport other materials that may be more hazardous to handle, thus reducing the risk of exposure to the worker and for possible environmental contamination if improperly handled.

The primary functions of hypochlorous acid are as an anti-microbial, sporicidal, and bactericidal agent. Some currently allowed alternatives to hypochlorous acid are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peracetic/peroxyacetic acid, citric acid, acetic acid, ascorbic acid, vinegar are some of the materials currently allowed for use.

Electrolyzed water, although produced via a different mechanism, has the same mode of action as sodium and calcium hypochlorite (both of these materials are currently on the National List). In fact, the main active ingredient in their dilute aqueous solution form is hypochlorous acid, the same material produced as the anolyte component of electrolyzed water.

During the public comment period prior to the fall 2014 NOSB meeting there were several public comments submitted in response to the NOP's decision to halt the allowed use of hypochlorous acid per their memo PM 14-3 sent out on June 9, 2014. One of those organic stakeholders provided written public comment on September 28, 2014 that included multiple peer-reviewed scientific journal articles. These articles provided support to the claim that electrolyzed water was a safe sanitizer, providing the

same degree of anti-microbial control without the toxic risk to employees, the crops, or the harvested products it is applied to.

This material does look like it could provide organic handling operations a material that has strong antimicrobial properties and is more compatible with the fundamental principles of organic production.

Evaluation Criteria

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Move to classify hypochlorous acid as synthetic.

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

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

Listing Motion: Move to list hypochlorous acid at §205.605(b), chlorine materials.

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

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

Approved by Harold V. Austin IV, Handling Subcommittee Chair, to transmit to NOSB February 16, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 1. Adverse impacts on humans or the environment? Hypochlorous 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		According to the petition electrolyzed water can be made on-site. In this process there would not be any residual product to dispose of. If produced off-site and sold as a finished product then there could be a possibility of environmental contamination as the result of an accident or a spill. The TR does state that in forms of hypochlorous acid that are at a pH<4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, but also creating possible human health and safety issues (Fisher, 2009). The more neutral, the pH of the material, the safer and more stable the substance appears to become.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		x		This substance is formed by the electrolysis of a sodium chloride solution. Any environmental concerns would be from a spill during manufacturing or transport of a formulated end product.
3. Are there any adverse impacts on biodiversity? (§205.200)	x			The TR, (lines 596-612) does state that hypochlorous acid in aqueous solutions at pH< 7 was of minimal toxicity to birds, but could be very toxic to fish and freshwater invertebrates.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		Contaminants listed in the US Food and Drug Administration’s Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, are unlikely to be found in hypochlorous acid since it is the electrolysis product of two generally recognized as safe materials, salt and water (TR lines 568-571).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	x			The TR (lines 140-153) mentions that there can be a reaction with organic material (humic acid) which can lead to some potential concerns. It does go onto state though: It is generally accepted that carcinogenic and teratogenic trihalomethanes and haloacetic acids are not formed by the action of hypochlorous acid in neutral or near-neutral solutions (Satyawli et al., 2007).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		According to the TR (lines 602-612) hypochlorous acid solution decomposes very slowly in the dark but more rapidly in the presence of light, rapidly in full sun light by producing hydrogen chloride and oxygen. Released into the environment it is distributed into water and air, with an estimated half-life of 1-4 hours. A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity.
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		Information provided in the petition states that compared to other types of chlorine, electrolyzed water is usually used at an active rate that is ten thousand times less than that of common household bleach. The TR (lines 624-626) mentions that the human innate immune system uses hypochlorous acid to fight infection but also directs it against host tissue in inflammatory diseases (Kettle et al.,2013). Chlorine disinfectants have been shown to cause occupational dermatitis or skin irritation (TR line 662).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		x		See the answer to question #5 above.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		x		

Category 2. Is the Substance Essential for Organic Production? Hypochlorous 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			Electrolyzed water is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane. This process creates hypochlorous acid, hypochlorite ion, and hydrochlorite at the anode and sodium hydroxide at the cathode. (TR lines 48-68) August 13, 2015 TR.

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		
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 acids such as citric acid, lactic acid, malic acid, and vinegar are some alternative materials.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			Hot water can be used in some instances.
8. Are there any alternative substances? [§6518(m)(6)]	x			Some alternative substances are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peroxyacetic acid, citric acid, acetic acid, ascorbic acid, and vinegar. Copper sulfate is another possible alternative depending on the use.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		

Category 3. Is the substance compatible with organic production practices? Hypochlorous 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			Compared to many of the alternative materials currently being used electrolyzed water could provide a safer and effective alternative. (especially when produced using the on-site electrolysis process)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			See answer to question #1 of this category.
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			May be used to sanitize equipment

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Sodium Dodecylbenzene Sulfonate
January 23, 2016

Background

On October 9, 2015 the NOP received a petition to add Sodium Dodecylbenzene Sulfonate (SDBS) (CAS # 25155-30-0) to the National List at §205.605 - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)) (b) Synthetics Allowed. This petition was forwarded to the Handling Subcommittee on November 2, 2015 for the appropriate petitioned material process to be conducted.

The petition was submitted by Ecolab, Inc. Sodium dodecylbenzene sulfonate is being petitioned for use as an active ingredient (1 of 2 active ingredients, the other is lactic acid) in an antimicrobial formulation, for use in treating fruits and vegetables in the premises of organic food retail establishments. The Ecolab antimicrobial material is: AFVT-Antimicrobial Fruit & Vegetable Treatment.

The petitioner does not manufacture SDBS, but uses it as 1 of 2 active ingredients in their product (AFVT) formulation. They listed 3 companies that SDBS is manufactured by:

1. Pilot Chemical Company – Santa Fe Springs, CA.
2. Stepan Company – Northfield, IL.
3. Unger Fabrikker A.S. – Fredrikstad, Norway

Sodium dodecylbenzene sulfonate is currently used (an anionic surfactant) in industrial, institutional, chemical detergents & cleaners, specialty cleaners, sanitization products, emulsifiers, suspension or wetting agents, absorbents in pesticide and other agricultural chemicals, along with numerous other uses. (Toxnet 2014).

Manufacturing

There are several ways to manufacture Sodium dodecylbenzene sulfonate. The primary source is to start with LAS (Linear alkylbenzene sulfonate) which is made by the sulfonation of alkylbenzenes prepared from petroleum distillates. In one of the most common processes benzene is alkylated by long chain monoalkenes (e.g. dodecene) using hydrogen fluoride as a catalyst. The purified dodecylbenzenes (and related derivatives) then form dodecylbenzene sulfonic acid, which is then subsequently neutralized with sodium hydroxide (Kurt Kosswig, “Surfactants in Ullman’s Encyclopedia of Industrial Chemistry, Wiley-VCH, 2005). The final slurry can then be dried by either drum drying (this forms flakes or powder) or by using a spray drier system, (this forms beads) to create the desired form of Sodium dodecylbenzene sulfonate.

According to information provided in the petition, the sulfonation technology has been considerably improved, with the most modern systems beginning to use falling film reactors (FFR) (mono-tube or multi-tube) and SO₃, found in many sulfonation facilities in Europe. Also mentioned in the petition: in the mid 90’s there was a new form of alkylation technology introduced that is now being used in Europe, based on heterogeneous catalyst in a fixed-bed reactor. This new technology offers: process simplification, elimination of acids handling and disposal (HF, HCl) as well as an overall production yield improvement and improved LAB quality.

Discussion

The petitioner (Ecolab, Inc.) is trying to get SDBS added to the National List as a processing aid, so that it may be used as one of two active ingredients in their antimicrobial product. This product (Ecolab's Antimicrobial Fruit and Vegetable Treatment) specifically formulated for use in food retail environments such as restaurants, cafeterias, food service operations, commissaries and kitchens. They state that it would help to provide the organic users a new reliable tool to aid in the battle against microorganisms that cause food borne illness outbreaks. The petitioner further states that when SDBS is used as one of two active ingredients in their formulated product it is very effective in helping to control pathogens (*Escherchia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella enterica*) when used in wash water or on surfaces of raw or processed fruits and vegetables.

The petitioner states that in the mode of action there are three mechanisms that SDBS works by providing. These are: Protein denaturing; essential enzyme inactivation; and by membrane disruption and alteration of cell permeability.

SDBS has been cleared for use as an antimicrobial agent in produce wash water by the Food and Drug Administration (FDA) under 21CFR 173.405. But, it is not listed as GRAS.

Sodium dodecylbenzene sulfonate does not appear to pose any serious human health or environmental concerns under the proposed use pattern. But, according to the New Jersey Department of Health and Senior Services Hazardous Substance Fact Sheet (revised May, 2002) and the MSDS for SDBS, it can be a skin irritant, could possibly cause eye damage, and if inhaled be an irritant of the nose, throat, and lungs. This same fact sheet also states that repeated exposure could cause bronchitis to develop. SDBS according to the Material Data Sheet is listed as: DOT: UN3077, Rq, Environmentally Hazardous Substance, Solid, N.O.S. (Sodium Dodecylbenzene Sulfonate), 9, III, Marine Pollutant (Linear Alkylbenzene Sulfonate). Also, it has been noted that SDBS is slightly toxic to Bobwhite quail and green algae and moderately toxic to some species of fish.

Information provided in the EPA 2006 Registration Eligibility Document (RED) states: No environmental exposure is expected to occur from the majority of linear alkylbenzene sulfonate uses and it is unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur from limited commercial down-the-drain use because of the very small number of pounds for these uses plus their rapid degradation in the environment.

There is one area of possible concern regarding SDBS and its use and compatibility with organic crop production in that according to one report (Estrin et al. 1982), it states that SDBS contains impurities that could include: neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and possibly lead (Pb). The levels of these impurities, was not defined. It is not clear if the new methods of formulation mentioned in the petition further remove any of these impurities or not.

There currently are alternative materials in use by organic handlers which would include: lactic acid, citric acid, acidified sodium chlorite, and peracetic acid. The petitioner states that while these materials are available for use by organic handlers and retailers, that SDBS would enable the petitioner to provide a formulated product for use at the food retail, kitchen, restaurant level, etc. where there currently is not such a product available. It is their position that the other available materials are normally used at the processing level and not necessarily at the food retail levels for raw and ready to eat fruits and vegetables.

It would help the full committee during their deliberation of this material if organic stakeholders could provide us with the following information:

- What are retailers currently using to address these concerns?
- Are any of the alternatives mentioned in the petition currently used at the retail level and if so are they effective in addressing these areas of food safety concerns?
- What are the level (if any) of impurities as mentioned in this document found in SDBS?

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

	Criteria Satisfied?
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

Substance Fails Criteria Category: [2] **Comments:** Alternatives available

Subcommittee Action & Vote

Classification Motion: Move to classify sodium dodecylbenzene sulfonate as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Listing Motion: Move to list sodium dodecylbenzene sulfonate at §205.605 - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” of the National List.

Motion by: Harold V. Austin IV

Seconded by: Tom Chapman

Yes: 1 No: 5 Abstain: 1 Absent: 1 Recuse: 0

Approved by Harold Austin, Handling Subcommittee Chair, to transmit to NOSB February 23, 2016

NOSB Evaluation Criteria for Substances Added To the National List – Handling

Category 1. Adverse impacts on humans or the environment? Sodium dodecylbenzene sulfonate (SDBS)

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		Information provided in the EPA 2006 Registration Eligibility Document (RED) states: No environmental exposure is expected to occur from the majority of linear alkylbenzene sulfonate uses and it is unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur from limited commercial down-the-drain use because of the very small number of pounds for these uses plus their rapid degradation in the environment.
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)]				See answer to question 5 below.
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		It is biodegraded rapidly under aerobic conditions with a half-life of approximately 1-3 weeks; oxidative degradation initiating at the alkyl chain. Under anaerobic conditions it degrades very slowly or not at all, causing it to exist in high concentrations in sewage sludge. This is thought to not be of a concern as it will rapidly degrade once returned to an oxygenated environment. (Jenson, John February 1999, “Fate and effects of linear alkylbenzene sulfonates (LAS) in the terrestrial environment”).
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			According to the New Jersey Department of Health and Senior Services Hazardous Substance Fact Sheet (revised May, 2002) and the MSDS for this material, it can be a skin irritant, could possibly cause eye damage, and if inhaled can be an irritant to the nose, throat, and lungs. Repeated exposure could cause bronchitis to develop, according to the N.J. Dept.of Health Fact Sheet.

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		SDBS contains impurities that include neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and lead (Pb). (Estrin et al.1982). The level of these impurities was not defined. It is not clear if the new methods for formulating SDBS (as stated in the petition) further remove any of these impurities or not.

Category 2. Is the Substance Essential for Organic Production? Sodium dodecylbenzene sulfonate (SDBS)

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			<p>There are multiple ways to manufacture SDBS: One process is by reacting dodecylbenzene with sulfuric acid (Oleum Process) or air/SO₂ to produce dodecylbenzene acid (CTFA 1991a). The dodecylbenzene sulfonic acid is then neutralized with sodium hydroxide.</p> <p>The most common process is: Benzene is alkylated by long chain monoalkenes (e.g. dodecene) using hydrogen fluoride as a catalyst. The purified dodecylbenzenes (and related derivatives) then form dodecylbenzene sulfonic acid, which is then subsequently neutralized with sodium hydroxide (Kurt Kosswig, "Surfactants in Ullman's Encyclopedia of Industrial Chemistry, Wiley-VCH, 2005). The final slurry can then be dried by either drum drying (this forms flakes or powder) or by using a spray drier system (this forms beads).</p> <p>According to information provided in the petition the sulfonation technology has been considerably improved, with the modern systems beginning to use falling film reactors (FFR) (mono-tube or multi-tube) and SO₃, in many of the sulfonation facilities in Europe. Also mentioned in the petition: in the mid 90's there was a new form of alkylation technology introduced that is now being used in Europe, based on heterogeneous</p>

				catalyst in a fixed-bed reactor. This new technology offers: process simplification, elimination of acids handling and disposal (HF, HCl) as well as an overall production yield improvement and improved LAB quality.
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		
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			According to information provided by the petition citric or lactic acid could serve as possibly substitutes (For the AFVT product's intended use).
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			According to information provided by the petition either citric or lactic acid could possibly be used as a substitute for this material for microbial control.
9. Are there any alternative substances? [§6518(m)(6)]	X			Yes for the overall intended use of the material (when used in the finished product that the petitioner is requesting this material be added to the National List so it can be used as one of two active ingredients in), then acidified sodium chlorite or peracetic acid could be used instead. But they do mention that these materials are more apt to be used in commercial food processing establishments and not in restaurants, kitchens, etc. as is the intended area of use proposed by the AFVT product label.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Current processes in place utilizing materials already allowed for use in organic handling and processing.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 3. Is the substance compatible with organic handling practices? Sodium dodecylbenzene Sulfonate (SDBS)

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			
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 [?]			X	none
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		
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		

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)] **Sodium Dodecylbenzene Sulfonate**

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	
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?:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
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	

**National Organic Standards Board
Handling Subcommittee
Ancillary Substances Procedure - Proposal
February 16, 2016**

Background

Ancillary substances have been discussed by the NOSB for several years now, with an overall policy being passed in 2014 and ancillaries being looked at in Technical Reports (TR) and NOSB reviews since then.

However, attempts to pass a separate ancillary substance proposal to accompany the review of specific National List entries have all been withdrawn by the board due to issues brought up by the public during the comment period. So far these have included ancillaries in microorganisms (brought forward 3 times), pectin, and yeast. Additional listings from the National List were recently renewed in the Sunset 2017 process that also have ancillary substances, including enzymes and nutrient vitamins and minerals. While ancillaries were covered in the TRs for these, it was decided not to bring forward proposals until the previous ones were approved and a standard format could be established.

Discussion

The main issues raised in public comment have been examined by the Handling Subcommittee (HS) and are as follows:

- Accredited Certifying Agents (ACA) would have to do a lot more paperwork to verify ancillary substances by functional class. Right now most specification sheets may list names of ancillaries but not specify the functional class each one is in.
- While the charts presented of the known ancillary substances are helpful, there is no clear procedure for ACAs to evaluate those that are not on the chart.
- Allowing other ancillaries that are not on the chart could result in some very problematic substances being allowed, specifically preservatives.
- A separate proposal and vote is not necessarily needed for those ancillaries that are allowed, but is needed for any that the NOSB wishes to prohibit.
- All ancillary substances should be reviewed separately and added to the National List. (This was rejected by the NOSB in the 2014 recommendation but it still keeps coming back in public comment).

In light of some of these issues, the HS has decided to propose an additional set of criteria and procedures for ACAs and suppliers of ingredients so that it is clear what tools everyone can use for compliance with the 2014 recommendation. If these are adopted and followed, there will not be a need for a separate ancillary substance proposal for each listing on the National List.

The proposal includes:

1. A definition of Ancillary Substance
2. Criteria used to review ancillary substances that can be used by both the NOSB in initial review and ACAs in subsequent verifications.
3. Procedures for the NOSB to follow for those materials that may have ancillary substances to be reviewed.
4. (optional) Example of a standardized template for ACAs to determine compliance.

Proposal

1. Definition

Ancillary Substance: Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for “incidental additives,” which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3) i to iii4). To illustrate: Enzymes are listed on 205.605(a). The enzymes might contain the following additives, which are considered by the organic industry as “ancillary ingredients”: calcium silicate (anticaking agent), calcium phosphate (carrier and/or filler), stearic acid (preservative), sorbitol (stabilizer), sodium citrate (pH control, buffer).

2. Criteria for Compliance

At least **one** must apply:

1. The ancillary ingredient was considered part of the manufacturing process that has already been reviewed by the NOSB.
2. The ancillary ingredient is certified organic, on the National List 205.605 or 205.606, or is agricultural (e.g., sugars as standardizing agents in pectin).
3. The ancillary ingredient is approved by FDA as GRAS for the particular use.
4. The ancillary ingredient is approved by FDA as a direct food additive or incidental additive for the particular use.
5. The ancillary ingredient is approved by FDA as a food contact substance for the particular use, as evidenced by a Food Contact Notification (FCN).

Additionally, the ancillary ingredient **cannot** be a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP). A compiled list is published by the American Cancer Society at <http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens>

Examples of ancillaries that are listed on the IARC and/or NTP list, and would therefore be prohibited, include formaldehyde and butylated hydroxyanisole (BHA)

3. Procedure for NOSB review of ancillaries

The first three of these procedures are already in place, but the last ones are different from the past approach.

- At the time of requesting a TR for a new or sunset substance, the NOSB will ask that information about identity and functional classes of ancillary substances be reviewed along with the other evaluation questions.
- For new substances, a chart of the ancillary substances by functional class will be incorporated in the checklist document or whatever review template is used.

- For sunset substances, a chart of the ancillary substances by functional class will be included in the first posting along with a request for new information about existing ancillaries and/or additional ancillary substances to be brought forward in public comment.
- The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved. Similarly, the vote to finalize the sunset review after the second posting will be considered to also approve ancillaries unless one is pulled out as not approved.
- Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a separate proposal that can be voted on at the same meeting or a subsequent meeting of the board.

4. Example of Information for an Ancillary Substances Compliance Template.

For ancillary substances that are already on the list of those reviewed by the NOSB, another form may not be needed. But for new ancillary substances, and if ACAs wish to develop a compliance template, the following information should be included on the template:

1. Definition of ancillary ingredients (see 1 above)
2. A request for the name of the non-organic ingredient that the ancillary ingredient is in (e.g., pectin)
3. A request for the name of the ancillary ingredients in the product and CAS #'s (e.g., dextrose, CAS#: 50-99-7)
4. The Criteria for Compliance (see 2 above)
5. A request for the justification that ancillary ingredients meet the criteria (e.g., the FDA regulatory reference and confirmation that the ancillary is not a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP)).
6. A request for a specification sheet with full ingredient disclosure for the non-organic ingredient (e.g., a specification sheet with full ingredient disclosure listing pectin and also the dextrose, which is used as a standardizing agent).
7. A request for the name, signature and date of the party signing the compliance declaration.
8. Language that speaks to the legal ramifications of falsifying information to ACAs.

Note: All requested information is required to be completed by the responsible party in order for the compliance declaration to be accepted by the ACA.

Motion to adopt the proposal as stated above for the definition, criteria for compliance, and procedure for the review of ancillary substances.

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

**National Organic Standards Board
Handling Subcommittee
Nutrient Vitamins and Minerals §205.605(b) Annotation Change - Discussion Document
February 23, 2016**

Introduction

The Handling Subcommittee would like to change the annotation for the listing for Nutrient Vitamins and Minerals. It has been acknowledged that it needs to change since the Federal Rule first came out, but there have been mixed opinions on how to change it. This Discussion Document covers the background on the issue and presents several options for changes to the annotation. Members of the Handling Subcommittee are not unanimous on any of these options but wish to explain them and solicit public input on the pros and cons of them.

Background and Relevant Areas of the Rule

Reference: §205.605(b) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Technical Report: [1995 TAP - Minerals](#); [1995 TAP - Vitamins](#); [Technical Report \(2015\) \(PDF\)](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2011 Handling Subcommittee Proposal](#); [04/2011 sunset recommendation](#), [10/2015 sunset review](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)), Proposed Rule published 01/12 2012 ([77 FR 1980](#)), Sunset Review 2012, Interim rule published 09/27/2012 ([77 FR 59287](#)).

Sunset Date: 10/21/2017

Brief History of this issue

- In 1995 the NOSB added nutrient vitamins and minerals to the National List with the following annotation, “Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.”¹ A second recommendation was also passed entitled “Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.” This stated, “Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.”
- The final rule that was published in 2000 (65 FR 13512) came out with the current annotation. It was recognized soon after that the cross reference to the FDA’s fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing is necessary.²

The existing annotation is not what the original NOSB recommended in 1995. In 2011, the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to

¹ NOSB, 1995. Final Minutes of the National Organic Standards Board Full Board Meeting Austin, Texas, October 31–November 4, 1995, available at:

<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

² 77 FR 1980 – NOP proposed rule from 2012.

the April 2011 NOSB meeting and the NOSB supported relisting with existing annotation for the 2012 sunset review.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamin and minerals. In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a [memo to the NOSB in April 2010](#) explaining this clarification.
- On January 12, 2012 a proposed rule was published in the Federal Register ([77 FR 1980](#)) to change the annotation to:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”
(b) *Synthetics allowed*
Vitamins and minerals. For food— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10.³
- This clarified that the "nutrients" that were not on these CFR sections had to be petitioned individually for the National List because this listing did not cover them.
- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule ([77 FR 59287](#)), which renewed without change the original listing, as per the NOSB April 2011 recommendation.
- In 2011 through 2013 many such items were petitioned. A few were recommended to be listed by the NOSB and most were not. No rulemaking has happened to add the recommended substances or clarify the current reference, so the prohibited ones are still in use and the recommended ones have not been added to the National List.
- In 2014 the Handling Subcommittee commissioned a new Technical Report in preparation for Sunset 2017 reviews. This was completed in February 2015. It clarifies a lot about which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.
- Both the TR and the proposed rule are required reading to understand this issue.

Discussion

All members of the Handling Subcommittee agree that the proposed language in the 2012 proposed rule would change the title of the listing from "Nutrient Vitamins and Minerals" to " Vitamins and minerals. For food" is a preferred choice. Some believe in limiting the category further than what was proposed and some do not. In addition, the Handling Subcommittee believes that the past decisions of the NOSB regarding petitioned nutrients for infant formula needs to be acted upon by the NOP as soon as possible.

Option 1 for discussion:

Some members of the Handling Subcommittee believe that the original intent of the NOSB is what should form the backbone of the listing and annotation for Vitamins of Minerals and, to achieve this, they have proposed three related annotations.

Proposed Annotation #1: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed only when

³ 77 FR 1980 – NOP proposed rule from 2012.

their use is required by law or to meet an FDA standard of identity in which they are incorporated.

This has a lot of advantages:

- It is in alignment with all other international organic standards (and what we have now is not).
- (from the proposed rule 2012): 1. The authority citation for 7 CFR part 205 continues to read as follows: Authority: 7 U.S.C. 6501–6522. 2. Section 205.605(b) is amended by: A. Removing the listing for “Nutrient vitamins and minerals”. B. Adding a listing for “Vitamins and minerals”.
- With new information from the FDA and the Technical Report we can now spell out which exact fortifications and enrichments are required by law. They are:

Standards of Identity in Title 21 CFR that require Nutrient Fortification ⁴

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.100 21 CFR 107.10	All nutrients known to be essential and listed therein
Margarine	21 CFR 166.110	Vitamin A
Milk	21 CFR Part 131	Vitamins A & D (required by some states)

Examples of other specific regulations include the following:

Food class	Regulation	Specific vitamins or minerals
Milk for Women, Infant and Children (WIC) program	7 CFR 246.10	Vitamins A & D
Soy-based beverage (milk alternative) for WIC	7 CFR 246.10	Vitamins A & D, calcium, magnesium, phosphorus, riboflavin, vitamin B12
Fruit juice for WIC	7 CFR 246.10	Vitamin C
Infant cereals (WIC)	7 CFR 246.10	Iron
Adult cereals (WIC)	7 CFR 246.10	Iron

There are many products out there that are currently fortified with synthetic vitamins and minerals that are not required to be. Consumers have repeatedly stated that they do not want synthetic ingredients in their organic food and that they should have the right to make informed decisions about their food choices. Nutrient supplementation is one of those choices that some consumers may choose but others would like to avoid. Therefore we propose a second annotation:

Proposed Annotation #2: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic” (except as noted in annotation #1).

- Some Handling Subcommittee members' hold the opinion that this is exactly why the "Made with organic" category was written into the rule. It enables products to be made with organic agricultural ingredients, but still have desirable synthetic ingredients added to them.

⁴ Excerpted from [2015 TR, Nutrient Vitamins and Minerals](#)

- This lessens the economic burden for companies who would not have to re-formulate entirely, but only have to change their label to a Made with Organic claim.
- Consumers can easily understand this, contrary to some industry claims.

These two annotations would set the course straight for limiting synthetic vitamins and minerals in organic foods but there is one loose end from these changes. The recent TR points out that many of the Vitamins in use are made from fermentation processes and could be determined to be nonsynthetic. It also points out that biotechnology is being increasingly used in the production of some vitamins. See Evaluation Question #1 from the 2015 TR (lines 425- 459). Since we believe that the public's concern is primarily with synthetic vitamins and minerals, we suggest that the nonsynthetic forms should continue to be allowed, but this means placing them on §205.605(a). ACA's would have to determine which forms meet a nonsynthetic allowance, but the TR refers primarily to Vitamins D2, B2, B12, E, F, K, and C.

Proposed Annotation #3: §205.605 (a) Vitamins and minerals, non-synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled Organic.

Option 2 for discussion:

Some members of the Handling Subcommittee believe that the language in the 2012 proposed rule should be adopted for both the Organic and Made with Organic Categories of products.

Proposed Annotation #4: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and “made with organic (specified ingredients or food group(s))”.

- This removes the old incorrect 21 CFR citation and substitutes the correct ones for both adult food and infant formula.
- This has the least impact on companies with products that are already supplemented with vitamins and minerals.
- Consumers still have a choice to not purchase products with synthetic ingredients because they are listed on the label.

Questions for Public Comment:

1. Which of these options do you prefer, and why?
2. Is there another option that should be considered instead of these?
3. Are there mandatory international fortification requirements that should be taken into consideration for products being exported and, if so, how should the annotation be revised?

Subcommittee Vote

Motion to adopt the discussion document on Nutrient Vitamins and Minerals

Motion by: Zea Sonnabend

Second: Harold Austin

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Sunset 2018 Review Summary
Meeting 1 - Request for Public Comment
Crops Substances
April 2016

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 on the National List used in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2018. 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 or recommendations on these substances until the fall 2016 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2016 public meeting. These comments should be provided through www.regulations.gov by April 14, 2016 as explained in the meeting notice published in the Federal Register.

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 substances currently on the National List were added to the list based on evidence available to the NOSB at the time. 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 April 14, 2016 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2018 Review Summary
Meeting 1 - Request for Public Comment
Crops Substances
April 2016

Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.
(Linked below)

[Copper sulfate](#)

[Ozone gas](#)

[Peracetic acid](#)

[EPA List 3 - Inerts of Unknown Toxicity](#)

Reference: 7 CFR §205.602 Nonsynthetic substances prohibited for use in organic crop production.

[Calcium chloride](#)

Copper sulfate

Reference:

205.601(a)(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent; and,

205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Technical Report: [1995 TAP \(Copper Sulfate and Other Coppers\)](#); [2001 TAP](#); [2011 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [04/2011 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Background

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were recently reviewed for Sunset 2017 and the [documents were posted](#) regarding the review criteria in

regards to copper. The listings under review now are for copper used in aquatic rice production to control algae or tadpole shrimp (§205.601(a)(3) and §205.601(e)(4), respectively). Because the copper sulfate is used in aquatic systems the current annotations include specific requirements for application rates.

Additional information requested by NOSB:

1. Has there been any new information regarding the viability of alternatives to these uses of copper?
2. Have ACAs noticed any increase in baseline soil test values for copper and done anything about it?

Ozone gas

Reference: 205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.

Technical Report: [2002 TAP](#)

Petition(s): [2001](#)

Past NOSB Actions: [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Background

Ozone was petitioned for use for weed control in crop production. It was suggested that ozone be injected through irrigation drip tape under plastic mulch. A subsequent additional request was made for use of ozone as an antimicrobial agent to clean irrigation lines. Ozone is a strong oxidant and works by oxidizing plant tissue and bacterial membranes.

In the 2002 TAP review, one reviewer objected strongly to use of “a known and problematic air pollutant” in organic farming. Two reviewers felt that ozone should be permitted with restrictions.

Ozone was not approved for use in weed control, but was listed for use as an irrigation system cleaner in September, 2002. Used as an irrigation cleaner, ozone is much less likely to be released into the atmosphere. Used for weed control, ozone could escape into the atmosphere. At sunset in November 2007, ozone was relisted by a vote of 14 to 0. At sunset in December 2011, ozone was relisted by a vote of 13 to 0.

Additional information requested by NOSB:

The Crops Subcommittee would like to know if ozone is currently in use for irrigation system cleaning. The Subcommittee asks certifiers, inspectors, and producers to provide feedback on whether or not ozone is listed on organic system plans and used in organic crop production, to help evaluate if it is still necessary for ozone to remain on the National List.

Peracetic acid

Reference:

205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label; and, 205.601(i)(8) Peracetic acid - for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

Technical Report: [2000 TAP](#)

Petition(s): [2008](#)

Past NOSB Actions: [11/2007 recommendation](#); [11/2009 annotation change](#); [12/2011 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset Review 10/09/2008 [73 FR 59479](#) ; Annotation change 05/28/2013 ([78 FR 31815](#))

Sunset Date: 5/29/2018

Specific Uses of the Substance: Peracetic acid in organic crop production is used to disinfect equipment. It can also be used to treat seeds or asexually propagated planting materials as a disinfectant. It can be used to disinfect pruning equipment to help prevent the spread of the fire blight bacterium or used in one of the hydrogen peroxide formulations for control on the tree canopy of this same disease. Peracetic acid is also used in formulations of hydrogen peroxide, allowed at a concentration of no more than 6%, for use in organic crop production. (The Handling listing for Peracetic acid, a 2016 Sunset Review material, has recently been voted on to re-list its allowed use).

Technical Report: The Crops subcommittee has requested a new Technical Evaluation Report for peracetic acid, but it has not yet arrived and thus any additional information that it might provide will be in the 2nd posting for this material review (Fall 2016 NOSB meeting).

Discussion: This appears to be a pretty straightforward material: made from and decomposes back to acetic acid, oxygen, and water. Peracetic acid is a very strong oxidizing agent. This substance was first developed in 1950. Historically it has been used to treat fruits and vegetables to reduce spoilage from bacteria and various fungi. It is used to treat bulbs, to disinfect potting soil, clean irrigation equipment, and in seed treatment to inactivate fungi or other plants diseases. Additionally, in organic crop production it is also used as a bactericide/fungicide in wash waters to help decrease *Escherichia coli* O157:H7 on some fruit and vegetable crops. With the recent removal of two antibiotics previously allowed for use in organic crop production to assist in fire blight reduction, use of this substance as part of a rotational control and fire blight prevention program has increased, according to information provided by some organic stakeholders during recent public comment periods.

In the December 2, 2011 NOSB recommendation for the 2013 Sunset Review of peracetic acid for the 2 Crops listings at §205.601(a)(6) and §205.601(i)(8), the board clarified the annotation change from the 2009 recommendation and supported it. The original recommended annotation change was:

§205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

§205.601(i)(8) Peracetic acid—for use to control fire blight bacteria. Permitted in hydrogen peroxide formulations at concentrations of no more than 5%.

This annotation was later implemented by the NOP with a slight change. The recommended 5 percent limit was changed to a 6 percent limit, based on information provided during public comment stating the recommended 5% limit was too low compared to percentages in use at the time. This has brought some slight confusion into this review, so we are going to try and clean up this historic information and also seek to get some clarity on what impact, if any, this annotation had on the various stakeholders that are involved.

Additional information requested by NOSB:

1. Can organic crop producers or certifiers provide the full committee with any information that can explain why this material (or one of the alternative materials) is a better option for use, in organic crop production, for the listed allowed uses?
2. Has anything changed during the current sunset cycle that would make this material no longer necessary for its intended uses for organic crop production? If so, please help to explain.
3. It would help the NOSB in the review of this material if we could get feedback as to whether the current annotation (at a concentration of no more than 6%) presents any unforeseen problems for organic stakeholders, certifiers, or for product formulation. Also, could you provide input as to whether or not this annotation is even necessary?

EPA List 3 - Inerts of Unknown Toxicity

Reference: 205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Technical Report: N/A

Petition(s): NA

Past NOSB Actions: [10/2002 meeting minutes and vote \(see pheromones\)](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset Review 10/09/2008 [73 FR 59479](#) Sunset Review 10/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

This listing will be superseded by the annotation change approved by the NOSB for EPA List 4 and List inerts (§205.601(m)(1)). The NOSB is continuing the sunset review process for these EPA List 3 inerts in case that change cannot be implemented through rulemaking before the 11/03/2018 sunset of EPA List 3 inerts.

Additional information requested by NOSB:

None

Calcium chloride

Reference: 205.602 - Nonsynthetic substances prohibited for use in organic crop production.

(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

Technical Report: [2007 TAP](#)

Petition(s): [2005](#); [2015](#)

Past NOSB Actions: [09/1996 minutes and vote](#); [11/2006 annotation change \(failed\)](#); [11/2007 sunset recommendation](#); [12/2011 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

Sunset Date: 11/03/2018

Background

The NOSB originally voted to allow calcium chloride for use to control bitter pit in apples and as an emergency defoliant for cotton; the material was categorized as nonsynthetic and was not included on sections 205.601 or 205.602. Calcium chloride was subsequently petitioned and added to National List section 205.602 as a nonsynthetic substance prohibited for use in organic crop production. The annotation states: “brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.”

This material has historically not been allowed for direct soil applications due to high chloride and high solubility concerns, however a 2015 petition for removal of the prohibition contests these concerns and argues the contrary. Natural substitutes including limestone, gypsum, rock phosphate and bone meal are unable to supply calcium in sufficient quantities when faced with limited calcium uptake conditions. There are currently 20 registered OMRI products and 10 WSDA registered products.

The Subcommittee has no concerns regarding the continued listing of calcium chloride.

Additional information requested by NOSB:

None

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal - Ash from Manure Burning
January 5, 2016**

Summary of Proposed Action:

EnergyWorks BioPower, LLC submitted a petition to revise 7 CFR 205.602(a), Ash from Manure Burning, to include the following annotation: “except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients.” The petition states that EnergyWorks, “owns and operates a facility in PA that uses a staged thermochemical reactor to extract over 30 tons of minerals from 240 tons of egg-layer poultry manure each day.” The petitioner argues that annotation approval will provide the following benefits: will generate renewable electricity; will prevent excess nutrients in the environment; and will increase development of similar commercial processing facilities throughout the US.

Poultry manure is sourced from concentrated animal feeding operations (CAFOs), dried to normalize moisture content, conveyed to a thermochemical reactor, exposed to heat and oxygen to achieve proper conversion of organic material into combustible biogas (where the primary goal of the process is denitrification), and mineral ash is removed, cooled, tested and sold.

As referenced above, ash from manure burning is currently listed at §205.602 as a nonsynthetic substance prohibited for use in organic production. The petitioner claims that this “NOP prohibition was established because burning of manure was seen as being wasteful of nutrients.” They explain their petition rationale by 1) “suggest[ing] that extraction of minerals by controlled combustion preserves their non-synthetic nature”, 2) “while allowing organic growers to derive increased value from manure as a nutrient resource.”

The Subcommittee did not request a TR having determined not to add the annotation to the material listing; the continued blanket prohibition aligns with previous board recommendations. All prior board recommendations have supported the prohibition of ash from manure burning. At the fall 2015 NOSB meeting, the Board renewed the prohibition during the Sunset 2017 material reviews, stating, “ash from manure burning was placed on §205.602 based on its incompatibility with organic production; burning these materials is not an appropriate method to use to recycle organic wastes.”

The Crops Subcommittee has determined that the annotation amendment fails the OFPA criteria and should not be added to the National List.

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

	Criteria Satisfied?
1. Impact on Humans and Environment	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

Substance Fails Criteria Category: [3] **Comments:** Ash from manure burning was originally placed on §205.602 based on its incompatibility with organic production. Burning removes carbon and nitrogen from the final ash product and lessens its soil-building value. Utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of CAFOs by creating an organic industry demand for ash. Utilizing ash from manure burning in order to assist CAFOs in their

reduction of environmental and human health contamination is not a compelling argument for consideration for addition to the National List.

Subcommittee Action & Vote

Motion to annotate ash from manure burning at §205.602 - nonsynthetic substances prohibited for use in organic crop production - with the following annotation: “except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients.”

Motion by: Carmela Beck
 Seconded by: Colehour Bondera
 Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

The motion failed, thus the Subcommittee supports retaining the existing prohibition of manure ash in organic crop production.

Approved by Subcommittee Chair, Zea Sonnabend, to transmit to NOSB February 26, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment? Ash from Manure Burning:

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			CAFOs contribute to environmental pollution and human health issues
2. Is there a probability of environmental contamination during, manufacture or disposal? [§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 potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		

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		Provided 205.203 requirements are met.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

Category 2. Is the Substance Essential for Organic Production?

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			Egg-layer poultry manure
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Manufactured using a thermo-chemical reactor exposed to heat and oxygen to achieve proper conversion of organic material into combustible biogas (where the primary goal of the process is denitrification), mineral ash is removed, cooled, tested and sold.
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			
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		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			

Category 3. Is the substance compatible with organic production practices? Ash from Manure Burning:

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		Ash from manure burning is a by-product of the poultry factory farm industry, while we support the need to find creative solutions to prevent environmental pollution and public health concerns due to the build-up of excess manure accumulation, we don't support the industry creating the need.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		See above.
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		

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal - Squid & Squid Byproducts
March 1, 2016

Introduction

Shoreside Organics, LLC submitted a petition in April, 2015 to add “Squid and Squid Byproducts” to the National List of Allowed and Prohibited Substances section 205.601(j)(7) for use as a fertilizer.

205.601 Synthetic substances allowed for use in organic crop production. ...the following synthetic substances may be used in organic crop production: Provided, that, use of such substances do not contribute to contamination of crops, soil or water... (j) As plant or soil amendments. (7) Liquid fish products – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

The petitioner would like acid-adjusted squid products to be categorized as fish products for use in organic production.

Background

The use of squid and squid byproducts for use in agriculture date back to the 1800’s when much of the product was shipped from CA market squid fisheries to Asian countries for consumption and fertilizer applications. Squid byproducts make up 52% of the total body weight and include the squid ink, pen, skin, milt, liver and viscera and are typically discarded as waste. There are several uses for these byproducts including food, medicinal and soil amendment uses. Squid and squid byproducts are the starting ingredients in the production of enzymatically produced hydrolysates with N-P-K values ranging from 2-2-2 to 3.3-7.3-2 or more. Seafood derived hydrolysates, including squid and squid byproducts, have been used both as foliar sprays and soil amendments for propagating cranberries, cherries and apples. In general, squid byproducts are chopped, heated, digested with natural enzymes and stabilized with an acid such as phosphoric, sulfuric or citric acid to prevent microbial growth.

Squid are commercially harvested using nets directly above spawning grounds during mating season primarily for calamari. Fisherman target spawning squid because they die shortly after reproduction. There are several squid fisheries throughout the world. There are two main squid fisheries in the US including along the Atlantic coast for long finned squid and along the Pacific coast for market squid. The US Pacific squid fishery is managed by the CA Department of Fish and Game, the National Oceanographic and Atmospheric Administration (NOAA) Fisheries, and the Pacific Fishery Management Council. Atlantic squid are managed in federal waters by NOAA Fisheries in conjunction with the Mid-Atlantic Fishery Management Council. Management includes seasonal catch limits, timed fishery closures, administration of permit issuance and limitations on using lights to attract squid to ensure uninterrupted spawning.

Discussion

Squid are littoral invertebrates classified into the phylum Mollusca, class Cephalopoda and order Loligo (later renamed Doryteuthis). There are an estimated 300 squid species known throughout the world. Common to the northeastern Atlantic coast is the longfin squid, species *Doryteuthis (Loligo) pealli*. Common to the US west coast is the market squid, species *Doryteuthis (Loligo) opalescens*.

Per the TR, squid differ anatomically and phylogenetically from fish. The US Food and Drug Administration (FDA) defines “fish” to mean fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the

roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption. The term “fishery products” means any human food product in which fish is a characterizing ingredient. Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle. This definition is not inclusive of squid, despite its classification as a mollusk. Scientifically, squids are cephalopod mollusks; however, for legal purposes and because they are part of a defined fishery, squid can be included “as other forms of aquatic life” per the FDA fish definition. Squid and squid byproduct hydrolysate have potential uses as food products.

The Canadian Organic Standard allows for the use of fish products; in Canadian fisheries, the definition of fish includes marine invertebrates such as squid. The EU Organic Standard allows the use of molluscan (squid) products from sustainable fisheries and may be used in organic production of feeds for non-herbivores; squid products are not explicitly authorized for use in organic production. The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources; mollusks (squid) are included in Japanese fisheries. IFOAM permits the use of fish and shell products and food processing of animal origin.

The Subcommittee recommends amending the current listing to read: Liquid fish and squid products – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

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

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Move to classify Squid & Squid Byproducts as synthetic.

Motion by: Carmela Beck

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list Squid & Squid Byproducts at §205.601(j) of the National List – with the annotation – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

Motion by: Carmela Beck

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB March 1, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment? Squid & Squid Byproducts

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		TR (219-220; 562-563): If squid or squid byproduct fertilizers are over applied they can leach nitrogen and phosphate into the soil. Discharges of dead squid & wastewater boost ammonia concentrations & reduce oxygen content in the water posing a threat to marine life.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		TR (191-192): Disposal is regulated as a solid waste by the US EPA.
3. Are there any adverse impacts on biodiversity? (§205.200)		X		TR (78-81): Even without fishing, the entire population replaces itself annually. The stock is entirely dependent on successful spawning from each generation coupled with good survival of recruits to adulthood.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]			X	
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		TR (489-490; 524-525): Squid & squid byproduct hydrolysate is used as fertilizer in crop production providing organic matter. At high levels of application there is greater potential for leaching of nitrogen and phosphorus.
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		TR (674-676; 718; 727-733) Manufacture waste of fats and oils must be properly treated or can lead to pollution. International squid fishing remains a concern of human rights advocacy particularly in SE Asia & NZ where debt bondage and captive enslavement are practiced. Illegal, unreported & unregulated fishing is a significant problem affecting the marine ecosystem (examples cited China, Chile, Thailand, and India).

9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		TR (614-615; 622-623): Decomposition of squid & squid byproducts provide starting ingredients for humus formation which comprises much of the organic matter in soil. Microbial activity is higher in soils fertilized with squid & squid byproducts hydrolysate than comparable soils fertilized with other organic fertilizers or synthetic mineral products.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Squid & Squid Byproducts

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 (464; 479-482): Squid and squid byproduct hydrolysates are similar in composition to fish emulsions. The addition of sulfuric and phosphoric acid are considered synthetic.
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			
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		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		TR (738-739): Raw animal manure, composted plant and animal materials & uncomposted plant and animal materials.
8. Are there any alternative substances? [§6518(m)(6)]	X			TR (742-746): Aquatic plant extracts, elemental sulfur, humic acids, lignin sulfonate, micronutrients, & liquid fish products.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			TR (775-781): Use of cover crops, crop rotations, no-till and the application of plant and animal materials.

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 3. Is the substance compatible with organic production practices? Squid & Squid Byproducts

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			
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
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 toxins derived from bacteria				
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			(TR 298-304): OFPA does not specifically list squid or squid byproducts, however, it does list fish emulsion. In US law, the term “fish” is often taken to mean finfish, mollusks, crustaceans, and all other marine animal and plant life with the exclusion of marine mammals and birds. Squid are considered mollusks.
livestock parasiticides and medicines				
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers				

National Organic Standards Board
Crop Subcommittee
Petitioned Material Proposal - Hypochlorous Acid
February 16, 2016

Summary of Proposed Action:

On May 29, 2015 the NOP received a petition to add Hypochlorous Acid (CAS #7790-92-3) to the National List at §205.601 - Synthetic substances allowed for use in organic crop production. This material is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products. The petition was forwarded to the Handling Subcommittee on June 3, 2015 and later that summer the Crops Subcommittee was asked to review this material as well, since there are multiple listings being requested by the petitioner. The Livestock Subcommittee is also reviewing hypochlorous acid.

The petition was submitted by Botanical Food Company Pty Ltd. Hypochlorous acid (electrolyzed water) is being petitioned for use in organic crop production for a couple of different uses, including: a) as a post-harvest sanitizer for raw herb and spice materials <60ppm and b) as an equipment and cold room sanitizer <200ppm.

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water. The memo was issued as a response to requests asking for the National Organic Program to clarify whether electrolyzed water (EW) was allowed as a sanitizer and antimicrobial agent for use in organic production and handling.

The NOP felt that the allowance of EW by a certifier or a material evaluation program were based on an incorrect interpretation of the allowance for chlorine materials on the National List of Allowed and Prohibited Substances at 7CFR §205.600-606. The NOP requested that certifiers ensure that the use of EW was not allowed in organic handling or production and that any party wishing for further consideration of EW for use in organic handling or production, should then submit a petition to get it added to the National List. Thus, the rationale for the petition currently before the Crops subcommittee and the full NOSB is in response to the NOP policy memo.

Manufacture and Uses of the Substance:

Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode, but permits ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochloric acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. (TR lines 48-68).

The effectiveness of hypochlorous acid as an active sanitizing agent is determined in large part by the solution pH. Hypochlorous acid exists interchangeably with other chlorine species, including chlorine, hydrogen chloride (aqueous and gaseous) and hypochlorite. In a controlled pH environment hypochlorous acid will exist as the dominant chlorine species under pH conditions ranging from 2 to 7. (TR lines 84-89).

EW has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of EW against foodborne pathogens on raw agricultural products. Similar studies and actual in field use (and facility use) has demonstrated similar activity when used to sanitize equipment and storage facilities. This material was (prior to the USDA/NOP memo PM 14-3 Electrolyzed Water) previously approved by at least one material review organization and multiple certifiers for use on crops and allowed for uses other than what is currently being petitioned. Prior

to the NOP memo it was also beginning to be used for control of powdery mildew in apples and to aid in prevention of other pathogens or microbial contamination on fresh fruits and vegetables (leafy lettuce) that might pose a risk to human health.

According to the Hypochlorous Acid TR (August 13, 2015) it states that some of the advantages of using EW are: 1) EW is as effective as any chlorine treatment, 2) it is not necessary to handle potentially dangerous chemicals, e.g. chlorine gas, chlorine dioxide, bleach, etc., 3) the apparatus used to produce EW is relatively inexpensive and easy to operate, 4) because only water and sodium chloride (salt) are used in EW production, it is environmentally more friendly of a compound compared to some of the alternative materials, and 5) the properties of EW are controlled on site during the electrolysis process. It should also be mentioned that since the materials from both of the cathodes are actually used during this process and final product use, there are no bi-products created during the formulation of Electrolyzed Water and therefore nothing to dispose of or that could be considered to be of a negative environmental concern.

Discussion:

From an environmental impact perspective, EW would appear to pose less of a risk for the environment than some of the alternatives since it is made from water and salt. There are no by-products to be disposed of since all of the materials are formulated and used in the final application process. Also, it would appear that EW would pose less of a risk to human health and/or worker health compared to some of the possible alternative products as well. According to the August 13, 2015 TR hypochlorous acid at a pH 6.0 to 7.5 is safer to use than other disinfectants containing chlorine. The level of chlorine in EW is usually over ten thousand times less than that of common household bleach. The on-site production helps to alleviate the need to transport other materials that may be more hazardous to handle, thus reducing the risk of exposure to the worker and for possible environmental contamination if improperly handled. The optimum range for the material that previously was being used in organic farming or currently is being used (in conventional farming) is at a pH of 6.0 to 7.5 according to the petitioner. This pH range gives a more effective and a more stable product that is safer for the environment and human safety as well than those using the lower pH levels. According to the TR it mentions that in forms of hypochlorous acid that are at a pH < 4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, but also creating possible human health and safety issues (Fisher, 2009). The more neutral, the pH of the material, the safer and more stable the substance appears to become.

The primary functions of EW are as an anti-microbial, sporicidal, and bactericidal agent. Some currently allowed alternatives to EW are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peroxyacetic acid, citric acid, acetic acid, ascorbic acid, vinegar are some of the materials currently used.

The petition seeks to add electrolyzed water/hypochlorous acid to the National List for use in organic crop production as an alternative to the other substances currently allowed. The petitioner states that EW will be used post-harvest on farm as a sanitizer for use on raw herbs and spices including, but not limited to; basil, cilantro, parsley, chili peppers, garlic, and ginger. EW would also be used on farm to sanitize equipment and as a cold room sanitizer.

Electrolyzed water, although produced via a different mechanism, has the same mode of action as sodium and calcium hypochlorite (both of these materials are currently on the National List). In fact, the main active ingredient in their dilute aqueous solution form is hypochlorous acid, the same material produced as the Anolyte component of electrolyzed water. The reason hypochlorous acid can be ten thousand times less concentrated than sodium and calcium hypochlorous solutions and still be an effective sanitizer is that sodium and calcium hypochlorite solutions (bleach) have a high pH. When the pH is high, the hypochlorous acid/hypochlorite chemical equilibrium strongly shifts towards the presence of hypochlorite, whereas at neutral pH the chemical equilibrium shifts towards the presence of hypochlorous acid, the effective

sanitizing compound. Therefore, hypochlorous acid (EW) is a safer product, for the environment and for human health, than chlorine sanitizer materials currently on the National List.

During the public comment period prior to the fall 2014 NOSB meeting there were several public comments submitted in response to the NOP's decision to halt the allowed use of Hypochlorous acid per their memo PM 14-3 sent out on June 9, 2014. One of those organic stakeholders provided written public comment on September 28, 2014 that included multiple peer-reviewed scientific journal articles. These articles provided support to the claim that electrolyzed water was a safe sanitizer, providing the same degree of anti-microbial control without the toxic risk to employees, the crops, or the harvested products it is applied to. These articles also helped to provide support that this material might better support the basic fundamental principles of organic crop production compared to many of the alternatives currently being used. These also helped to support the petitioners claim as to why this material is needed – because it is safer to use on such crops as lettuce, spinach, and other sensitive vegetables and herb crops.

This material does appear like it could help the organic crop producers meet the requirements of compliance with the FDA's Food Safety Modernization Act, while at the same time providing the producer with a material more compatible with the fundamental principles of organic crop production. It could possibly be looked at to provide a material that is less concerning for its impact on human and environmental health, while helping to meet a necessary need of the organic producer for materials that they can use in the sanitizer/anti-microbial listing for use in organic crop production.

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

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Move to classify hypochlorous acid as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Francis Thicke

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Move to list hypochlorous acid at §205.601 of the National List: Synthetic substances allowed for use in organic crop production. §205.601(a) As algicide, disinfectants, and sanitizer. (2)chlorine materials (iv) Hypochlorous acid.

Motion by: Harold V. Austin IV

Seconded by: Emily Oakley

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 16, 2016

NOSB Evaluation Criteria for Substances Added To the National List – Crops

Category 1. Adverse impacts on humans or the environment? Hypochlorous 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		According to the petition electrolyzed water can be made on-site. In this process there would not be any residual product to dispose of. If produced off-site and sold as a finished product then there could be a possibility of environmental contamination as the result of an accident or a spill. The TR does state that in forms of hypochlorous acid that are at a pH<4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, but also creating possible human health and safety issues (Fisher, 2009). The more neutral, the pH of the material, the safer and more stable the substance appears to become.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		x		This substance is formed by the electrolysis of a sodium chloride solution. Any environmental concerns would be from a spill during manufacturing or transport of a formulated end product.
3. Are there any adverse impacts on biodiversity? (§205.200)	x			The TR, (lines 596-612) does state that hypochlorous acid in aqueous solutions at pH< 7. Was of minimal toxicity to birds, but could be very toxic to fish and freshwater invertebrates.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		Contaminants listed in the US Food and Drug Administration’s Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, are unlikely to be found in hypochlorous acid since it is the electrolysis product of two generally recognized as safe materials, salt and water (TR lines 568-571).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	x			The TR (lines 140-153) mentions that there can be a reaction with organic material (humic acid) which can lead to some potential concerns. It does go onto state though: It is generally accepted that carcinogenic and teratogenic trihalomethanes and haloacetic acids are not formed by the action of hypochlorous acid in neutral or near-neutral solutions (Satyawli et al., 2007).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		According to the TR (lines 602-612) hypochlorous acid solution decomposes very slowly in the dark but more rapidly in the presence of light, rapidly in full sun light by producing hydrogen chloride and oxygen. Released into the environment it is distributed into water and air, with an estimated half-life of 1-4 hours. A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity.
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		Information provided in the petition states that compared to other types of chlorine, electrolyzed water is usually used at an active rate that is ten thousand times less than that of common household bleach. The TR (lines 624-626) mentions that the human innate immune system uses hypochlorous acid to fight infection but also directs it against host tissue in inflammatory diseases (Kettle et al.,2013). Chlorine disinfectants have been shown to cause occupational dermatitis or skin irritation (TR line 662).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		x		See the answer to question #5 above.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		x		

Category 2. Is the Substance Essential for Organic Production? Hypochlorous 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			Electrolyzed water is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane. This process creates hypochlorous acid, hypochlorite ion, and hydrochlorite at the anode and sodium hydroxide at the cathode. (TR lines 48-68) August 13, 2015 TR.
3. Is the substance formulated or manufactured by a process that chemically		x		

changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]				
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 acids such as citric acid, lactic acid, malic acid, and vinegar are some alternative materials.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			Hot water can be used in some instances.
8. Are there any alternative substances? [§6518(m)(6)]	x			Some alternative substances are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peroxyacetic acid, citric acid, acetic acid, ascorbic acid, and vinegar. Copper sulfate is another possible alternative depending on the use.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		

Category 3. Is the substance compatible with organic production practices? Hypochlorous 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			Compared to many of the alternative materials currently being used electrolyzed water could provide a safer and effective alternative. (especially when produced using the on-site electrolysis process)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			See answer to question #1 of this category.
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			May be used to sanitize equipment

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Checklist - Soy Wax
January 19, 2016**

Summary of Proposed Action:

Soy wax has been petitioned as a synthetic substance for use in organic mushroom production to seal plugs and ends of logs inoculated with mushroom spawn. Soy wax is intended to be used for the same purpose as microcrystalline cheesewax, which is currently listed at §205.601(o) as a production aid in the production of mushrooms grown on logs.

Soy wax is produced from oil extracted from soybeans. The oil is hydrogenated, making it a solid at room temperature. Crystalline cheesewax, which is currently listed for the use, is made from petroleum. Soy wax, which is now available from non-GMO, domestically-produced soybeans, was petitioned for use because it has fewer environmental and health impacts than products made from petroleum.

Soy wax is considered synthetic because it undergoes a chemical change that does not happen naturally when it is hydrogenated. Hydrogenation is the process whereby the poly- and mono-unsaturated oils are solidified in order to increase the viscosity. As the petition describes it, this process involves the reaction of hydrogen with soybean oil at elevated temperature (140-225°C) in the presence of a nickel catalyst. Therefore, even if soy wax were made from organic soybeans by this process, it would be synthetic.

The Crops Subcommittee supports the addition of soy wax made from non-GMO plant material to the National List as an alternative to microcrystalline cheesewax, which is made from petroleum.

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

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

Criteria Satisfied?

- | | | |
|---|-----------------------------|------------------------------|
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

Subcommittee Action & Vote:

Classification Motion: Move to classify soy wax as synthetic.

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 4 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list soy wax at §205.601 of the National List (o) - As production aids. Soy wax (CAS # 8016-70-4) - for use in log grown mushroom production. Must be made from non-GMO soybeans.

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 4 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Proposed Annotation: Must be made from non-GMO soybean oil.

Basis for annotation: To meet criteria above Other regulatory criteria Citation

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment? Soy Wax

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		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Soy wax (hydrogenated soy oil) is biodegradable and non-toxic
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		Soy wax breaks down into carbon dioxide and water.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Soy wax is hydrogenated soybean oil and non-toxic and biodegradable in soil.
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		Soy wax for mushroom production is not intended to be ingested, but would not be harmful if it were.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 2. Is the Substance Essential for Organic Production? Soy Wax

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			Hydrogenation of soybean oil
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			The chemical change is hydrogenation, which alters carbon bonding with hydrogen.
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		Soy wax could be made with organic soybean oil, but would still be considered synthetic.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			Microcrystalline cheesewax, which is currently on the National List.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		The sealing of log ends and plug holes is considered necessary in mushroom production.

Category 3. Is the substance compatible with organic production practices? Soy Wax

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			Soy wax is more consistent and compatible with organic farming and sustainable agriculture than the petroleum-based microcrystalline cheesewax currently in use.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See #1 above.
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			

National Organic Standards Board
Crops Subcommittee
Discussion Document - EPA List 4 on §205.601(m) Annotation Change
February 2, 2016

Introduction

The Crops Subcommittee is working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The NOSB supported a [recommendation](#) to change the existing listing for inert ingredients at its October 2015 meeting. An additional annotation change is proposed for posting (but not voting) so that all stakeholders can be aware of an impending proposal for a change to the listing.

Background

For background here are the final two paragraphs of the EPA List 4 Sunset Review:

The Crops Subcommittee (CS) fully agrees with the frustration over how long it is taking to implement the NOSB recommendation to review inerts. We sincerely hope that the vote to proceed will be taken soon so that the program to work with the Safer Choice Program can begin in 2016. Once it begins, the inerts manufacturers will have to submit their products to Safer Choice to be reviewed. This will clearly favor those inerts that have the best chance of being approved, because the ones that are not likely to be approved will not apply until absolutely forced to do so. The CS believed that it would be better to put some of the inerts categories that are unlikely to end up on the SCIL list on notice sooner than the very end of the whole SCP project so that they could start moving towards reformulation sooner rather than later. That is why we requested a Technical Report for [nonylphenol ethoxylates](#) (NPEs) and are considering Technical Report requests for other categories that will not pass the SCP. We are doing this with the expectation that there will be a long period of time before full implementation of this program, so that everyone doesn't complain at the end that there wasn't enough notice.

The accompanying annotation discussion proposal to remove NPEs from organic products has one clear message from the NOSB: START REFORMULATING NOW! The change will definitely not be sudden, but it is clear that eventually NPEs will not be allowed in organic. Unless all stakeholders communicate this in their messaging to their constituents, this will bog down the change even further.

Discussion: Proposal to Prohibit NPEs

As stated above, if the goal is to get NPEs out of organic products without disrupting the tools that organic farmers use we need to give as much notice as possible. No matter how we approach it companies will likely object about not having enough notice and time. They did the same thing when List 3 was first prohibited. The 2000 Final Rule establishing the organic regulations allowed an 18-month period for compliance with the new prohibition on List 3 inerts, and the EPA cooperated by fast-tracking some chemicals that were on List 3 to move to List 4. This proved to be enough time for products to either be reformulated or get re-classified. In the end, only a few products came off the list and these were soon replaced by acceptable organic alternatives.

One of the biggest challenges, however, is reaching the formulators and suppliers of the products that need to be reformulated. We are requesting input from the public on how to reach this group of stakeholders so that there is plenty of notice.

Both the information in the TR and the comments from the public were clear that NPEs are a group that we should attempt to remove from organic products. Because this is a discussion document the Crops Subcommittee has not prepared a checklist at this time, but readers are encouraged to read the 2015 [Technical Report](#) on NPEs for the details.

The Crops Subcommittee believes that a 3-year notice should be enough time to remove the most problematic inerts. If the NOSB waits until all the other inerts are reviewed through the SCP process to announce which ones are prohibited it will take a lot longer. For NPEs, Crops has chosen to put forth a discussion document on a proposed annotation to make the public aware of its intention. The document will circulate until fall of 2016, at which time the NOSB will vote on it. Expect another 18 months for rule change with a comment period and perhaps a grace period in the rule as there was for List 3 inerts. This would be 3 to 4 years at least. So why not start now?

The Proposed Annotation change for discussion is as follows:

§205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. Except for inerts from the group known as Nonylphenol Ethoxylates.

Discussion Questions

1. Is the timeline outlined above enough time to reformulate products?
2. For Accredited Certification Agencies and Materials Review Organizations: how many products that you approve contain NPEs and can you characterize the generic categories that they fall into?
3. Please provide suggestions for outreach to the parties affected by this change.

Motion to approve this discussion document for posting, and work in conjunction with the Livestock Subcommittee on the proposal.

Motion by Zea Sonnabend
Seconded by Harold V. Austin, IV
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 2, 2016