



**National Organic Standards Board Meeting**  
**Chase Park Plaza, St. Louis, MO**  
**November 16-18, 2016**

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**National Organic Standards Board**  
**Certification and Accreditation Subcommittee (CACs) Discussion Document**  
**Personnel Performance Evaluations of Inspectors**  
**September 14, 2016**

## **I INTRODUCTION**

Over the last year and a half certifiers have been working to meet the requirements of [NOP 2027, \*Instruction: Personnel Performance Evaluations\*](#), promulgated by the NOP on August 2, 2013 and revised effective March 31 2016. This Instruction appears to require that every inspector should be evaluated in the field every year. Many certifiers have expressed considerable concern for the logistics and expense of meeting this Instruction and the potential negative impact it will have on the organic community over time.

This Discussion Document seeks to provide an opportunity for stakeholders to respond to the NOSB request for further public comment on this issue.

## **II BACKGROUND**

On December 2, 2011 the NOSB voted 13:1 with 1 abstention to “provide all inspectors with performance assessment and oversight: a. Witness audits by ACA to be conducted at a minimum every 300 inspections or 3 years whichever is less. Results must be documented. Witness audits may be conducted by certification management, senior inspectors or senior reviewers.”

On August 2, 2013 the NOP issued *Instruction 2027* requiring in-field evaluations “at least annually.”

In 2014 the International Organic Inspectors Association (IOIA) explored a pilot program to assist certifiers in developing and managing an in-field inspector evaluation program. IOIA developed an evaluation form, recruited evaluators and in consultation with several certifiers, implemented a fee for service program in 2015. In 2016, IOIA expanded this program.

On September 4, 2015 the Accredited Certifiers Association (ACA) submitted a [letter to the NOP](#) providing some observations and concerns about the impact of this Instruction and provided several recommendations for improving this requirement. ACA referenced the 2011 NOSB recommendation and requested *Instruction 2027* be amended to permit certifiers to develop risk-based plans to evaluate the inspectors they work with across a rotational cycle and not limited to one calendar year. ACA also requested certifiers be permitted to shared evaluations.

On December 8, 2015 the NOP issued [NOP 2501 \*Evaluating Auditor Performance\*](#) (of NOP Auditors), which requires in-field evaluation every 3 years. “5.2b A Witness Appraisal shall be conducted at least once every 3 years.”

On February 15, 2016 the IOIA submitted a Report to the NOP on the pilot in-field evaluation program.

In response to concerns about implementation of the in-field evaluation of every inspector world wide every year, the NOP revised *NOP 2027* effective March 31, 2016 to include a provision, at 3.2 b ii, that “Certifiers may use the field evaluations of another accredited certifier. The revised Instruction at, 3.2 b iii, also included a provision that “Certifiers may submit alternative proposals for field evaluation to their Accreditation Manager.”

During spring and summer 2016 the IOIA reports that they are working with 10 certifiers to provide in-field evaluations of 106 inspectors.

### III RELEVANT AREAS OF THE RULE

USDA Organic Regulations (7 CFR Part 205) § 205.501 General requirements for accreditation.

- (a) A private or governmental entity accredited as a certifying agent under this subpart must: ...
  - (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.

### IV DISCUSSION

In response to public comment in spring 2016 the CACS reached out to both NOP staff and certifiers to better understand how *NOP 2027* was impacting the certification process.

Stakeholders agree that all inspectors must be professionally evaluated every year. Indeed, inspectors are professionally evaluated on a regular basis via review of their inspection reports and anecdotal and statistical feedback from certified operations. Stakeholders agree that in-field evaluations must take place, but many certifiers disagree about the requirement of an in-field evaluation of every inspector every year, worldwide. This disagreement is based primarily on logistics but also cost.

The NOP expressed considerable concern about the quality of work of some inspectors that the NOP auditors had witnessed during mid-term or 5 year review of some certifiers in recent years. The NOP interprets §205.501 to require in-field evaluation of every inspector world wide every year, and that this is necessary to ensure consistency in organic certification.

The ACA provided feedback from a range of certifiers. For some state-run certifiers the annual in-field inspections do not appear to be a serious concern either logistically or financially. Some certifiers see this requirement as beneficial in encouraging inspectors to increase their ongoing education.

For many other certifiers however, large and small, considerable concern has been raised regarding costs, logistics, inequities between certifiers and a range of other issues. Below are some comments and feedback encapsulated from outreach with stakeholders.

- It's unclear if NOP will approve alternative plans but certifiers would appreciate the option.
- Evaluating an inspector used only a few times a year is not feasible.
- Some certifiers are already relying heavily on shared evaluations and offering them to other certifiers at no charge. Others are trading evaluations or charging a fee.
- The most expensive evaluations are those in remote areas since the remote location is often the reason a certifier is using an outside inspector.
- Many certifiers believe strongly that in-field evaluations are a positive for their organization and the industry. Conducting them internally carries a high value. Evaluations received from other sources vary in quality and do not cover adherence to a certifier's own policies, nor do they present an opportunity to observe personal, interactive skills essential to good inspections. However, some find the cost-benefit just doesn't work out for every inspector every year. A risk-

based approach would be more effective and efficient at achieving the desired results.

- Some certifiers have seen a number of new applicants and have had to find new inspectors, or certifiers have had to turn to more inspectors than planned late in the year. This presents an even greater workload to ensure these inspectors are evaluated. The logistics and entire process is time consuming for all involved and presents difficulties and disincentives.

There are reasonable arguments for enforcing this in-field evaluation of every inspector world wide every year, and reasonable arguments for allowing flexibility in how certifiers meet the intent of 205.501.

The implementation of the IOIA field evaluation is only in its second year, and time will tell if the programs in place now will be sustainable over time without loss of inspectors or increased fees to clients at a time when there is increasing demand for certification of operations worldwide.

#### **V REQUEST FOR PUBLIC COMMENT**

The NOSB seeks public comment from certifiers, providers of evaluation services such as IOIA, individual inspectors, and organic producers about the requirement of every inspector being evaluated in the field every year:

1. **For certifiers:** To date, what have you observed about the benefits, costs and logistics of meeting this requirement?
2. **For certifiers:** Have you been able to meet this requirement for inspectors in overseas locations?
3. **For certifiers:** If given an option to present alternative evaluation plans to the every inspector, every year, what would these look like? If a risk-based approach, how do you define risk?
4. **For certifiers and inspectors:** What has been your experience sharing evaluation forms and processes? What have been the challenges associated with this sharing?
5. **For inspectors:** To date, what are the concerns and benefits that you have observed?
6. **For organic operators:** To date, what are the concerns and benefits that you have observed or experienced during in-field audits conducted on your operation?
7. **For all stakeholders:** What mechanisms are in place to ensure that client files being shared between evaluators and inspectors are taking place on completely secure computer systems?
8. **For all stakeholders:** What are the in-field audit requirements for auditors of other inspection or certification schemes such as GFSI, Global GAP, SQF etc.?

Motion to approve the discussion document for posting for the fall 2016 NOSB meeting

Motion by: Scott Rice

Seconded by: Harriet Behar

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

**Approved by Carmela Beck, Subcommittee Chair, to transmit to NOSB September 14, 2016**



**Sunset 2018 Review Summary**  
**Meeting 2 – Subcommittee Review**  
**Handling Substances § 205.605(a), §205.605(b), §205.606**  
**November 2016**

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

**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

### Subcommittee Review

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 not permitted for use in organic production in Japan. It 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.

With regard to harm 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 though that no studies were found to indicate whether or the not the harvesting of agarophytes in particular is harmful to biodiversity on 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 and a limited technical report has been requested. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

A variety of organizations and manufacturers commented in support of keeping agar-agar on the National List. There were no commenters opposed. Two organizations commented that they would support relisting of the non-synthetic form only. A proposed annotation was “from Gelidium species only, processed without alkaline treatment and sourced from areas managed for sustainability”.

At the first posting for agar-agar, the Handling Subcommittee asked the public for input on any new developments with alternatives to agar-agar, why it’s used instead of alternatives, and what the unique characteristics are that make it essential to organic handling? Responses included: since there is no source for organic gelatin, agar-agar is essential for the manufacture of gummy products because it is superior to using carrageenan and gellan gum; it is used as a stabilizer and the alternative is carrageenan; it is used as thickener in soy cheese and no suitable alternatives have been found; it has stronger setting properties than animal based gelatins; it is less temperature sensitive than certain alternatives.

The Handling Subcommittee proposes that agar-agar remain on the National List

**Additional Information Requested:**

Based on information reviewed, the Subcommittee is not aware of any ancillary substances used in agar-agar. If the public is aware of any ancillaries please provide information via public comment.

**Motion to Remove**

The Subcommittee proposes removal of agar-agar from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

**Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Ashely Swaffar

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

## 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, CODEX, EU, IFOAM, and Japan.

### 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.

### Additional Information Requested:

- 1). During the 2017 sunset review of enzymes (non-animal) the following chart was posted and the public submitted additional ancillary substances (now included in the chart). If you know of ancillary substances used in animal enzymes that are not found on the chart below, please submit spec sheets or names of materials. If there are ancillary substances on the chart that you think should not be allowed, please submit public comment explaining why.
- 2). “Mineral oils, untreated or mildly treated” are on the combined IARC/NTP list. The latest technical

evaluation report (TR) (March 12, 2015) for mineral oil that was done for the Livestock Subcommittee states that for refined mineral oil, the refining process removes the materials that pose the carcinogen concerns. It also mentions that according to the FDA database for “Everything Added to Food in the United States” (EAFUS), mineral oils are approved for use as direct, secondary direct, and indirect food additives for human and animal feed (FDA, 2014). FDA permits the direct addition of mineral oil to food for consumption under 21 CFR 172.842 and 172.878. Could you provide the committee with any information as to how prevalent or necessary mineral oil is as an ancillary for animal enzymes? Also, could you provide us with any information as to the type of mineral oil currently being used? For example: refined, mildly treated, or untreated mineral oil?

<b>Ancillary Substances by Food Additive Functional Class</b>	
Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide, calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium
Carriers and fillers	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate, calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, purity gum (starch), saccharose, sorbitol, soy flour, sunflower oil, trehalose, vegetable oil, micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate,
Preservatives	Sodium benzoate, potassium sorbate, ascorbic acid, alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.
Stabilizers	Maltodextrin, betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers	Acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

**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, can 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 the use of excluded methods to produce it.

The 2000 TAP review for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Public comment during the first posting included a number of producers in favor of animal enzymes remaining on the National List. Multiple commenters stated it was essential for making certain varieties of cheeses and that organically derived animal enzymes were not available. Multiple organizations commented that organic alternatives should be explored more fully; if not currently available the barriers should be identified as well as how to overcome them. One organization felt animal enzymes were probably not essential since the majority of enzymes of used in the U.S. were non-animal.

The Handling Subcommittee proposes that animal enzymes remain on the National List

### **Motion to Remove**

The Subcommittee proposes removal of animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

### **Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

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

## **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

### **Subcommittee Review:**

Uses:

- Coagulate 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)
- Jelling ingredient
- Baking powder

- Sequestrant, 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, it is ground and separated. It is normally sold in pure form but may contain impurities of calcium carbonate and natural occurring silica. The material 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/baker’s yeast. Carrier” but not restricted to mined sources. Japan – restricted to “Limited to be used as coagulating agent or used for confectionary, the processed beans products or bread yeast” but not restricted to mined sources. Canada – restricted to “as a carrier for cakes and biscuits; for soybean products; and for bakers’ yeast” and source is restricted to “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 not restricted to mined sources.

Ancillary substances: None reported in 2001 TAP

Discussion:

Several comments were received on this substance. Manufacturers and Trade Associations emphasized its use in tofu production. Several companies noted it was critical to production of tofu and soy cheese. One manufacturer noted they would like it retained but they currently use magnesium chloride instead. Another manufacturer noted magnesium chloride produced a softer tofu than calcium sulfate. It was also noted that calcium sulfate was used in the brewing industry to adjust the mineral content of water. One interest group asked that its use be limited to coagulation of bean curd noting evidence was not available for its use in other food applications. Another interest group raised concerns about the environmental and human health concerns of mining and noted a toxicological review completed by the National Toxicology Program in 2006<sup>1</sup>. This review noted: “None of the long-term studies can be considered adequate tests of chronic toxicity or carcinogenicity by modern standards.” Furthermore it focused more on exposure from the 2001 World Trade Center attacks, and the limited information from mine workers was from a 1976 study that was available during the original TAP. While the handling subcommittee finds enough information at the current time to renew calcium sulfate, future NOSB’s should consider if a new Technical Review would be useful to review current data on alternative manufacturing methods, any new data available on environmental or human health concerns, and/or whether an annotation should be recommended.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of calcium sulfate.

<sup>1</sup> [https://ntp.niehs.nih.gov/ntp/htdocs/chem\\_background/pubnomsupport/gypsum1\\_508.pdf](https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/pubnomsupport/gypsum1_508.pdf)

### Motion to Remove

The Subcommittee proposes removal of calcium sulfate-mined, from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
none

### Vote in Subcommittee

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

## 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 ‘carrageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### Subcommittee Review

#### 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 centuries.

#### Manufacture

During the 2012 sunset review concerns were raised about whether the manufacturing process to create carrageenan from seaweed might turn it into a synthetic material by the NOSB definition. Concerns were also raised about the environmental consequences of growing and harvesting these red seaweeds. As far as classification, the NOSB is still waiting for final guidance on the Classification of Materials and will not re-visit this issue until the guidance is final. A comprehensive technical report on issues related to seaweed harvesting is in development, but the results were not available in time for this review.

## Effect on Human Health

During the 2012 sunset review, public comment indicated considerable 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 supported 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 (see 2016 limited scope TR, linked 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. The Subcommittee posed very specific questions 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).

It is also worth noting that in the time since the last review, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 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).

In the first posting the Handling Subcommittee made the following statement: "We are troubled that the research showing inflammation and glucose intolerance is all from one research team and has not been replicated". Public comment from the first posting reached almost 1000 pages, much of it with scientific debate and opinion about whose research to believe and whose to discard.

We have examined most of the references that were provided as citations regarding the replication issue and found that the claims of replication could not be substantiated. There were studies that had not been conducted yet<sup>2</sup>, studies by the same authors as the ones who showed inflammation<sup>3</sup>, studies using carrageenan as an agent to test other chemicals (but not the carrageenan itself)<sup>4,5</sup>, and studies that were cited but without conclusions that supported the glucose intolerance issue.<sup>6</sup> Furthermore, one study claimed to support carrageenan extensively degrading into poligeenan in the digestive tract,

<sup>2</sup> "The clinical impact of carrageenan and diabetes, currently being studied in Germany" (University of Tuebingen, Dr. Robert Wagner and Dr. Norbert Stefan). <https://clinicaltrials.gov/ct2/show/NCT02629705>.

<sup>3</sup> Bhattacharyya S, Feferman L, Unterman T, Tobacman JK. Exposure to common food additive carrageenan alone leads to fasting hyperglycemia and in combination with high fat diet exacerbates glucose intolerance and hyperlipidemia without effect on weight. *J Diabetes Res*. 2015;2015:513429. doi: 10.1155/2015/513429

<sup>4</sup> Jung TW, Lee S, Hong HC, et al. AMPK activator-mediated inhibition of endoplasmic reticulum stress ameliorates carrageenan-induced insulin resistance through the suppression of selenoprotein P in HepG2 hepatocytes. *Mol Cell Endocrinol* 2014;382:56-73.

<sup>5</sup> Baek HS, Yoon JW. Direct involvement of macrophages in destruction of beta-cells leading to development of diabetes in virus-infected mice. *Diabetes* 1991;40(12):1586-97

<sup>6</sup> Taché S, Peiffer G, Millet A-S, Corpet DE. Carrageenan gel and aberrant crypt foci in the colon of conventional and human flora-associated rats. *Nutr Cancer* 37:193–198 (2000).

but in fact did not show that result."<sup>7</sup>

The Subcommittee also looked at very recent work from the researchers who attempted to replicate these results.<sup>8</sup> One of the key points made in the McKim article of 2016 was the challenge of using in vitro adverse effect data to predict risk for human disease. Among the conclusions presented: "The present work has shown that CGN does not cross intestinal epithelial cells, and is not cytotoxic to these cells. CGN did not increase cellular oxidative stress nor did CGN induce the expression of pro-inflammatory genes."

We understand why the TR came back with a somewhat nebulous statement about the research, because the experimental methods used in many experiments on both sides of the issue appear to be flawed. Without good research methodology and scientists who disagree over every conceivable point regarding carrageenan research, we can only agree that definitive conclusions cannot be made about the effects of carrageenan in the diet on human health.

The NOSB Handling Subcommittee is aware of research that came to our attention in the sunset review of other emulsifiers such as lecithin and guar gum which suggested that all of these ingredients may be contributing to metabolic syndrome, inflammatory bowel disease and obesity, simply by their impact on microbes in the gastrointestinal tract.<sup>9</sup> This had been supported by previous research on Crohn's disease.<sup>10</sup> While carrageenan has been more extensively studied than the other non-synthetic emulsifiers, there may be reason for concern that all emulsifiers can lead to inflammation and it is not a unique function of carrageenan.

### **Alternatives**

The OFPA at 6518(m)(6) specifically directs that the NOSB "shall consider – the alternatives to using the substance in terms of practices or other available materials." Therefore, in the first posting of carrageenan, for the April 2016 NOSB meeting, the NOSB requested specific information about use of carrageenan, alternatives and necessity for this material.

Stakeholder responses indicated that carrageenan has been removed from many products over the last few years, and the products are either made without any replacement material, or with a different material. Stakeholder comments indicated that for the following products, for example, carrageenan was no longer necessary: whipping and heavy cream, chocolate milk, protein shakes, milk powders, yogurt, sour cream, cottage cheese, sugar free spreads, puddings, pie fillings, gummy bears, frozen soy desert, soy milk, processed meats, non-dairy beverages (nut and grain "milks") and beer.

We found that for some uses, particularly in dairy products and non-dairy milk-like beverages, there were suitable alternatives such as gellan gum, xanthan gum, and guar gum, although without carrageenan there is a tendency for sediments to collect at the bottom, and the beverage has to be shaken vigorously.

<sup>7</sup> Pittman KA, Golberg L, Coulston F. Carrageenan: the effect of molecular weight and polymer type on its uptake, excretion and degradation in animals. *Food Cosmet Toxicol* 1976;14:85–93.

<sup>8</sup> McKim J.M. et al. *Food and Chemical Toxicology* 96 (2016) 1 - 10

<sup>9</sup> Chassaing, B. et al. Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome. *Nature* 519, 92–96 (March 2015)

<sup>10</sup> Roberts, C. et al. Hypothesis: Increased consumption of emulsifiers as an explanation for the rising incidence of Crohn's disease *Journal of Crohn's and Colitis*, Volume 7, Issue 4, 1 May 2013, Pages 338–341

There is some question as to whether there are alternatives to carrageenan in some infant formulas where it is needed to keep all the other synthetic nutrients in the liquid solution. However, we note that there is infant formula without carrageenan available in Europe.

For processed meat, such as sliced sandwich meats, commenters reported both success and lack of success in removing carrageenan. The shelf life of some of these meats is compromised without carrageenan since they don't hold together as well.

There are categories of organic products where no substitute has emerged. One key group is in vegetarian/vegan foods where gelatin is not acceptable because it is made from animals. These include gel capsules for vegetarian and vegan supplements.

### **Discussion**

The Handling Subcommittee examined the issue of scientific bias, and found that there was no evidence to support the sweeping claims that all research in support of the safety of carrageenan is funded by industry. All scientific papers are peer reviewed and there is no evidence that the reviewers are influenced by industry. We are unable to draw any conclusions from the bitter fight going on between scientists.

During the first posting (April 2016) the Subcommittee posed a question regarding sensitivity to carrageenan, and whether or not that was enough reason to prohibit it in organic food. It appears that there are no epidemiological studies of populations regarding sensitivity but there are a number of anecdotal reports. Statements were made that the pathways of inflammation triggered by carrageenan were universal in all humans, but like the lack of replication, there was no evidence given in support of this statement.

The NOSB has spent a considerable amount of time reviewing research and public comment on carrageenan since the 2012 sunset review of this material. We find that the body of scientific evidence does not support claims of widespread negative human health impacts from consumption of carrageenan in processed foods. We appreciate that there may be some individuals who have sensitivity to the material, but even that is not entirely clear from the body of scientific research.

We recognize that consumer demand to remove carrageenan has already led to the removal of carrageenan from a number of categories of products and that other alternatives could be used to replace carrageenan in additional products. Subcommittee members think that there are alternatives to using carrageenan and recommend removing this material from the National List.

The Handling Subcommittee notes that any member of the public could petition for an annotation to limit the use to only those products for which there are no alternatives.

### **Motion to Remove**

The Subcommittee proposes removal of carrageenan from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA 6518(m)(6) - availability of alternatives.

### **Vote in Subcommittee**

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

Yes: 5 No: 2 Abstain: 0 Absent: 1 Recuse: 0

## 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

### Subcommittee Review

#### 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 pg. 10-11). Other processes to make GDL involve oxidation with bromine water (which is not allowed by the National List annotation) 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 produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu, sulfate salts produce soft tofu and GDL produces silken tofu. Citrus and Lactic acids produce acidified tofu where are 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 (not the most common form of production).

The Handling Subcommittee sought further information from the public. In particular, if GDL is being used in applications other than tofu production for organic processed foods. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic good. Further, the handling subcommittee asked if GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salt sufficient to produce all forms of tofu. In response companies commented that alternatives on the list result in distinctly different and more firm tofu and that GDL is critical to silken, jelly-like tofu. Several tofu manufacturers commented for in favor of retaining GDL. Lastly, it was asked, should GDL produced from enzymes be prohibited or further restricted due to concerns about GMOs. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means, however, no information was presented on the commercial viability of this approach.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of Glucono delta-lactone.

**Motion to Remove:**

The Subcommittee proposes removal of glucono delta-lactone from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
none

Motion by Tom Chapman

Seconded by Ashley Swaffer

Yes: 0 No: 6 Abstain: 1 Absent: 1 Recuse: 0

## 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

### Subcommittee Review

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 (C<sub>4</sub>H<sub>6</sub>O<sub>6</sub>; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredients 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 GFSA 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).

Discussion:

The Handling Subcommittee, in its initial request for public comment, asked for comments regarding the use of tartaric acid and its essentiality in organic processing.

During the Spring 2016 meeting the NOSB received several comments in support of the relisting of tartaric acid. Those comments included:

- “Tartaric Acid is used in our process to correct natural acid deficiencies in grape juice/wine and to reduce the pH of grape juice/wine where ameliorating material is used in the production of grape wine. The removal of Tartaric Acid from the National List will have a direct impact on our quality of wine. To my knowledge there has been no organic replacement or any other material that has the same effect or provides the same quality as the material in question.”
- “Every wine we make has tartaric acid in it. It is used as a preservative and stabilizes the wine color by lowering the pH of wine. If we weren’t able to lower the pH we would have to use a higher amount of sulfur dioxide as a preservative that would exceed the 100 ppm total amount. It is also used as a stylistic tool to enhance the flavor and mouthfeel of the wine. We would discontinue our organic wines if we lost tartaric acid.”
- “We should investigate whether tartaric acid from organic grape wine is available or would be available if we didn’t have this listing.”
- “Tartaric acid is the single most important input allowed in organic winemaking that helps counteract California’s warm climate that causes low pH in grapes. It is therefore vital in producing quality wine made from organic grapes. Nearly all wines produced need some acid adjustment because very rarely do grapes ripen to the proper acid level to make wine. They therefore require pH and acidity correction to ensure proper fermentation and aging. Our almost 50 years of winemaking have demonstrated to us that some acid correction is almost always necessary, and tartaric acid is the most effective product available to make this adjustment. Tartaric Acid is a very important part of the organic winemaking process and we strongly support its continued use.”
- “Tartaric acid is used in sour candies to enhance fruit flavors and sour intensity. Alternatives are less stable to warm temperature environments.”
- “Tartaric acid is an absolute necessity for winemaking in California and for most warm weather winemaking regions. As grapes come in we replace some of the lost acidity with tartaric acid. Without it the wine would become susceptible to spoilage organisms and lack in flavor.”

Tartaric acid satisfies the OFPA evaluation criteria and the Handling Subcommittee supports its relisting.

#### **Motion to Remove**

The Subcommittee proposes removal of tartaric acid - made from grape wine, from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None

**Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

**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

**Subcommittee Review:**

Cellulose (CAS # 9004-34-6 alpha cellulose) is available in several different forms, each with 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/non-edible 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.

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)(TR 2-11-2016). Most commercially available cellulose (powdered) is produced from wood pulp 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. The original process for making regenerated cellulose casing 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). Cellulose is considered GRAS under CFR 121.101 (LSRO 1973).

The current Sunset review of cellulose by the Handling Subcommittee and ultimately the full NOSB included: a review of historic information, information provided during public comment period (oral and written) for the Spring and Fall 2016 NOSB meetings, a new Technical Evaluation Report (Feb.11, 2016), and further research of available information that was conducted. This review also included a look at what possible ancillary substances might be used along with cellulose in its production for specific uses.

Internationally, cellulose is permitted under most organic standards outside of the U.S. for at least some uses and applications in organic processing or handling. Some examples of those allowed uses are:

- **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).
- **Codex and Japan** - No uses identified.

Discussion:

During the 1<sup>st</sup> posting of cellulose the Handling Subcommittee asked 5 specific questions to aid in its review:

- The NOP is still working on the 2012 NOSB recommendation to add the word “powdered” to part of the annotation. Thus, no NOSB action on this issue is required at this time. Numerous comments on this discussion point gave a mixed reaction as to what impact the addition of the more restrictive wording to the annotation might have on organic handling. It was inconclusive.
- Organic handlers and some certifiers acknowledged that cellulose is still very much in use in organic handling and/or processing, and that for these specific uses there still does not seem to be a suitable alternative at this time. Thus, organic stakeholders that use this material via one of the three currently allowed uses, have provided information on how necessary cellulose is to their handling process.
- The TR states that: Although it is theoretically possible to use cotton and other natural fibers as sources of cellulose for filtering, making food-grade cellulose in a functional form requires synthetic processes. Alternative plant sources are also limited by technical considerations and production capacity.
- During public comment and also mentioned in the TR were concerns (also stated during previous sunset reviews) regarding the use of wood pulp as a source for cellulose and the environmental impact that this could possibly have. Also, concerns were raised about environmental problems caused by waste cellulose generated from food processing. The new TR states that conversion of cellulosic food wastes into useful products is the subject of research, as well as that involving additional cellulose waste from filtration aids and/or spent casings. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs, and governmental regulations. Thus, research is underway looking at the best use of the waste products and/or spent materials, which should help to ease those concerns in due time.

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in processing, many may remain in the final product in tiny amounts.

Information provided in the latest Technical Evaluation Report (TR) (Feb. 11, 2016) and also during

public testimony (written and oral) provided the Subcommittee the following list of ancillary substances that are sometimes used in the production of cellulose for use in organic handling and processing. The TR was very clear that there are well defined sources of commercially available cellulose that do not include any ancillary substance, as well as those that might use ancillaries listed in the chart below:

Functional Class	Ancillary Substance Name
Carriers and fillers, agricultural or non-synthetic	Potato starch, dextrose
Carriers and fillers, synthetic	Propylene glycol
Preservatives	Polysorbate 80, enzymes
Binder/Plasticizer	Lecithin, propylene glycol, mineral oil
Anti-caking & anti-stick agents	Mineral oil, animal oil, vegetable oil, resin
Releasing agents	Mineral oil

**Subcommittee discussion points and request for additional input:**

- “Mineral oils, untreated or mildly treated” are on the combined IARC/NTP list. The latest Technical Evaluation Report (March 12, 2015) for mineral oil that was done for the Livestock Subcommittee states that for refined mineral oil, the refining process removes the materials that pose the carcinogen concerns. It also mentions that according to the FDA database for “Everything Added to Food in the United States” (EAFUS), mineral oils are approved for use as direct, secondary direct, and indirect food additives for human and animal feed (FDA, 2014). FDA permits the direct addition of mineral oil to food for consumption under 21 CFR 172.842 and 172.878. Please provide the Subcommittee with any information as to whether or not mineral oil is needed/or used as an ancillary for cellulose? Also, please provide us with any information as to the type of mineral oil currently being used? For example: refined, mildly treated, or untreated mineral oil.
- The TR mentions releasing agents that are used for peeling, retaining moisture, or that help to add smoke in sausage making, but no specific ones were mentioned (we were able to identify one: mineral oils). The Handling Subcommittee requests from handlers who are using releasing agents a list of any releasing agents that you are aware of, so that we could amend our list of allowed ancillaries for use in cellulose formulations. Also, please provide us with any other ancillary substances that are currently in use that we have not listed.
- It appears that processed cheese can be made with/or without cellulose. Thus, it brings into question whether or not cellulose is necessary or essential in organic shredded cheese production (it appears manufacturers are making it both ways). Could you provide the NOSB with information as to why some shredded cheeses are made with cellulose, while others are

not? What makes the use of cellulose necessary in your process?

### Motion to Remove

The Subcommittee proposes removal of cellulose from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None.

### Vote in Subcommittee

Motion by: Harold V. Austin IV

Seconded by: Lisa De Lima

Yes: 1 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## 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 petition to 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

### Subcommittee Review

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 that 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.

#### Discussion:

The Handling Subcommittee in its initial request for public comment asked:

1. For what purposes is potassium hydroxide used in organic processing?
2. Are there alternatives for those uses?

Public comments:

During the Spring 2016 meeting the NOSB received several comments regarding potassium hydroxide. Those comments included:

- Potassium hydroxide is used as a cleaning agent and is not used in our organic product as it is also prohibited by TTB to be added to wine but is approved as a cleaning agent. The removal of Potassium hydroxide from the National will have a huge impact for us; there is nothing at the moment that can be used as a replacement to effectively clean as well as potassium hydroxide. To my knowledge there has been no organic replacement or any other material that has the same effect or provides the same quality as the material in question.
- It is a better fit as a processing aid that is much gentler to the proteins in buttermilk
- Potassium hydroxide is a hazardous material, possibly one of the most hazardous and toxic on the National List.
- Of the certifiers that wrote in stated approximately 74 of their clients use this product.

While there is concern about the toxicity and hazards of this material the Subcommittee would like to see public comments address the questions put forth in this document.

This material satisfies the OFPA evaluation criteria and the Handling Subcommittee supports the relisting of potassium hydroxide.

**Motion to Remove**

The Subcommittee proposes removal of potassium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None

**Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Scott Rice

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

**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

**Subcommittee Review**

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
- Used in organic seed pellets

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, CODEX, European Union, IFOAM, and Japan. In the EU its use is restricted to an anticaking agent for herbs & 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 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 Committee 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 non-synthetic 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 its 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 Subcommittee asks if silicone dioxide should remain on the list based on §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

During the first posting, the Handling Subcommittee asked the public for the following information:

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 was the undesired result that lead to the need to use silicon dioxide?

Public comment in response to the above questions included:

Silicon dioxide is essential for certified organic seed pellets; for anticaking agent in organic powders, including organic cheese powders; rice hulls aren't able to meet the various applications where silicon dioxide is used; in organic dry flavors rice hulls have not performed as needed to disburse flavor actives evenly, and take up moisture; the rice hull application as a substitution for silicon dioxide as an anti-caking agent has not worked at the 2% application, instead the rice hull rate has been 15-50%; rice hulls do not function like silicon dioxide when used as a flow agent for rice syrup solids; used in beer clarification.

Comment from multiple organizations asked that the NOSB revisit the original annotation put forth by the Board in 2011, in order to encourage the development and commercialization of alternative organic silica products. No new information was brought forth to indicate that the manufacture or use of silicon dioxide is harmful to people or the environment. Public comment by producers indicated that organic rice hulls are not a viable alternative for all current uses. The Subcommittee recommends that silicon dioxide remain on the National List.

#### Additional Information Requested:

Based on information reviewed, the Subcommittee is not aware of any ancillary substances used in silicon dioxide. If the public is aware of any ancillaries please provide information via public comment.

#### **Motion to Remove**

The Subcommittee proposes removal of silicon dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

#### **Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Tom Chapman

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

## 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

### Subcommittee Review

#### 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 CO<sub>2</sub>, 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,  $\beta$ -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,  $\beta$ -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  $\beta$ -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 wild-crafted, or cultivated?
5. When used as a color, is this material also a source of Vitamin A?

Public comment on continued listing of this material indicates support from producers of the colors and support from those producers who use the color. Some certifiers indicate that the material is not widely used. Consumer groups consider this color is not essential (205.600(b) (6) ), and if made from carrots, that organic carrots are available (205.600(b) (1) ) and thus this material is not compatible with sustainable agriculture (OFPA 6518(m) (7) ), and that the substance’s primary use is a color (205.600 (b) (4)).

**Motion to Remove**

The Subcommittee proposes removal of beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) 6518 (m) (7) and 7 CFR 205.600(b) (1) and (4) and (7) .

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 2 No: 5 Abstain: 0 Absent: 1 Recuse: 0

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Sodium chlorite, for the generation of chlorine dioxide gas  
August 16, 2016**

**Summary of Petition (initial [petition](#); petition [addendum](#)):**

On October 8, 2015, the NOP received a petition to add chlorine dioxide (ClO<sub>2</sub>) (CAS #10049-04-4) dry gas to §205.605 (b) of the National List, nonagricultural (nonorganic) synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” The petition was revised November 30, 2015, revised again on December 1, 2015 and forwarded to the Handling Subcommittee (HS) December 2, 2015.

This material is petitioned for use as an anti-microbial pesticide, sanitizer and/or disinfectant for fruits and vegetables. It is used for the direct treatment of fruits and vegetables during storage, transportation and food preparation applications with no requirement for post treatment rinse.

ClO<sub>2</sub> gas is produced by impregnating zeolite with sodium chlorite and then activating the zeolite with a solid or liquid acid such as citric acid. An unspecified buffer is used.

ClO<sub>2</sub> gas is used in post-harvest handling as a disinfectant to kill microorganisms. It is used in the direct treatment of vegetables, fruits and nuts to reduce spoilage and pathogenic organisms. In these applications the mode of ClO<sub>2</sub> is a killing agent of these pathogenic organisms.

It is applied as a dry pure gas in closed containment. Treatment is done over several hours until the substance is completely consumed. ClO<sub>2</sub> is converted to a chloride ion on the food products. In processing facilities, use of this material is used as an oxidizer, cleaner, deodorizing agent. It is applied as a dry pure gas at the point of need. Application rates vary and will convert to chloride ion when reacting with a wide variety of organic matter.

**Summary of Review:**

The HS’s initial review of the petition determined a need for revision by the petitioner. The HS found the initial petition sought to list a process rather than a material. If reviewed as petitioned, the HS would have reviewed several materials: sodium chlorite, zeolite acting as a carrier which is impregnated with sodium chlorite, acidic chlorine dioxide activators and related buffers. When used together as directed, these materials produce ClO<sub>2</sub> gas.

The HS returned the petition to the petitioner April 18, 2016, with a request to revise to “sodium chlorite, for the generation of chlorine dioxide gas.” The HS believes a petition considering sodium chlorite for the particular use of gas generation is more consistent with how other sodium chlorite materials have been reviewed. It is very similar to the acidified sodium chlorite that is already on the list at 205.605(b), however that substance was petitioned as a solution, whereas this one is used as a fumigant gas.

Therefore, the HS asked that the petitioner revise the petition to “sodium chlorite, for generation of chlorine dioxide gas.” If listed, certifiers and/or material review organizations will review the sodium chlorite product and the attendant components noted above. In its revision request, the HS also asked

the petitioner if, as with use of other sodium chlorite materials, produce treated with ClO<sub>2</sub> dry gas requires a potable water rinse sufficient that residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

The petitioner responded to the two HS requests above, resubmitting the petition as “sodium chlorite, for generation of chlorine dioxide gas.” In response to the question regarding need for a post-treatment potable water rinse, the petitioner noted that ClO<sub>2</sub> gas rapidly reacts with produce surfaces and residues of concern, primarily ClO<sub>2</sub> or chlorite ion, do not persist. Gas applications are different than water solution applications and precautionary potable rinses are not required<sup>1</sup>.

Because of this material’s intended use as killing agent for pathogenic organisms, the petitioner’s formulated product is EPA registered. While the petitioner notes the target use of ClO<sub>2</sub> gas is for vegetables and fruit, the EPA label for the formulated product only allows for use on stored potatoes. It is likely the petitioner seeks EPA allowance for broader use on fruit and vegetables as evidenced by their formulated product name “FruitGard®.”

As noted, acidified sodium chlorite is already listed at 205.605(b) and at the April 2016 NOSB meeting, the Board voted unanimously to add hypochlorous acid to 205.605(b). Like acidified sodium chlorite and hypochlorous acid, ClO<sub>2</sub> gas has the potential to offer handling operations a material that has strong antimicrobial properties and is compatible with the fundamental principles of organic production.

### Category 1: Classification

1. Substance is for: X **Handling**
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance \_\_\_\_\_ **Agricultural** or X **Non-Agricultural**?  
Describe reasoning for this decision using NOP 5033-2 as a guide:

The substance is a mineral.

- b. If the substance is **Non-agricultural**, is the substance \_\_\_\_\_ **Non-synthetic** or X **Synthetic**?  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

The substance is not manufactured, produced or extracted from a natural source.

3. For **LIVESTOCK**: Reference to appropriate OFPA category  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern? N/A

<sup>1</sup> Smith, D.J. et al. Chloroxyanion residues in cantaloupe and tomatoes after chlorine dioxide gas sanitation. Journal of Agricultural and Food Chemistry, 2015, 63, 9640-9649.

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

ClO<sub>2</sub> gas is a known oxidizer. However, when used as prescribed in the petition, there are no known interactions with other substances used in organic production.

2. What is 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? [§6518(m)(2)]

ClO<sub>2</sub> gas is not persistent and not a known bio-accumulative substance. When used in the intended use in an enclosed environment and allowed to degrade to ClO<sub>2</sub> or the chlorite ion, there is no toxicity.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Manufacturing sodium chlorite produces some byproducts, such as chlorine dioxide, which cannot be immediately released into the environment. This petition is for the use of sodium chlorite as chlorine dioxide gas. As noted above, if used as intended, the substance degrades to ClO<sub>2</sub> or chlorite ions.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

As noted in the petition, the primary concern of exposure to the substance is acute toxicity related to inhalation where the substance is a known irritant to eyes and mucal membranes. Severe exposure (beyond amounts available by petitioned product) can result in chemically induced pneumonia and or death. However, if used as intended, the substance degrades to ClO<sub>2</sub> or chlorite ions.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts in the agroecosystem.

6. Are there any adverse impacts on biodiversity? (§205.200)

When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts on biodiversity.

## Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are some fluid alternatives such as sodium hypochlorite or chlorine dioxide in liquid form, the latter of which is already listed on the National List. However, presently there are no antimicrobial pesticides, sanitizers or disinfectants in gas form on the National List.

2. **For Livestock substances, and Nonsynthetic substances used in Handling:** In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

N/A

**Category 4: Additional criteria for synthetic substances used in Handling** (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

The substance is a mineral not derived from a natural mined source.

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

When used as intended, the substance degrades to ClO<sub>2</sub> or chlorite ions that have no adverse effects on the environment.

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

Neither the nutritional quality of the food nor human health is impacted with use of ClO<sub>2</sub> gas or its breakdown products of ClO<sub>2</sub> or chlorite ions.

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

The petitioner describes the preservative qualities in the use of this substance. However, the preservative qualities are secondary to its primary action, which is a disinfectant used to kill microorganisms.

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

Sodium chlorite, for the generation of ClO<sub>2</sub> gas does not appear in the FDA GRAS inventory.

However, ClO<sub>2</sub> generated using sodium chlorite in calcined or sulfated kaolin clay<sup>2</sup>, and ClO<sub>2</sub> generated from particles composed of sodium polyphosphate, magnesium sulfate, sodium silicate and sodium chlorite that are incorporated into low density polyethylene (LDPE) food-packaging films appear in the FDA GRAS inventory<sup>3</sup>.

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

While other sanitizers and disinfectant substances appear on the National List, none are currently present in gas form. As a gas form, ClO<sub>2</sub> reacts rapidly and completely thereby reducing or negating the need for de-chlorination of waste water streams. Liquid forms of ClO<sub>2</sub> mainly treat the rinse waters and are not as effective in treating microorganisms on produce. Dry gas applications appear to have greater effectiveness in penetrating coarse or porous produce. The use of ClO<sub>2</sub> in gas form stands to reduce water usage.

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

Like acidified sodium chlorite and hypochlorous acid, ClO<sub>2</sub> gas has the potential to offer handling operations a material that has strong antimicrobial properties and is compatible with the fundamental principles of organic production.

**Category 5: Additional criteria for agricultural substances used in Handling** (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

N/A

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?

N/A

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?

N/A

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

<sup>2</sup> Tarantino, FDA Agency Response Letter GRAS Notice No. GRN 000161, 2005.

<sup>3</sup> Rulis, FDA Agency Response Letter GRAS Notice No. GRN 000062, 2001.

an essential function in a system of organic handling?

N/A

5. Does the industry information about unavailability include (but is not limited to) the following?:  
Regions of production (including factors such as climate and number of regions);

- a. Number of suppliers and amount produced;

N/A

- b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

N/A

- c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

N/A

- d. Other issues which may present a challenge to a consistent supply?

N/A

6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

N/A

**Classification Motion:**

Motion to classify sodium chlorite, for the generation of chlorine dioxide gas as nonagricultural, synthetic.

Motion by: Scott Rice

Seconded by: Jean Richardson

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National List Motion:**

Motion to add sodium chlorite, for the generation of chlorine dioxide gas as petitioned at 205.605(b)

Motion by: Scott Rice

Seconded by: Ashley Swaffar

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Oat Protein Concentrate  
May 17, 2016**

**Summary of**

**Petition** <https://www.ams.usda.gov/sites/default/files/media/Oat%20Protein%20Concentrate.pdf>

Oat protein concentrate is being petitioned by manufacturer Tate & Lyle for addition to §205.606, as a natural component of oats, an agricultural commodity. According to the petition the substance is isolated from oat bran through a simple process of grinding, heating, and water extraction. No synthetic chemical additions or solvents are used in the manufacturing process (pH adjustment and/or solvent extraction) being petitioned. The only additives used in producing oat protein concentrate are water and enzymes. The alpha-amylase enzyme used is derived from a non-pathogenic, non-GE/GM microorganism.

Oat protein concentrate is a vegan, non-GMO protein source and is a good source of certain essential amino acids. The petition also notes that it has better digestibility than other cereal proteins because it is primarily composed of globulin proteins. Additionally, due to its bland flavor and low impact on texture it can be used to supplement protein content in a wide range of foods. Examples listed in the petition include vegan entrees, cereal bars, baked goods, breakfast cereals, pasta, and meal replacement shakes.

Overall oat protein concentrate appears to have no significant negative impacts on human health. Unlike other proteins used as supplements (milk, soy, egg), this ingredient can be used in foods targeted for individuals with these specific allergies.

The petition states that oat protein concentrate is used in handling, not crop production, and therefore it has no effect on soil, crops, or livestock. However, the Subcommittee would like to point out that according to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats. Conventionally grown oats are what oat protein concentrate is derived from.

The petition states that currently there is no source of organic oat protein concentrate, despite organic oats and organic 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 protein concentrate is manufactured, organic oat quantities are limited. The petition goes on to state that if the demand for organic oat protein concentrate was to increase, the Nordic manufacturing facilities could purchase organic oats from the U.S. The petitioner thought this scenario was unlikely to happen anytime soon due to the undetermined demand for oat protein concentrate in organic form.

**Summary of Review:**

The Handling Subcommittee would like to point out that geographical location is not sufficient justification for arguing the commercial non-availability of a commodity. The Subcommittee sees no reason why oat protein concentrate could not be manufactured organically. Therefore, the Subcommittee recommends that the petitioned material, oat protein concentrate, should not be placed

on the National List as it fails the “Essentiality & Availability” criteria, as well as the “Commercial Supply is Fragile or Potentially Unavailable as Organic” criteria.

### Category 1: Classification

1. **Substance is for:** Handling
2. **For HANDLING use:**
  - a. Is the substance agricultural or non-agricultural? Substance is agricultural  
Describe reasoning for this decision using NOP 5033-2 as a guide:

Oat protein concentrate is extracted from whole oats. The oats are first de-hulled and then the oat bran and oat flour are separated through a dry milling process. Then the oat bran goes through a wet milling process, and using alpha-amylase enzyme the protein is separated from the bran.

The oat protein remains intact throughout the manufacturing process. The protein is isolated through grinding, heating, and water extraction. No synthetic chemicals additions or solvents are used.

### Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**  
N/A
2. **What is 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? [§6518(m)(2)]**  
N/A
3. **Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**  
N/A
4. **Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

Oat protein concentrate can be used to boost protein in content in foods that are suitable for vegetarians, vegans, and those with allergies to milk, soy, wheat or celiac disease.

5. **Discuss any effects the substance may have 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. [§6518(m)(5)]**

The final substance does not have a direct effect on soil, but the conventional oats from which the oat protein concentrate is extracted, could. According to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

**6. Are there any adverse impacts on biodiversity? (§205.200)**

The final substance does not have a direct effect on soil, but the conventional oats from which the oat protein concentrate is extracted, could. According to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

**Category 3: Alternatives/Compatibility**

**1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

The alternative to using the substance would be to create an organic oat protein concentrate from organic oats. Additionally, there are other organic vegan proteins available on the market, for example: soy, hemp, pea, rice, quinoa, sunflower, pumpkin, mushroom, chia, amaranth, lentil, flax, goji, and peanut.

**2. For Livestock substances, and Nonsynthetic substances used in Handling: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

No.

**Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):**

N/A. Oat protein concentrate is agricultural

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))
2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))
3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))
4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))
5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

Yes, oat protein is GRAS. Designated GRN No. 000575

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))
7. In balancing the responses to the criteria in Category 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

**Category 5: Additional criteria for agricultural substances used in handling** (review of commercial unavailability of organic sources):

1. **Is a comparative description given as to why the non-organic form of the material /substance is necessary for use in organic handling provided?**

Yes, but not persuasive.

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?**

No.

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?**

No.

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?**

The petition claims that in Nordic countries, where a large amount of oat protein concentrate is manufactured, organic oat quantities are limited. The Nordic manufacturing facilities could purchase organic oats from the elsewhere, if they determined the demand for organic oat protein concentrate was sufficient for justifying manufacture of the substance. Additionally, the subcommittee believes there are organic oats available in Europe.

5. **Does the industry information about unavailability include (but is not limited to) the following: Regions of production (including factors such as climate and number of regions);**

- a. Number of suppliers and amount produced;  
No.

- b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;  
No.

c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or  
No.

d. Other issues which may present a challenge to a consistent supply?  
No.

6. **In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))**

No. The Handling Subcommittee sees no reason why an organic form of oat protein concentrate could not be produced. Additionally, oat protein concentrate does not appear to be necessary in organic handling.

**Classification Motion:**

Motion to classify oat protein concentrate as petitioned as agricultural.

Motion by: Lisa de Lima

Seconded by: Tom Chapman

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

**Listing Motion:**

Motion to add oat protein concentrate as petitioned at §205.606

Motion by: Lisa de Lima

Seconded by: Scott Rice

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



**National Organic Standards Board  
Handling Subcommittee Proposal  
Additional listing of Tocopherols at §205.605(a)  
September 14, 2016**

**Summary of Proposed Action:**

The Handling Subcommittee proposes an additional listing of Tocopherols at §205.605(a) of the National List.

**Subcommittee Review**

Tocopherols are listed at §205.605(b) of the National List with the following annotation: Derived from vegetable oil when rosemary extracts are not a suitable alternative.

Tocopherols function as antioxidants in foods, helping to preserve them and prevent rancidity. They are commonly extracted from distillates of vegetable oils. The term “tocopherols” refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol. Tocopherols that are derived from plant products are often referred to as “mixed tocopherols” because the mixture contains all four forms of tocopherol (CIR, 2002) (TR lines 41-43).

Tocopherols are separated from other compounds in vegetable oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation (Burdock, 1997; EFSA, 2008; Torres et al., 2011) (TR lines 87-89). Using the draft Classification of Materials guidance from the NOP, even tocopherols derived from natural sources could be considered synthetic, depending upon their extraction and refining processes.

The NOSB completed review of tocopherols as part of its 2017 Sunset review and voted at the Fall 2015 meeting in Stowe, Vermont, to retain the listing on the National List at §205.605(b). However, during the initial public comment period, several commenters asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic versions. In the final Sunset proposal for tocopherols, the Handling Subcommittee indicated that it was considering a proposal to reclassify tocopherols to §205.605(a) and was seeking input regarding the impact of that on the industry. The second round of public comments brought forth several objections to a reclassification of tocopherols, citing their importance in food safety and voicing concerns regarding commercial availability of non-synthetic versions.

The Handling Subcommittee strongly encourages industry to move to non-synthetic, organic versions of tocopherols but does recognize that at present, there is insufficient commercial availability of organic tocopherols. For that reason, we are proposing a duplicate listing at 205.605(a) so that those manufacturers who wish to move to non-synthetic tocopherols – while waiting on commercial availability of organic versions – are incentivized to do so.

**Determination of Synthetic/Non-synthetic Status of Tocopherols**

In March, 2013, the National Organic Program issued draft guidance on the classification of materials used in Organic production in the document NOP 5033 - Classification of Materials. Background Section 3.1 states: “The Organic Foods Production Act of 1990 (OFPA) authorizes the USDA to establish the National List of Allowed and Prohibited Substances (National List). The National List is implemented in the USDA organic regulations at 7 CFR 205.600-607.

Under the OFPA, the National List must contain an itemization of each synthetic substance that is permitted and each natural substance that is prohibited for organic production. Due to this unique construction of the National List, definitions and classification are important to determine whether a substance is allowed or prohibited in organic production, whether it needs to be included on the National List, and where on the National List it should be placed. “

“For the handling or processing of organic agricultural products, the National List includes a list of agricultural and nonagricultural substances which are allowed in the handling of organic agricultural products. Nonagricultural substances are differentiated as either nonsynthetic (natural) or synthetic. Thus, the proper determination of a substance as agricultural or nonagricultural, or as synthetic or natural is important for proper placement on the National List.”

Section 4.3 under Inputs for Organic Processing and Handling, NOP 5033 states: “Petitioned ingredients and processing aids for handling and processing are classified by the NOSB to determine placement of substances on the National List, sections 205.605-205.606. Substances must first be classified as agricultural or nonagricultural according to the classification decision tree, [NOP 5033-2](#). Nonagricultural substances should be further classified as nonsynthetic or synthetic to determine placement on section §205.605(a) or §205.605(b), respectively.”

Section 4.6, Extraction of Non-Organic Materials, provides direction on the extraction of distillates such as those used in the creation of tocopherols: “For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

While draft guidance NOP 5033 on classification of materials has not been finalized, the decision tree, [NOP 5033-2](#), as published on April 27, 2013, will be used to determine the non-synthetic/synthetic status of tocopherols until such time as NOP guidance may be finalized.

#### **Vote in Subcommittee**

Motion to list Tocopherols at §205.605(a) of the National List. Tocopherols – derived from vegetable oil

Motion by: Scott Rice

Seconded by: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB on September 6, 2016.**

**National Organic Standards Board  
Handling Subcommittee Proposal  
Annotation change for the listing of Tocopherols at §205.605(b)  
September 14, 2016**

**Summary of Proposed Action:**

The Handling Subcommittee proposes to eliminate the annotation of the listing of Tocopherols at §205.605(b) of the National List: “Derived from vegetable oil when rosemary extracts are not a suitable alternative.”

**Subcommittee Review**

Tocopherols are listed at §205.605(b) of the National List with the following annotation: “Derived from vegetable oil when rosemary extracts are not a suitable alternative.”

The NOSB completed review of tocopherols as part of its 2017 Sunset review and voted at the Fall 2015 meeting in Stowe, Vermont to retain the listing on the National List at 205.605(b). However, during the initial public comment period, several commenters asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic. In the final Sunset proposal for tocopherols, the Handling Subcommittee indicated that it was considering a proposal to reclassify tocopherols to §205.605(a) and was seeking input regarding the impact of that on the industry, however, the second round of public comments brought forth several objections to any reclassification of tocopherols, citing their importance in food safety and voicing concerns regarding commercial availability of non-synthetic versions.

Because the Handling Subcommittee strongly encourages industry to move to the use of non-synthetic, organic versions of tocopherols but does recognize that at present, there is insufficient commercial availability of organic tocopherols, the Subcommittee recently voted to send to the full NOSB a proposal to create an additional listing for tocopherols at §205.605(a) of the National List. That proposal duplicated the listing at 205.605(b) but with the annotation modified to state: “Derived from vegetable oil.” Public comment in the earlier Sunset review of tocopherols indicated that rarely is rosemary extract used as an alternative. Further, because the current annotation does not specify that rosemary extract must be organic, the subcommittee felt that part of the annotation should be eliminated. In order to have consistency between the listings at §205.605(ab) and §205.605(b), and to eliminate confusion among producers and certifiers, the subcommittee is proposing to eliminate that part of the current annotation at §205.605(b). But, to ensure that the source of tocopherols is limited and not randomly open to “any” synthetic tocopherol we are recommending to keep “Derived from vegetable oil” as part of both listings for consistency.

As stated in the proposal for the new listing at §205.605(a), while the draft guidance on classification of materials (NOP 5033) has not been finalized, the decision tree, [NOP 5033-2](#), as published on April 27, 2013, will be used to determine the non-synthetic/synthetic status of tocopherols until such time as NOP guidance may be finalized.

**Vote in Subcommittee**

Motion to amend the annotation for tocopherols listed at §205.605(b) of the National List to read as follows: Tocopherols – Derived from vegetable oil.

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB on September 12, 2016.**



**National Organic Standards Board**  
**Handling Subcommittee**  
**Cumulative impact of phosphates in organic processed foods**  
**Discussion Document**  
**August 16, 2016**

## **I INTRODUCTION**

Recent research indicates that phosphate intake has increased dramatically in the general population due to widespread use of phosphate food additives in processed foods in the United States. Consumers may be unaware of phosphorous levels when reading labels on products because phosphorous may not be disclosed on the nutrition panel. Phosphorous is an essential nutrient and deficiency is extremely rare. However, high levels of phosphates can result in a range of human health problems.

Outside the US and Canada, the only phosphate additive allowed in organic processed food is monocalcium phosphate, and only as a leavening agent.

During Sunset Review in 2015 the Handling subcommittee received public comment which included new research indicating potential serious human health impacts from the cumulative effects of phosphates which are added to processed foods. The NOSB evaluated the substances according to the criteria in OFPA, especially with regards Criteria 4, 6, and 7, and with reference to CFR 205.600(b) especially with regard 3 and 4. There was inadequate data to implicate any single phosphate, or any individual food item, as an isolated risk factor and thus the NOSB did not recommend that any of the phosphates be removed from the National List at Sunset. However the cumulative impact of these ingredients or processing aids remains an issue which merits further Discussion.

This Discussion Document outlines the issues and seeks public comment to determine the range of use of phosphates in organic processed foods, the extent to which they are really necessary, and to seek additional new medical and nutrition research on the human health impacts of these additives and their cumulative impact.

If public comment and associated research finding indicate need for further action, the NOSB may recommend increased restrictions through annotations or removal of phosphate food additives.

## **II BACKGROUND**

In 2015, during its Review of Sunset 2017 materials, the NOSB received public comment, based on recent scientific research, raising concerns about the cumulative negative impact of phosphate food additives.

In July 2015, because several of the phosphates on the National List had not been fully reviewed in formal Technical Reports (TR), the NOSB requested a comprehensive TR to cover all the Phosphates, with particular emphasis on cumulative health impacts. The NOSB received this Technical Evaluation Report (TR) in February 2016. This TR did not include Tetrasodium pyrophosphate because a 2002 TR was already available and the material had been voted to be removed from the national list in April 2015.

The February 2016 TR presented a range of issues of concern which are further discussed below. However, at its October 2015 meeting in Stowe Vermont, while acknowledging the cumulative negative health impacts of phosphates, the NOSB voted to continue to list the phosphate materials as there was insufficient research to indicate that the tiny amounts of any one phosphate additive alone, as an isolated risk factor,

was sufficient to suggest removal from the List. The NOSB members and public comment indicated need for further discussion of this issue.

### III RELEVANT AREAS OF THE RULE

Phosphate salts are allowed under the National Organic Program (NOP) Regulations at:

7 CFR 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)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

205.605(b) Synthetics allowed:

**Calcium phosphate** (monobasic, dibasic, and tribasic).

**Potassium phosphate**- for use only in agricultural products labeled “made with organic (specific ingredients or food group(s))” prohibited in agricultural products labeled “organic”.

**Sodium acid pyrophosphate** (CAS # 7758-16-9) –for use only as a leavening agent.

**Sodium phosphates** – for use only in dairy foods.

**Tetrasodium pyrophosphates** – (CAS # 7722-88-5) for use only in meat analog products. (This material was recommended by the NOSB, April 2015, for Removal from the National List and is presently in rulemaking).

The Organic Foods Production Act (OFPA) requires that the NOSB evaluate each substance according to 7 criteria as specified in 7 USC Section 6518(m) of the Act. The criteria of particular relevance to this discussion are:

- (4) The effect of the substance on Human Health, and
- (6) The alternatives to using the substance in terms of practices or other available materials and
- (7) Compatibility with a system of sustainable agriculture.

In addition, CFR Section 205.600 (b) requires that any synthetic substance used as a processing aid or adjuvant will be evaluated against 6 additional criteria, where criteria 3, 4, 5, and 6 are particularly relevant to this discussion:

- (1) The substance cannot be produced from a natural source and there are no organic substitutes;
- (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
- (3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing except where the replacement of nutrients is required by law;

- (5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- (6) The substance is essential for the handling of organically produced agricultural products.

#### **IV DISCUSSION**

##### **1). Technical Reports:**

It is clear that the NOSB has expressed concern about the health impacts of phosphates for a number of years, and requested several Technical Reports (TR), Technical Evaluation Reports (TR), and Technical Advisory Panel Reports (TAP). These reports have consistently included concerns for human health. The following TR and TAP are incorporated by reference herewith:

*Calcium phosphate:* TAP 1995 and TR Phosphates Feb 10, 2016;

*Potassium phosphate:* TAP 1995 and Phosphates TR Feb 10, 2016;

*Sodium acid pyrophosphate:* Sodium phosphates TAP Sept. 21, 2001, and SAP TR Sept 17, 2010 for rejected petition for expanded use in 2010, and Phosphates TR Feb 10, 2016;

*Sodium phosphates:* TAP Sept 21, 2001 and TR Phosphates Feb 10, 2016;

*Tetrasodium pyrophosphate:* TAP July 29, 2002; Limited scope TR June 9, 2014;

Note: These substances are also bioavailable sources of the nutrients calcium, phosphorus, potassium and sodium, and all but one are allowed by FDA as nutrient supplements in foods. However, their use as nutrient sources in foods labeled as organic is the subject of a separate Technical Report for Nutrient Vitamins and Minerals in 2015.

##### **2). Uses of phosphate additives in processed products:**

Phosphates are common additives found in many processed foods to increase shelf life, thicken, aid in gelling, stabilize, texturize, pH buffer, leavening etc. In recent years, as production of processed organic foods has increased, processors who typically produce non-organic foods, simply used some of the same additives as they expanded their production into organic. The result is widespread use of phosphate additives in organic processed foods.

###### **(a) Phosphates in Organic foods**

A survey and sampling of grocery stores in the Cleveland, Ohio area found that 44% of the best-selling grocery items contained phosphorus additives. The additives were particularly common in prepared frozen foods (72%), dry food mixes (70%), packaged meat (65%), bread and baked goods (57%), soup (54%), and yogurt (51%) categories.

Some companies produce the same or essentially the same organic product both with and without added phosphates. For example : Kraft Macaroni & Cheese Dinner™ is “organic” with added phosphate, and Kraft Organic Cheddar Macaroni & Cheese Dinner™ is produced without added phosphate.

Phosphorus additive-containing foods averaged 67 mg phosphorus per 100 g more than matched non-additive containing foods. Sample meals comprised mostly of phosphorus additive-containing foods had 736 mg more phosphorus per day compared to meals consisting only of additive-free foods. Phosphorus additive-free meals cost an average of \$2.00 more per day (Leon, Sullivan, and Sehgal 2013) (TR 2016 lines 678-687)

Due to the present annotations on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce the phosphorus intake. De Lorenzo et al. (2010) compared those

who ate an "Italian Mediterranean Organic Diet" to participants who followed a similar diet with phosphate additives and found reduced serum homocysteine and phosphorus levels, reduced microalbuminuria, and reduced cardiovascular disease risk in healthy individuals and in those with Chronic Kidney Disease (CKD). The results of this European trial cannot be extrapolated to the U.S. without some reservations. The EU organic regulations allow addition of only one phosphate, monocalcium phosphate, which can only be used as a leavening agent, whereas USDA organic regulations allow sodium pyrophosphate for this purpose and several other phosphates for other uses. These differences could be important, since Karp et al. (Karp, Ekholm, Kemi, Itkonen, et al. 2012) found that the conventional cereal product with the highest total phosphate content (216 mg/100 g), all of which was digestible, was industrial muffins that contained sodium acid pyrophosphate as the leavening agent. (TR 2016, 665-676)

**(b) Specific phosphates and their uses.**

***Calcium phosphate (monobasic, dibasic, and tribasic).***

Calcium phosphates are used in conventional foods as leavening agents, dough strengtheners and conditioners, nutrients, malting or fermenting aids and yeast foods (all three forms); the monobasic form is used as a buffer, firming agent and sequestrant; tribasic is used as an anticaking agent or free-flow agent, buffer or pH control agent, thickener or stabilizer. The NOP regulations at 7 CFR 205.605(b) do not impose additional restrictions on the use of calcium phosphates in processed organic foods. Tricalcium phosphate is commonly used in organic non-dairy beverages (soy 'milk', almond 'milk', orange juice, etc.) to provide the nutrients calcium and phosphorus. Dicalcium phosphate is the inert diluent and carrier for Vitamin B12 in fortified organic foods. Monocalcium phosphate is used as a component of chemical leavening agents ("baking powder"). Tricalcium phosphate is commonly used in non-dairy beverages as a source of calcium since these beverages displace cows' milk from the diet. Organic orange juice that is calcium-fortified contains tricalcium phosphate. Some organic yogurts and some non-dairy yogurt-like foods also contain tricalcium phosphate. Without this calcium fortification, these non-dairy beverages would be practically devoid of calcium.

***Potassium phosphate- for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic".***

Potassium phosphate is used as a pH control agent in milk products, as a nutrient supplement, sequestrant and emulsifier, a malting or fermentation aid, and a stabilizer and thickener. Dipotassium phosphate is the only form of potassium phosphate cited by FDA for use in pasteurized process cheese (21 CFR 133.169) and pasteurized process cheese food (21 CFR 133.173).

***Sodium acid pyrophosphate (CAS # 7758-16-9) –for use only as a leavening agent.***

Sodium acid pyrophosphate is used in conventional foods as a chemical leavening agent in baked goods; a sequestrant (chelating agent) to maintain the appearance of cooked and uncooked fruits and vegetables, particularly processed potatoes; an emulsifying agent and stabilizer in cheeses and related products; an inhibitor of struvite<sup>1</sup> formation in canned tuna; and a curing accelerator in processed meat and poultry products.

***Sodium phosphates – for use only in dairy foods.***

Sodium phosphates are used in conventional foods as pH control agents and buffers, sequestrants, texturizers and nutrients. Monobasic sodium phosphate is used as an acidulant. Some organic products containing cheddar cheese, such as cheese crackers or macaroni and cheese, may contain organic cheddar cheese with added sodium phosphate.

***Tetrasodium pyrophosphates*** – (CAS # 7722-88-5) for use only in meat analog products

Tetrasodium pyrophosphate (TSPP) is used as a synthetic food additive in the manufacture of meat substitutes (analogs) serving a number of purposes that compensate for insufficient gelling requirements. The effects of TSPP are to improve texture, adjust pH, act as a pH buffer, and reduce cooking loss. This material has been recommended for Removal from the National List

**3). Approved Legal Uses of the Substance:**

Each of the phosphate salts listed in the NOP regulations at 7 CFR 205.605(b) is identified by FDA in 21 CFR 182 as “Generally Recognized As Safe” (GRAS) for use in food for the various purposes shown below in Table 4 of the TR 2016. The only potassium phosphate salt that is the subject of a GRAS citation as a food ingredient is dipotassium phosphate. Nevertheless, monopotassium phosphate is permitted in frozen eggs (21 CFR 160.110(b)), and all of the potassium phosphates (mono-, di- and tripotassium) are GRAS for incidental food use in adhesives in articles intended for use in packaging, transporting or holding food (21 CFR 175.105). The USDA Food Safety Inspection Service (FSIS) permits both monopotassium phosphate and dipotassium phosphate in certain meat- and poultry-containing products (9 CFR 318.7 and 9 CFR 424.21).

FDA permits addition of sodium phosphates by name as an optional ingredient in several classes of dairy foods: pasteurized process cheese (21 CFR 133.169); pasteurized process cheese food (21 CFR 133.173); pasteurized process cheese spread (21 CFR 133.179); ice cream and frozen custard (21 CFR 135.110); and frozen eggs (21 CFR 160.110). The generic optional ingredient designation “stabilizer,” which frequently is sodium or potassium phosphate, is permitted in a variety of dairy foods, such as acidified milk (21 CFR 131.111), cultured milk (21 CFR 131.112), evaporated milk (21 CFR 131.130), heavy cream (21 CFR 131.150), light cream (21 CFR 131.155), light whipping cream (21 CFR 131.157), eggnog (21 CFR 131.170), yogurt (21 CFR 131.200), and cream cheese (21 CFR 133.133).

Because most dairy foods naturally contain substantial amounts of both sodium and phosphorus from the milk, the small incremental amount of sodium and phosphorus contributed by a sodium phosphate stabilizer may exempt sodium phosphate from the requirement to be declared as an ingredient on the label. This practice is allowed by FDA at 21 CFR 101.100(a)(3)(ii)(b). The only FDA-regulated foods where this exemption from labeling is not permissible are hypoallergenic foods (21 CFR 105.62) and infant foods (21 CFR 105.65).

FSIS also requires labeling of all food additives for meat products. Thus, the absence of sodium phosphate from the ingredient declaration of an FDA-regulated food does not necessarily mean that this substance has not been added to the food.

FSIS regulates meat- and poultry-containing foods and is responsible for determining the suitability of FDA-approved substances in meat and poultry products. FSIS lists allowed food ingredients at 9 CFR 318.7 and 9 CFR 424.31. Phosphates, including sodium acid phosphates, trisodium phosphate, and mono- and dipotassium phosphates, are allowed at 9 CFR 319.180 in a variety of prepared meat-containing foods, particularly cooked sausage, which includes frankfurter, frank, hotdog, weiner, vienna sausage, bologna, knockwurst and similar products.

The NOP regulations at 7 CFR 205.605(b) restrict the use of sodium phosphates to organic dairy products only, so added phosphates are not permitted in prepared organic meat products .

**4). International:**

The Canadian Organic Standards align with the NOP regulations with regard to phosphates and the restrictions on their use. In contrast, the CODEX Guidelines, the European Regulation, the Japanese

Agricultural Standard and the IFOAM norms only allow monocalcium phosphate and only for use as a leavening agent.

**5). Nutritional Value of Food (TR 2016 lines 346-405):**

An important nutritional consideration of a diet is its calcium-to-phosphorus (Ca:P) ratio. During periods of rapid skeletal growth, such as in infancy, the dietary calcium-to-phosphorus ratio should not fall below 1.0. The FDA infant formula regulation (21 CFR 107.100(e)) requires a Ca:P ratio not less than 1.0 and not more than 2.0. In later life, calcium metabolism is closely regulated by Vitamin D metabolites, particularly calcitriol. High levels of blood phosphorus suppress the formation of calcitriol (Institute of Medicine 1997). The dangers of too much dietary phosphate include excessive bone loss and other effects.

The nutrient phosphorus is not subject to mandatory listing in the Nutrition Facts of a food label (21 CFR 101.9(c)(8)(ii)), and the ingredient declaration may not declare an added phosphate if exempted by 21 CFR 101.100(a)(3)(ii)(b). Consequently, 'silent' addition of phosphates as functional additives can alter the Ca:P ratio of food, and thus the diet, without the consumer being aware of the fact.

Sodium and potassium are two electrolyte minerals essential to life. Sodium and potassium interact nutritionally. Potassium salts are more expensive than their sodium counterparts, and potassium has a greater molecular weight than sodium, so a greater weight of potassium salts must be added. For these reasons, sodium phosphates are used far more frequently than are potassium phosphates in any application where the two are functionally interchangeable. However, since our diets in general provide much less potassium than is advised and much more sodium than is advised, using the potassium salt would be nutritionally advantageous. Note that sodium chloride (table salt) is the primary source of sodium in the diet and a much greater contributor of sodium to the American diet than the sodium phosphates (Institute of Medicine 2005).

**6). Effects on Human Health: (see TR 2016 lines 438-687 and citations)**

Phosphorus interacts with other mineral elements, particularly calcium, magnesium and potassium, in bone formation, kidney function, and other physiological processes. Understanding this interaction is important for understanding the effects of phosphates on human health and nutrition. The Ca:P ratio of a diet is important. The relation of these two well-known minerals to the lesser studied mineral magnesium is also important. Sodium also interacts with these mineral nutrients, particularly potassium.

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to continuously assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations and provides a correlation of nutrient intakes with health as well as socioeconomic status. The NHANES data provides a foundation base but it is understood that total phosphorus intake may be much higher.

The NHANES data on phosphorus, sodium, calcium and magnesium, and potassium intakes for adult American (~20 to ~50 years of age), compared to the dietary reference intakes for these nutrients, indicate the following for phosphorus:

Phosphorus: The Estimated Average Requirement (EAR) for adult men and women is 580 mg per day. The Recommended Dietary Allowance (RDA) is 700 mg per day and the Tolerable Upper Intake Level (UL) is 4000 mg per day (Institute of Medicine 1997). Mean daily intakes were reported as 1701 mg for men (243% of the RDA) and 1179 mg for women (168% of the RDA). The average intake of women in the lowest quartile of phosphorus intakes was reported as 671 mg per day, 15% greater than the EAR (Lee and Cho 2015). (TER, 2016, 464-469)

An analysis of NHANES data found that, after adjusting for demographics, cardiovascular risk factors, kidney function, and energy intake, a higher phosphorus intake was associated with higher all-cause mortality in individuals who consumed more than 1400 mg/day, but at intake levels less than 1400 mg/day, there was no association (Chang et al. 2014). Analysis of the NHANES data for individuals with moderate chronic kidney disease (“CKD”) found that high dietary phosphorus intakes were not associated with increased mortality in moderate CKD (Murtaugh et al. 2012). A higher phosphorus intake was associated with higher calcium intake and was positively associated with bone mineral content in female teenagers, and it was also positively associated with bone mineral content and bone mineral density, as well as reduced risk of osteoporosis, in adults over 20 years of age (Lee and Cho 2015). (TER 2016, 480-490)

### **7). Health effects of phosphorus provided by phosphate additives versus natural phosphorus in foods.**

Elevated serum phosphate is a risk factor for certain diseases and disease outcomes. In healthy individuals, higher serum phosphate levels have been associated with greater risk for end-stage renal disease and mortality (Sim et al. 2013; Dominguez et al. 2013), abnormally low blood circulation (Meng et al. 2010), abnormally high arterial stiffness (Ix et al. 2009; Kendrick et al. 2010), increased risk of cardiovascular disease (Dhingra et al. 2007) and twice the risk of developing heart failure (Dhingra et al. 2010). Higher levels of serum phosphorus have also been shown to predict coronary artery disease development and progression (Tuttle and Short 2009).

Sodium and potassium phosphates and sodium acid pyrophosphate are very soluble in water. Consequently, the phosphorus in these additives, commonly referred to as “additive phosphorus,” is immediately and completely bioavailable upon consumption. In contrast, the phosphorus naturally present in most foods (“food phosphorus”) is much less available, in part due to the physical structure of the food and also because digestion of phosphate complexes may be required before the phosphorus can be absorbed.

The digestibility of phosphorus in various foods has been estimated by in vitro studies (Karp, Ekholm, Kemi, Hirvonen, et al. 2012; Karp, Ekholm, Kemi, Itkonen, et al. 2012). Only 6% of the phosphorus in sesame seeds with intact hulls was found to be digestible. In legumes, where much of the phosphorus is present as phytate, the average in vitro phosphorus digestibility was 38%. In contrast, the “additive phosphorus” in cola drinks and beer was 87-100% digestible. In cereal products the highest total phosphorus content and digestibility were found in industrial muffins containing “additive phosphorus” in the form of sodium pyrophosphate as a leavening agent.

### **8). Summary:**

- The American diet provides very large amounts of phosphorus and sodium.
- The published phosphorus content is not based on analysis, so the amount of phosphorus consumed is understated.
- Half of the adult American population consumes less than the Estimated Average Requirement, EAR of magnesium and essentially no one nowadays consumes the Adequate Intake, AI of potassium.
- A substantial proportion of Americans, almost 40%, consume less than the EAR of calcium (Fulgoni et al. 2011).
- The major mineral content of the adult American diet is severely imbalanced.
- It is difficult to fully assess the health impacts of phosphate additives in processed organic foods, in part because scientific research typically focuses on one aspect of one material at a time. This allows the specific question posed in the research to be answered, but rarely allows for an understanding of the synergistic effects or cumulative impacts over time. A comprehensive meta-analysis may provide greater insight.

- Consumers typically do not calculate the total intake of every material as they eat their standard diet, both organic and conventional, processed or unprocessed, and often take additional mineral or nutritional supplements.
- The phosphate in phosphate additives is highly bioavailable and more potent for increasing blood phosphate levels than natural phosphate from food.
- High blood phosphate levels are associated with kidney and vascular disease.
- A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium.

## **V REQUEST FOR PUBLIC COMMENT**

The NOSB recognizes that although no single phosphate can be implicated as an isolated risk factor, it is clear that there are health implications from cumulative impact of phosphate additives in processed organic foods.

Please provide answers to the following questions:

1. If some brands of organic processed dairy products can be produced without use of phosphates, why not all of them? What are the alternatives?
2. If European, Japanese, CODEX and IFOAM standards limit phosphates to only monocalcium phosphate – only as a leavening agent, why are all the other phosphates necessary in U.S organic food processing?
3. Should phosphate food additives in processed organic foods be phased out, and if so should just some of them be phased out or should it be allowed in only some products?

## **Vote in Subcommittee**

Motion to accept the discussion document on phosphates as written

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 7 No: 0 Recuse: 0 Absent: 1 Abstain: 0

**National Organic Standards Board**  
**Livestock Subcommittee Discussion Document**  
**Marine algae listings on National List**  
**September 6, 2016**

## **I INTRODUCTION**

During its recent five year sunset review of almost 200 materials the NOSB noted that there are a number of materials listed that are either marine algae or extracts of marine algae. The National List includes overlap in species in the various material listings. Some of the materials listed lack a Technical Report (TR) which limited full review of all algal materials. Public comment during Sunset Review indicated serious concerns about the following:

- Conservation of wild marine algae species
- Overharvesting of some species in some geographic areas
- Need for clarification of which species are used, and from which geographic areas
- Need for clarification of which species can or are being cultivated
- Clarification of wild harvesting techniques
- Feasibility of harvesting by individual species selection as opposed to multi-species harvesting by littoral or marine zone
- Extraction methods
- Sequestration of metals or other contaminants in some wild algal species

Because of public comment the NOSB requested a limited scope TR to address these concerns. The TR was received on August 9, 2016.

The goal of this discussion document is to present a brief analysis of our present understanding of the 9 marine algae on the National List and request public comment. Depending on public comment the NOSB may develop a proposal to annotate some of the materials on the list, or clarify the naming convention used to list these marine materials because many of the naming conventions may be duplicative and redundant. Alternatively, the NOSB may recommend that the NOP provide further guidance on use of seaweeds in organic production.

## **II BACKGROUND**

Seaweeds have been commonly used, in many ways, throughout human history. They comprise a seemingly unlimited renewable resource subject, however, to the usual depletion through unintended over harvesting and pollution. Open oceans, tidal and intertidal zones appear to be relatively open to public harvesting. The laws that control harvesting, establish conservation zones and seek to ensure sustainable seaweed harvest, while protecting marine ecosystems worldwide, are highly variable, and typically poorly articulated and not easy to enforce.

In the face of exponentially growing pressure on marine resources, decline in fisheries, decline in species, decline in habitats, and depletion of seaweed species in many geographic areas, the European Commission in May 2016 held a conference to focus on ***Organic Seaweed Rules, Blue Growth and the Bioeconomy***<sup>1</sup>. The conference provided examples of good management in areas of high ecological quality which were not contaminated, and where environmental assessment and estimation of biomass was undertaken at the outset, and a sustainable management plan is in place.

<sup>11</sup> <http://coastwatch.org/europe/wp-content/uploads/2016/05/Organic-Seaweed-Coastwatch.pdf>

However, most of the seaweed harvested for human use is not certified organic, but simply harvested from or cultivated in marine environments worldwide. Some marine environments are polluted by run off from terrestrial activities taking place over generations. Some seaweed species grow back very fast following harvest, while others take many years. Because of high demand, harvesting does not necessarily protect biomass and rarely involves ecosystem management. Little is really understood about the multi-tropic impact on seaweed harvesting or cultivation.

It is within this context of a desire to allow use of marine plants and algae in organic production, while at the same time ensuring long term sustainability, that the marine materials on the National List must be reviewed.

There are nine separate listings for marine materials on the National List which are the subject of this document:

1. **Aquatic plant extracts** (TR 2006) - aquatic plant (algae) extracts are most commonly derived from kelp such as *Ascophyllum* species and *Ecklonia maxima* (Sea Bamboo) as well as other seaweeds harvested from the North Atlantic. *Ascophyllum nodosum*, (Rockweed) a species known to be overharvested in many geographic regions, is in the *Fucaceae*, a brown seaweed, Class *Phaeophyceae* – not able to be cultivated and known to be regionally overharvested.
2. **Alginic acid** (TR 2015) is primarily extracted from brown seaweeds, Class *Phaeophyceae*. Major commercial sources are from species that include *Ascophyllum* (North Atlantic), *Laminaria* and *Saccharina* (various northern hemisphere oceans) and *Macrocystis* (California and Mexico), with lesser sources from *Lessonia* (South America), *Durvillea* (Australia), *Ecklonia* (South Africa), *Sargassum*, and *Turbinaria*.
3. **Agar-Agar** (TR 2011) is typically derived from red seaweeds, Class: *Rhodophyceae*. The marine algae that produce agar-agar are widely distributed throughout the world and several different species are utilized for extraction. Most commercial agar-agar is extracted from *Gelidium* and *Gracilaria* species, but other commonly used species include *Pterocladia* and *Gelidiella*. The most important sources worldwide include the coasts of Japan, Spain, Portugal, Morocco, Senegal, Chile, Mexico, the southern United States, India, the Philippines, Madagascar, South Africa, Egypt, and New Zealand although many other countries also supply algae used to make agar-agar. Although most agar-agar is produced from algae that grow in the oceans, *Gracilaria* algae are also cultivated on a commercial scale by some countries.
4. **Carrageenan** (TR 2011) is a generic term for a family of linear polysaccharides derived from species of red seaweeds (*Rhodophyceae*). They can be wild harvested or cultivated. Typical species used are *Chondrus crispus*, *Mastocarpus stellatus*, *Euchema cottonii* and *Euचेuma spinosum*, which grow in the warm waters of the Philippines, Indonesia, and Tanzania and produce kappa- and iota-carrageenan, respectively. The Asia-Pacific region has remained the largest source of carrageenan-producing seaweed, supplying over 50% of the market from 1999 through 2009, and the Americas have similarly maintained 16-18% of the global market.
5. **Alginates** are derived from brown seaweeds (See TR 2015). Of the species in the class of brown seaweeds, 41 species are used for extracting alginates, including: *Ascophyllum nodosum* from Ireland, Norway, UK; *Cystoseira barbata* from Egypt; *Durvillaea potatorum* from Australia; *Fucus serratus*, *F. vesiculosus* from Ireland; *Laminaria digitata* from France, Ireland; *Laminaria*

*hyperborea* from Ireland, Norway, Spain, UK; *Laminaria japonica* from China; *Laminaria ochroleuca* from Spain; *Lessonia nigrescens* from Chile, Peru; *Lessonia trabeculata* from Chile; *Macrocystis integrifolia* from Peru; *Sargassum crassifolium*, *S. grammifolium*, *S. henslowianum*, *S. mcclurei*, *S. siliquosum*, *S. vachelliannum* from Vietnam; *Sargassum ilicifolium*, *S. myriocystum*, *S. wightii*, *Turbinaria conoides*, *T. decurrens*, *T. ornata* from India; *Sargassum polycystum* from Indonesia, Thailand.

6. **Beta-carotene from algae** (TR, 2011) is typically derived from green algae, Class: *Chlorophyceae*. The common source of beta-carotene color is derived from the micro-algae *Dunaliella salina* and *Dunaliella bardawil*. These species are cultivated. *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. 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  $\beta$ -carotene from *Dunaliella* will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature. (TR 2011, 530-545).

The following 3 materials did not have detailed TRs until 2016:

7. **Kelp** is a broad generic term for brown seaweeds, Class *Phaeophyceae*, in the Order *Laminariales*, with at least 30 genera and many species, and in the Order *Fucaceae* such as *Ascophyllum nodosum*. However the term “kelp” as used in fertilizer means ANY macroalgae seaweed, brown (*Phaeophyceae*), red (*Rhodophyceae*) or green (*Chlorophyceae*) (Assoc. of American Plant Food Controls (AAPFC)). Kelp used in organic livestock production must be certified organic, but for use in processing for humans non-organic kelp is allowed. Pacific Kombu, and *Undaria innatifida* are also Kelp species. *Fucus* species are intertidal, but *Laminaria* species are deep water.
8. **Seaweed- Pacific Kombu** is a kelp, often *Laminaria japonica*. This species is cultivated in waters of Japan, Korea and China.
9. **Wakame- *Undaria pinnatifida*** is a kelp species native to cold temperate coastal waters in Japan, Korea and China, but it has also become an invasive weed species in numerous other locations. *Undaria* is widely cultivated in China and Japan.

### III RELEVANT AREAS OF THE RULE, NOP GUIDANCE, AND NOP MEMOS

#### §205.601 Synthetic substances allowed for use in organic crop production

In accordance with restrictions specified in this section, 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.

(1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction.

#### §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).”

(a) *Nonsynthetics allowed:*

- Acids (Alginic; ...).
- Agar-agar.
- Carrageenan.
- (b) Synthetics allowed:
  - Alginates.

**§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 carriers and solvent systems or any artificial preservative.
  - (2) Beta-carotene extract color derived from carrots or algae (pigment CAS 1393-61-1).
- (l) Kelp – for use only as a thickener and dietary supplement.
- (t) Seaweed, Pacific Kombu.
- (x) Wakame Seaweed (*Undaria pinnatifida*).

**§205.207 Wild-crop harvesting practice standard.**

- (a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance as set forth in §205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.
- (b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

**NOP 5022, Guidance- Wild Crop Harvesting, effective July 22, 2011,** provides details to clarify §§205-207.

**NOP Policy Memo 12-1, Production and Certification of Aquatic Plants, issued September 12, 2012** provides further clarification, as follows:

*This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List of Allowed and Prohibited Substances at 7 Code of Federal Regulations (CFR) 205.601-205.602, as the basis for the production and certification of cultured and wild crop harvested aquatic plants.*

*While current USDA organic regulations specifically exclude aquatic animals from organic certification, no such exclusion exists for aquatic plants. Further, some parts of the USDA organic regulations specifically address aquatic plant production. For example, some aquatic plants, such as kelps and seaweeds, are listed in 7 CFR 205.606 of the USDA organic regulations, allowing their use in non-organic form when certified organic forms are not commercially available. Producers and certifiers are required to comply with the USDA organic regulations when producing or certifying cultured and wild crop harvested aquatic plants.*

*The use of ground and surface waters, ponds, streams, or other waterways for aquatic plant production may be regulated by Federal, State or local authorities. Aquatic plant producers should consult with Federal, State and local authorities to ensure compliance with all applicable laws, in addition to the USDA organic regulations, regarding the use of synthetic substances and other materials in ponds and waterways. Also, under 7 CFR 205.200, aquatic plant producers must ensure, and certifying agents must verify, that production practices maintain or improve the natural resources of the operation, including soil and water quality.*

**IV DISCUSSION:**

The NOSB submitted brief information on each of the nine materials and posed seven questions to the NOP for the limited scope TR. This TR was received in August 2016 and the responses to these questions are briefly discussed below. The TR cited a number of references but the literature review was limited. Some additional relevant references are included in this discussion.

1. ***Nomenclature:*** *Many of the National List listings are generic terms or overlapping terms lacking specificity, such as “agar-agar”, “carrageenan”, “aquatic plant extracts” or “kelp”. Should each listing include specific Latin names of approved algae? Should the word “plant” be replaced by the word “algae”?*

The TR provides sources of marine polysaccharides (TR 2016, Table 3) but acknowledges the somewhat arbitrary nomenclature of red algae. Thus it may be possible for the NOSB to propose some clarity in the listings through use of Latin names. However, it must be noted that taxonomic revision amongst algal species has become commonplace. Morphologically plastic species in the same geographical location and identical species in different geographic locations are frequently given different scientific names (TR 2011 631-634 and 689-716).

Habitat forming seaweeds include the *Laminariales* (*Laminaria* species and others) and *Fucales* (*Ascophyllum* and others). Currently many of these species are referred to by a single common name “kelp”. This creates confusion because macroalgal species are harvested by different methods, their life histories and growth rates differ, and thus the impacts of cutting and harvesting on these species will differ. Clarification in naming conventions is thus of importance if conservation of habitat and species is taken into consideration.

2. ***Overharvesting:*** *The nine listings include thousands of species of algae from many different geographic locations, the marine intertidal zone, deeper ocean areas, and wild harvested beds. Which species, genera, classes are being overharvested? Which geographic regions indicate overharvesting impact? What is the trend in harvesting marine algae? What is the present status and trends in harvesting and overharvesting of *Ascophyllum nodosum*?*

The TR provides examples of the following seaweeds being overharvested: Irish Moss (*Chondrus crispus*), Rockweed (*Ascophyllum nodosum*) and giant Kelp (*Macrocystis pyrifera*). It must also be noted that ocean warming and other environmental factors probably contribute to depletion of these species (see also: Halat et al, 2015<sup>2</sup>; Kay et al, 2016.<sup>3</sup>). Overharvesting impacts not only the specific plant species or genus, but all the associated plant and animal species that form the marine ecosystem in a given location. (see also Keats et al 1987<sup>4</sup> and Kelly, 2005<sup>5</sup>)

There is limited evidence to suggest that the harvesting of agarophytes (algae used to make agar-agar) may be harmful to biodiversity. The current world demand for agar-agar is reportedly increasing, which has placed pressure on the overharvested natural sources. Overharvesting of many wild *Gracilaria* strands has resulted in the destruction of some of the larger genetic reserves

<sup>2</sup>Laryssa Halat, Moira E Galway, Sara Gitto and David Garbary, Epidermal shedding in *Ascophyllum nodosum* (*Phaeophyceae*): seasonality, productivity and relationship to harvesting. *Phycology*, Vol.54(6), 599-608, 2015.

<sup>3</sup> Lauren M. Kay, Allison L. Schmidt, Kristen L. Wilson, Heike K. Lotze, Interactive effects of increasing temperature and nutrient loading on the habitat-forming rockweed *Ascophyllum nodosum*. *Aquatic Botany* 133, 70-78, 2010.

<sup>4</sup> Keats, D.W., Steele, DH and South, G.R. The role of fleshy macroalgae in the ecology of juvenile cod (*Gadus morhua*) in inshore waters off eastern Newfoundland. *Journal of Zoology*, 65:49-53, 1987.

<sup>5</sup> Kelly, E (ed) The role of Kelp in marine environment. Irish Wildlife Manuals, No. 17, National Parks and Wildlife Service, Dept. Environment, Heritage and Local Govt., Dublin, Ireland.

for the species. Harvesting of wild agarophytes may also reduce biodiversity on nearby beaches (TR 2011). In 2015 there was a global downturn in availability of agar-agar.

Carrageenan production levels have decreased in Europe and increased substantially in China. Cold water species of red seaweed used to make carrageenan (from Chile, Mexico, Canada, and France) are generally harvested from wild populations. Overharvesting of *Gigartina* species at its northernmost limit in Chile resulted in a severe reduction in population size and a complete crash in the total number of seaweed landings in the early 2000s (TR 2011). Most carrageenan production comes from cultivated beds.

3. Selective harvesting: *There are about 6,500 species of red algae (Rhodophyta) such as Chondrus species, Palmiria, Delessaria; about 2,000 species of brown algae (Phaeophyta) such as Laminaria species, Ascophyllum species, Sacharina, Fucus, Sargassum muticum; and about 1,500 green algae (Chlorophyta) such as Dunaliella, of which many are not marine. How many species of each class are being wild harvested? Can one species be harvested without impacting other species in the same location?*

The TR 2016 provides Table 5, outlining algal species harvested for economic purposes. The TR indicates that there is limited research on this topic. Additional literature search shows some work has been done on multi-tropic consequences of kelp harvest on the coast of Norway, indicating negative impacts of kelp harvesting on fish abundance and diminishment of coastal seabird foraging efficiency (Lorentsen et al, 2010<sup>6</sup>). Lorentsen points out that kelp fisheries are currently managed in order to maximize net harvest of kelp biomass, and the underlying effects on the ecosystem are partly ignored. Literature review did not turn up any scientific research comparing certified organic kelp harvesting with non-certified wild harvesting.

There is peer reviewed research on habitat impact of seaweed on common eider ducks, such as Blinn et al, 2008,<sup>7</sup> and fish impact in Nova Scotia, such as Black, 1991<sup>8</sup>, and impact of mechanical harvesting on *Ascophyllum*, such as Ang, 1993<sup>9</sup>, and Ang, 1996,<sup>10</sup> and Arzel, 1998<sup>11</sup>. And there is considerable research on *Ascophyllum* harvesting impacts.

4. Contamination: *Seaweeds can sequester metal ions such as arsenic, lead, zinc and copper. What is the indication from the most recent scientific research on sequestration of metals by marine algae? Is there a difference in sequestration between species of algae? Are there additional processing steps taken to reduce and control for metal content from the raw seaweed material?*

<sup>6</sup> Svein-Hakon Lorentsen, Kjersti Sjøtun and David Gremillet, Multi-tropic consequences of kelp harvest, *Biological Conservation*, 143, 2054-2062, 2010.

<sup>7</sup> Blinn, B.M., A.W. Diamond and D.J. Hamilton. Factors affecting selection of brood-rearing habitat by common eiders (*Somateria mollissima*) in the Bay of Fundy, New Brunswick, Canada. *Waterbirds* 31:520-529, 2008.

<sup>8</sup> Black, R & R.J. Miller, Use of intertidal zone by fish in Nova Scotia. *Env. Bio. Fishes*, 31:109-121, 1991.

<sup>9</sup> Ang, P.O., G.J. Sharp & R.E. Semple. Change in the populations structure of *Ascophyllum nodosum* due to mechanical harvesting. *Hydrobiologia*, 260/261:321-326, 1993.

<sup>10</sup> Ang, P.O, G.J. Sharp & R.E. Semple. Comparison of the structure of populations of *Ascophyllum nodosum*, (Fucales, Phaeophyta) with different harvest histories. *Hydrobiologia* 326/237 179-184.

<sup>11</sup> Arzel, P. Les luminaires sur les cotes bretonnes. Evolution de l'exploitation et de la flottille de peche, etata actuel et perspectives. Editions IFREMER BP 70-29280 Plouzane, France 139 pp.

Marine algae have a large capacity to sorb metals. In fact, algal species are often used as biosensors for contamination with arsenic and heavy metals. Their analysis in heavily contaminated areas, particularly agricultural soils, can be used to determine required bioremediation strategies (TR 2016 775-777). The EPA found that levels were well below safe levels in research conducted in the St. Lawrence. However, increased pollution will lead to higher levels of arsenic and heavy metal in algae for human consumption.

5. *Organic certified wild crafting: Which marine algal species are being harvested under the “wild crafting” organic standard, and in which geographic locations?*

7 CFR §205.207 provides the wild crop harvesting standard. This section is further clarified in NOP 5022 (7/22/2011) as follows:

4. Unmanaged, untrained and uninformed harvesting of wild products from a wild habitat without maintaining or improving the natural resources can disqualify the wild products from organic certification... and

5.4. Verification of lands or waterways:

1. In the case of public lands or waterways, the responsible authority of those lands or waterways should verify that no prohibited materials have been applied to or have contaminated the land or waterways for at least three years prior to harvest by providing a signed and dated affidavit to the certified operation.
2. In the case of private lands and waterways, the private owner shall provide a verification that no prohibited materials have been applied to or have contaminated the land or waterways for at least three years prior to harvest by providing a signed and dated affidavit to the certified operation.

There are 5 operations certified by the NOP to produce marine algae. One in Brazil harvests red algae; one in China produces nori (red algae); one in Iceland mechanically harvests both kelp (*Laminaria digitata*) and rock weed (*Ascophyllum nodosum*), and ecological concerns about changes in species diversity have been noted (TR 896-897.) In Argentina, several commercial species are harvested both by wild crafting and cultivation.

6. *Cultivation: Which species are being cultivated, and in which geographic locations? What are the environmental issues associated with farming marine algae?*

Increasing demand for seaweeds over the last 50 years has outstripped the ability to supply the market from natural wild stocks, and 90% of the market demand is met from cultivation (TR 2016, 189-190). However, not all marine algal species are easily or economically cultivated. For example, *Ascophyllum nodosum* (Rockweed) a species widely harvested, and over harvested, for aquatic plant extracts and alginic acid, is a brown seaweed, which is not economic to cultivate. The TR provides considerable detail on seaweed farming of many species worldwide.

7. *CO2 sequestration: What does recent research indicate about the ability of marine algae to positively impact the environment, including global climate change, by their ability to absorb excessive CO2?*

The TR 2016 briefly presents research indicating that marine algae are critical in their role as carbon sinks with substantial benefits for global climates. Note also the findings of Trevenhan-Tacket et al,

2015 which provides a comparative analysis of various seaweeds and their contribution to carbon sequestration<sup>12</sup>. See also Kay, 2010 cited above.

**Summary:**

All materials on the National List are reviewed as separate, individual materials, described by chemical or species name. However each marine material grows in a complex and not fully understood ecological context subject to internal and external stressors, never in homeostasis. In order to fully review a material against the required OFPA criteria each material must be assessed in the context of where it grows, and with an understanding of verifiable assurances of sustainability. Production of marine materials must be based on the maintenance of biodiversity of natural aquatic ecosystems, and the continuing health of the surrounding aquatic and terrestrial ecosystems. With these contexts in mind the NOSB asks the public for comment on the nine marine materials noted above.

**V REQUEST FOR PUBLIC COMMENT**

1. Should the naming conventions of the marine plant/algae listings on the National List be consolidated and/or clarified to avoid redundancies and duplication, using Latin binomials?
2. Should annotations be written to clarify specific uses, or harvesting guidelines for any of the marine algae listings, such as “no machine harvesting of *Ascophyllum*”, and “Not harvested from a conservation area identified by State, Federal or International bodies”?
3. Is there a need for further NOP Guidance on marine plants/algae?

Motion to accept the discussion document on marine algae listings on National List

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

<sup>12</sup> Teventhan-Tacket S.M., Kelleway J.J., Macreadie P.I., Beardall J., Ralph P., Bellgrove A., Comparison of marine macrophytes for their contribution to blue carbon sequestration. Ecology 96”3043-3057, 2015.

**National Organic Standards Board**  
**Handling Subcommittee**  
**Statement on proposed reclassification of xanthan gum**  
**September 6, 2016**

The Handling Subcommittee requested an updated technical report on xanthan gum, focusing on the manufacturing process, to determine if it is synthetic or non-synthetic. After reviewing the information provided, it appears that there is more than one way to produce xanthan gum; some of the methods may be non-synthetic while others may lead to what the NOSB would classify as synthetic. Based on this determination, the Handling Subcommittee has concluded to take no further action on re-classification of xanthan gum at this time.



**National Organic Standards Board  
Materials Subcommittee Proposal  
2016 Research Priorities  
August 9, 2016**

## **INTRODUCTION**

Since adopting its Research Priorities Framework in 2012, the National Organic Standards Board or NOSB, a Federal Advisory Committee, has presented a list of research priorities for organic food and agriculture. The priorities are proposed by the NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees and are published each year, prior to the fall meeting. The final priorities include feedback from organic stakeholders, which is publicly available through the Federal Register. This document reflects an effort by each Subcommittee to review and prioritize all previous years' priorities from 2012-2015. The topics listed below by subcommittee are the 2016 priorities, including some from previous years that the NOSB thinks are still relevant. The older priorities and their dates of adoption can be found in a list at the end of this proposal.

## **BACKGROUND**

Research needs are prioritized along the following criteria: 1) persistent and chronic, 2) challenging, 3) controversial, 4) nebulous, 5) lacking in primary research, and 6) relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List<sup>1</sup>.

The NOSB encourages collaboration with and between laboratories, federal agencies, universities, foundations and organizations, business interests, organic farmers, and the entire organic community to seek solutions to pressing issues in organic agriculture and processing/handling.

## **PROPOSAL: 2016 RESEARCH PRIORITIES**

Although the NOSB often deliberates on the merits of a single material or process, we recognize that organic operations are a part of a larger whole. The entire farm as a system impacts the welfare of the environment and the animals that are part of that environment. Therefore, the NOSB urges that all research topics presented should be undertaken with consideration of the whole farm system.

<sup>1</sup> The National List of Allowed and Prohibited Substances identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies a limited number of non-organic substances that may be used in or on processed organic products. The NOSB advises the National Organic Program (NOP) on which substances should be allowed or prohibited.

A whole-farm, systems-based research framework will ensure that the research questions posed demonstrate an understanding of the interplay of the agroecology and the necessary biodiversity of both native and farmed species of plants and animals. This whole-farm, agroecological framework will ensure that confounding variables are carefully recorded as part of a comprehensive and practical approach to the research. Such research could contribute to answering some of the broader questions in organic agriculture such as:

- How can crop species and varieties be specifically adapted to site-specific conditions through plant breeding or cultural practices?
- How does biodiversity contribute to pest and disease resistance?
- What is the relationship between nutrient balancing fertilization practices and microbial life in the soil to susceptibility or resistance to pests?
- How can the need for a diverse agroecological system be balanced with food safety concerns for sustainable organic farming systems?
- How can the complex whole environmental system inform, support, and educate a farmer in developing a farming system plan?

The NOSB encourages integrated research into the following areas:

## **Livestock**

### **Introduction**

In previous years the Livestock subcommittee has suggested basic research priorities on prevention and treatment of pneumonia and mastitis. The consumer expects all organic livestock to be treated well and be healthy. Animal welfare is of critical importance to producers, and consumers expect to be able to observe that their meat, wool, and egg-producing organic livestock are in good health.

In 2015, the NOSB suggested that the research priorities on herd and flock health be changed to reflect a systems review of successful models of livestock production nationwide. Which breeds are doing best under organic management? Are we selecting the most appropriate breeds for high levels of herd and flock health? Which grazing management systems and natural resource conservation practices are producing the highest quality organic product from the healthiest flocks and herds? What factors appear to be contributing to healthy livestock? What agroecosystem and management factors contribute to the healthiest herds and flocks?

In the context as described above, the Livestock subcommittee proposes the following research topics as priorities for 2016:

### **1. Evaluation of Methionine in the Context of a Systems Approach in Organic Poultry Production**

Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. As the organic community moves toward reducing, removing, or providing additional restricting synthetic methionine in the diets of poultry, a heightened need exists for the organic community to encourage omnivore producers to assist in marshaling our collective efforts

to find viable alternatives to synthetic methionine, and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB's unanimous resolution to encourage the industry to move away from the use of synthetic methionine passed at the La Jolla, California, Spring 2015 full board meeting. A systems approach that includes industry and independent research by USDA/ARS, on-farms, and agricultural land grant universities is needed for:

- a. evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems,
- b. evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine, and
- c. assessment of management practices for improving existing organic poultry welfare under different conditions.

Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. These types of research topics are complex, and it could take years to achieve the expressed NOSB resolution. However, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary.

The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives related to bringing these alternative sources into commercial production is also encouraged. Furthermore, research should be conducted on management practices that impact a flock's demand for methionine, such as flock management practices, access to pastures, and pasture management.

## **2. Prevention and Management of Parasites**

Livestock production places large numbers of cattle, sheep, goats, poultry, etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock are raised in a manner that accommodates the animal's natural behavior. The organic farmer can use a limited number of approved synthetic parasiticides in an emergency but not prophylactically. Use of synthetic parasiticides is limited in organic systems. Even if prophylactic treatment with parasiticides were possible, it is clear that parasite immunity to chemical control will inevitably occur. Thus prevention of parasites is critical.

The research question on prevention and management of parasites must be systems based. What farm systems, animal breeds, and herd or flock management systems have shown the best results with parasite control over the last 20 years? What regional differences exist in the U.S. in parasite prevention? Are there specific herbal, biodynamic, or other alternative

treatments that have been proven to work over time? What are the parasite-resistant animal breeds? Are there plant species in pastures and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

## **Crops**

### **1. Biodegradable Biobased Mulch Film** (*new priority in 2016*)

This type of mulch film was recently recommended by the NOSB but did not include a specific percentage of biobased components it must contain. In 2015, NOP issued a Policy Memo<sup>2</sup> that states that certifiers and material organizations should review biodegradable biobased mulch film products to verify that all of the polymer feedstocks are biobased. This requirement makes biobased mulches unavailable to organic producers, due to the petroleum-based polymers in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the NOSB requests answers to the following questions:

- How rapidly do biodegradable biobased mulch films fully decompose, and does the percentage of the polymers in the mulch film affect the decomposition rate? Are there metabolites of these mulches that do not fully decompose?
- Are there different cropping systems, climate, soil types, or other factors that affect the decomposition rate?
- What type of effect does the breakdown of these polymers have on soil and plant life as well as livestock that would graze either crop residues or forages grown the subsequent year after this mulch film was used?
- Does the use of these synthetic polymers over time affect the balance of soil biology?
- Is there any cumulative effect if this mulch film is used 3-5 years or more in the same location?
- Are the available testing regimens adequate to meet the decomposition standards in our definition and to validate the non-GMO status of source materials?

### **2. Organic No-Till**

Organic no-till practices are quite different from herbicide-based no-till systems. Organic no-till, using a terminated, in-place mulching system, can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. Even though this killed-in-place mulch practice has been used for more than a decade, widespread adoption has not occurred. This type of production is also attractive to conservation minded nonorganic farmers, and more practical information could result in the growth of domestic organic production. There are some land grant universities and federal agencies doing research on this type of production, but more work needs to be

<sup>2</sup> [Policy Memo 15-1](#)

done. Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops, such as commodity row crops and specialty crops, as well as perennial crops, such as tree fruits, berries, and grapes, would all benefit from these organic no-till practices. Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- Identification of mulch crops, systems, and timing of practices that provide weed management benefits with minimum interference to the crop and yields?
- Research on various techniques that would provide a variety of options for diverse cropping systems including, but not limited to: strip tillage within a killed mulch, mowing or other organically approved techniques versus rolling to terminate the mulch, and living mulches in standing crops.
- Development of systems that allow for either continuous no-till organic crops or for multiple years of organic no-till in the crop rotation.
- Research on how reduced soil disturbance contributes to pest, weed, and disease management?
- Benefits or drawbacks of using this mulching system on weed, pest and disease management, as well as soil fertility, in perennial cropping systems, such as fruits.
- Research about how the use of this system can be managed to improve water retention and permeation, both in annual crops and especially in perennial cropping systems.
- Biodiversity benefits to the living and/or killed mulches, and how they contribute to pest, weed, and disease management.
- Research into what effect the system would have on nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs.
- Research into how this system affects soil microbial life and nutrient availability, given that less soil disturbance improves plant decomposition and therefore provides higher organic matter, and if it results in crops that are less susceptible to disease and pests.

### **3. Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight**

Prior to October 2014, oxytetracycline and streptomycin were allowed for the control of fire blight in apple and pear trees only. Since 2014, neither substance may be used in any organic practice. Organic apple and pear growers must now find suitable alternatives to control the deadly fire blight disease. Since apples and pears are grown in many regions throughout the United States, alternatives must work in a variety of climates and management systems. The following research issues are important to investigate: location; planting density; choice of varieties of cultivar and rootstock; soil improvement practices; pruning practices and general sanitation; groundcovers or intercrops; pollinator management; dormant copper sprays; bloom thinning/lime sulfur; early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment; surveys for fire blight activity; and other cultural and preventative techniques.

#### 4. Alternatives to Copper for Disease and Algae Control

Organic producers have few alternatives to synthetic chemicals to control diseases. Copper has been used for more than a century to control serious diseases in crops such as late blight in tomatoes and fire blight in pears. Because the copper products degrade to elemental copper, continued use over time can cause copper to accumulate in soil. If used improperly or to excess, copper can be toxic to aquatic life and wildlife.

Alternative materials are not yet available to address the many diseases which copper treats. Targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations.

Some avenues for research:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases on which copper is now used.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Determining if alternatives, such as sodium carbonate peroxyhydrate or other materials, are suitable alternatives to control scum and algae in rice in an aquatic environment.

#### 5. Plant Disease Management

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

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

In particular, both biological control of plant diseases and bio-pesticides should be a research priority to support organic growers. A large body of research has shown that plant diseases caused by bacteria and fungi can often be prevented by the application of a non-pathogenic microorganism before infection occurs. Although much basic research has been done to identify microbial biological control agents, there is still a need for commercial development, field testing, and adoption by growers. Biological controls have been

researched for late blight of potato and tomato (*Phytophthora infestans*), several diseases caused by *Botrytis cinerea*, and powdery mildew (several species) controlled by mites, fungi, and bacteria.

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

## **6. Mitigation Measures for Residues in Compost**

Residues of pesticides in compost material are a problem that requires research, according to the Organic Materials Research Institute (OMRI). Because of the importance of compost to organic management systems, research is needed on: types of mitigation measures that are efficacious; identification of problematic feedstock (e.g. cotton-based materials and yard waste); types of corrective action; and if thresholds for allowable residues are established, testing guidelines. This is more important than ever with events of 2016 regarding contamination in compost.

## **Handling**

### **1. Chlorine Materials and Alternatives**

The three chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. New FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply. Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

The organic industry needs better information on how either alternative materials or appropriate chlorine materials are best suited for a specific use and control measure. This is especially important in determining if the industry can move away from the use of chlorine compounds in the future.

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chlorine is the best material to use.
- Research about whether rotation of materials for cleaning and disinfecting could help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens.
- Research on the absorption of chlorine by produce from its quantity and use in wash tanks, including information about amount of time of exposure. Would this be a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

## **2. Celery Powder**

Celery Powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (note: products must still be labeled “uncured”). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

## **3. Alternatives to Bisphenol A (BPA)**

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

## **4. Consumer Demand**

The NOSB often receives comments from stakeholders that consumers have expectations about what organic means and what inputs and ingredients should be in organic food. Sometimes there is a wide difference between what consumer activist groups claim and sales of specific categories of organic products in the marketplace. How can the NOSB determine whether the consumers and groups who speak up are truly representing all consumers of organic, and is there a better measure of consumer preference and expectations for organic products than sales figures? Research showing the distribution curve of consumer preferences and expectations around organic products would be helpful.

## **Materials/GMO**

In previous years, the Materials subcommittee has prioritized the Reduction of genetically modified content of breeding lines (2013) and seed purity from GMOs (2014). These issues are currently being addressed through an NOSB Seed Purity task force.

### **1. Fate of genetically engineered plant material in compost**

What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (*bacillus thuringiensis*) after composting that would result in persistence in the environment or plant uptake?

### **2. Integrity of breeding lines and ways to mitigate small amounts of genetic presence**

Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

### **3. Prevention of GMO contamination: Evaluation of effectiveness**

How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows?

Other questions could include: whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning; whether situating at-risk crop fields upwind from GMO crops can reduce contamination; and what role pollinators may have in spreading GMO pollen.

Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures, to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

## **Previous Years' Research Priorities**

For more detailed information about each topic, please see the relevant research priorities proposals. Each topic's listing year is indicated.

Whole Farm Systems (2012, 2013)

Evaluation of Copper Sulfate for Rice (2012)

Evaluation of Genetically Modified Vaccines (GMO) (2012, 2013)

Organic Aquaculture (2012, 2013)

Carageenan (2012)  
Aquatic Biodiversity (2013)  
Pastured Poultry and Salmonella (2013)  
Commercial Availability Assessments (2013)  
Herd and Flock Health (2013, 2014, 2015)  
Risk Reduction from Off-Target Exposure to Non-Permitted Materials (2014)  
Seed Purity from GMO (2014)  
Mastitis (2014)  
Pneumonia (2014)  
Plant Extracts (2014)  
Soil Building Practices (2014)

**Subcommittee Vote:**

Motion to adopt the proposal on 2016 NOSB Research Priorities

Motion by: Emily Oakley

Seconded by: Trace Favre

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

**National Organic Standards Board  
Materials/GMO Subcommittee Proposal  
Excluded Methods Terminology  
August 30, 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,<sup>1</sup> 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 2015<sup>2</sup> 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 the Research Institute of Organic Agriculture (FiBL) in Europe that involves an itemized chart with a yes/no column where the specific techniques could be itemized and evaluated. The Subcommittee made an informal recommendation, which was 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.

Both a Proposal and a Discussion Document were posted for the April 2016 NOSB meeting. While comment was generally favorable to the approach taken, there clearly was the need for some refinement of the definitions and criteria. There was also confusion about which techniques were part of the proposal and which remained to be discussed further.

### **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 States<sup>3</sup>. 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 and a half 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 Codex Alimentarius that were also in the Cartagena Protocol.

During the course of public comment and subsequent discussion, 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 provide common ground with other countries who are concerned about GMOs in organics.

Based on public comment from the spring 2016 proposal, we decided to add a definition for Classical/Traditional Plant Breeding. Traditional breeding is a term used in the Excluded Methods definition in the rule and is therefore important to clarify what it means. However because the other definitions and criteria are not unique to plants, we slightly changed the wording so that they are applicable to all organisms.

In October 2015 the International Federation of Organic Agriculture Movements (IFOAM) published a Discussion Paper on a proposed revision to their Position on Genetic Engineering.<sup>45</sup> Since other countries do not use the concept of "Excluded Methods", IFOAM 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 proposing that the following definitions of terms and acronyms, with sources, be adopted by the NOSB as Excluded Methods<sup>1</sup>:

**Genetic engineering (GE)** – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, 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 organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position cited above)

**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 traditional breeding and selection. (From Codex Alimentarius<sup>6</sup>)

**Synthetic Biology<sup>7</sup>** – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the 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 Diversity<sup>8</sup>)

**Non-GMO** – The term that is used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence. (Modified based on public comment from Spring 2016 NOSB)

<sup>1</sup> Both definitions and criteria were worked on in between the Spring and Fall NOSB meetings by an ad hoc group with the following members: Julie Dawson, University of Wisconsin; David Gould, International Federation of Organic Agriculture Movements (IFOAM); Michael Hansen, Consumers Reports; Jaydee Hanson, Center for Food Safety; Kristina Hubbard, Organic Seed Alliance; Melody Meyer, United Natural Foods; James Myers, Oregon State University; Dana Perls, Friends of the Earth; Erica Renaud, Vitalis Organic Seeds; Dan Seitz, National Organic Standards Board (NOSB); Michael Sligh, Rural Advancement Fund International; Zea Sonnabend, Fruitilicious Farm and NOSB; Jim Thomas, ETC Group; William Tracy, University of Wisconsin; Gwendolyn Wyard, Organic Trade Association.

**Classical/Traditional plant breeding** – Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

This series of definitions provides a better framework than the existing definition, as it elaborates 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 Manual<sup>9</sup>. The principles 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.

Regarding 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/gmos) and products produced by or through the use of genetic engineering are prohibited.

The following principals of Organic Agriculture are used by IFOAM<sup>10</sup> 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:

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the 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.

2. The ability of a variety to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are refrained from (e.g. Terminator technology).<sup>11</sup>
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes are refrained from).<sup>12</sup>

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.<sup>13</sup>

### **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 GMOs<sup>14</sup>, 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.<sup>15</sup> 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 animals<sup>16</sup>. 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.<sup>17</sup> 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.

For this version of the proposal, the ones that were marked "TBD" in the previous chart below are now moved to the accompanying Discussion Document. The ones presented here are those that we are voting on as either Excluded or Allowed. A column has been added for which criteria apply to the excluded techniques that have led to our conclusion to exclude them.

<b>Terminology Chart</b>				
Method and synonyms	Types	Excluded Methods	Criteria Applied	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	1, 3, 4	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	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering Dupont Seed Production Technology (SPT)	YES	1, 2, 4	These may pose 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	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	

Plastid Transformation		YES	1, 3, 4	
Marker Assisted Selection		NO		
Transduction		NO		

\* 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, Synthetic Biology, Non-GMO, and Classical/Traditional Plant Breeding 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

Motion to accept the three sections of this proposal as stated above.

Motion by: Zea Sonnabend

Second: Emily Oakley

Yes: 4 No: 0 Absent: 1 Abstain: 1 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 2015<sup>18</sup>. Some other definitions are from the NOSB previous discussion document<sup>19</sup> and from the FiBL 2015 plant breeding dossier.<sup>20</sup>

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.

<sup>1</sup> NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013.

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

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

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

<sup>4</sup> 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/75bdff144a46c1e451eecd10/files/Discussion\\_paper\\_on\\_GMO\\_position\\_2015.pdf](https://gallery.mailchimp.com/75bdff144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf)

<sup>5</sup> IFOAM – Organics International, 2002, Position on Genetic Engineering and Genetically Modified Organisms, P01, [https://gallery.mailchimp.com/75bdff144a46c1e451eecd10/files/IFOAM\\_GMO\\_Position\\_Paper.pdf](https://gallery.mailchimp.com/75bdff144a46c1e451eecd10/files/IFOAM_GMO_Position_Paper.pdf)

<sup>6</sup> Codex Alimentarius Commission (2003). "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology," *CAC/GL 44>2003*. Amended 2008, 2011, available at: <http://www.fao.org/faoDwhoDcodexalimentarius/shD>

[proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B44D2003%252FCXG\\_044e.pdf](http://www.fao.org/faoDwhoDcodexalimentarius/shDproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B44D2003%252FCXG_044e.pdf)

<sup>7</sup> 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)

<sup>8</sup> Link to the European Commission's draft definition with discussion:

[http://ec.europa.eu/health/scientific\\_committees/consultations/public\\_consultations/scenih\\_r\\_consultation\\_21\\_en.htm](http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenih_r_consultation_21_en.htm)

<sup>9</sup> NOSB Policy and Procedures Manual: <https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf>

<sup>10</sup> [http://www.ifoam.bio/sites/default/files/poa\\_english\\_web.pdf](http://www.ifoam.bio/sites/default/files/poa_english_web.pdf)

<sup>11</sup> FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

<sup>12</sup> FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

- <sup>13</sup> 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](https://gallery.mailchimp.com/75bdf144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf)
- <sup>14</sup> Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. *EMBO reports* 12: 883–888.
- <sup>15</sup> Kokotovich A, Kuzma J (2014) Conflicting Futures: Environmental Regulation of Plant Targeted Genetic Modification. *Bulletin of Science, Technology & Society* 34: 108–120.
- <sup>16</sup> FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070
- <sup>17</sup> CFS Comments to the NOSB, 2015, Docket #AMS\_NOP\_15-0002-0874
- <sup>18</sup> CFS Comments to the NOSB, 2015. Reference List. <http://www.regulations.gov/#!documentDetail;D=AMS-NOP-15-0002-0875>
- <sup>19</sup> National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.
- <sup>20</sup> 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  
August 30, 2016**

*Note: The Materials Subcommittee is posting the same discussion document from February 2016 with one change. Embryo transfer in animals has been added to the terminology chart with a "TBD", after public comment from the Spring 2016 meeting indicated that it should be considered as allowed in organic livestock. This and all the issues within this document will warrant further discussion at future meetings once the proposal for definitions and criteria is in place. If you submitted comments to the Spring 2016 posting, you do not need to send them again.*

## **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.

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 FiBL<sup>i</sup>, 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 an 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		TBD	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		TBD	A very broad term that may need to be divided into some allowed and some excluded techniques.
Intragenesis		TBD	Similar to cisgenesis but gene sequences may be re-arranged.
Transposons		TBD	Used in animal vaccines. May be excluded in some situations but not others.
Cell Fusion within Plant Family		TBD	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		TBD	Many sources including FiBL think this is not excluded but more study of the methods is needed.
TILLING	Eco-TILLING	TBD	Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.
Agro-infiltration		TBD	<i>In vitro</i> nucleic acids are introduced to plant leaves to be infiltrated into them. More study needed.
Doubled Haploid Technology		TBD	There are several ways to make double haploids and some do not involve genetic engineering but some do.
Induced Mutagenesis		TBD	This is a very broad term and needs to be divided and classified based on what induces the mutations, chemicals, radiation, or other stresses.
Embryo transfer in animals	Embryo rescue in animals	TBD	FiBL distinguishes embryo rescue in plants from animals.

## 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

Seconded by: Emily Oakley

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

<sup>i i</sup> 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 Proposal  
Report to the USDA Secretary on Progress to Prevent GMO Incursion into Organic**

November 18, 2016

The Honorable Tom Vilsack  
Secretary of Agriculture  
US Department of Agriculture  
Washington, DC 20250

Re: An update of the National Organic Standards Board's work on eliminating the threats from GMO incursion into organic agriculture

Dear Honorable Secretary Vilsack,

As authorized in the Organic Foods Production Act (OFPA), the National Organic Standards Board (NOSB) provides advice to the National Organic Program (NOP) on the development of organic standards. (Organic Foods Production Act of 1990, 7 U.S.C. §6518 (a))

Five years ago, and at the request of the wider organic community, the NOSB accepted the responsibility for making recommendations to the NOP to address issues related to "excluded methods" as defined in the Federal Organic rule; specifically, to ensure that Genetically Modified Organisms (GMOs) are prohibited in organic production and handling.

The issues around GMOs in organic agriculture are complex and will require long-term efforts. Therefore, we believe that advising you on our efforts to date is worthwhile as we move towards a new Administration. In the NOSB's initial letter to you in March 2012 we stated, "We would like to open the door to continued dialogue with the USDA so that the responsibility to prevent GMO contamination of organics is shared by those who develop, use, and regulate this technology. USDA actions are critical to the integrity of the organic seal and consumer confidence." This report elaborates on the progress by the NOSB with regard to this shared responsibility.

**The Public's Message Is Clear**

The NOSB has the unique opportunity of having direct access to public comment prior to each of our twice-yearly board meetings, and one message has consistently, repeatedly and abundantly been made clear: consumers across the country have expectations there will be no GMOs in their organic food. The risk to the integrity of organic agriculture is significant, and seed producers, growers, processors and handlers are all potentially impacted by the risk of incursion of GMOs into an organic supply chain.

**NOSB Actions to Date**

To address public concerns, five years ago the NOSB established an ad hoc Committee on GMOs, which has since been incorporated into the standing NOSB's Materials subcommittee. Since 2012 the NOSB has undertaken the following:

- Developed a mission statement that states that we accept responsibility for making recommendations that aim to keep GMOs out of organic agricultural products, and that we will provide leadership in clarifying the rule regarding excluded methods.
- In 2012, began work on the issues of keeping seed stocks free from GMO incursion. The work included multiple discussion documents open for public comment, an expert discussion panel at the Spring 2015 NOSB meeting, and an update report on the work of the subcommittee. Most recently, the NOSB has requested an ongoing stakeholder task force to continue working on details of data collection and threshold identification of needs. While there is still much work to be done, we can say with confidence that the organic industry has reached consensus on several key points:
  - Seed is an important place to start to make sure that GMOs do not enter the organic agro-ecosystem.
  - More data is needed on the sources of how GMOs can contaminate organic systems; whether it enters through seed, through pollen, or through post-harvest handling activities.
  - The organic industry alone should not bear the costs of genetic trespass and incursion. The responsibility should particularly lay with the developers of these technologies that trespass on the integrity of organic production.
  - In 2013 we started to examine the definition of excluded methods in the Federal Rule to see how it could be strengthened. The definition had been developed in 1995, and many new technologies and approaches have been adopted since then. After two discussion documents and an initial proposal, the NOSB will vote on a final document this fall. This document proposes guidance on additional definitions to supplement the one in the Rule, as well as guidance on principles and criteria for the NOSB to use when reviewing future biotechnologies.
  - A comprehensive recommendation was passed unanimously by the NOSB in October 2015 on Prevention Strategies for Excluded Methods. This included best management practices (BMPs) to ensure the integrity of every step of organic production and handling.

These activities have kept the topic of genetic engineering on every NOSB agenda for the last five years and have given organic stakeholders ample opportunity to comment on these issues. Again, the message has been clear: organic consumers do not want GMOs in their food, and organic farmers do not want GMO incursion into their fields or the toxic pesticides and herbicides that the use of GMOs proliferates.

### **USDA Leadership Is Critical**

Recognition of the potential for unfair burden to be placed on non-biotech farming systems was clear in the mandate from your office to the USDA Advisory Committee on Biotechnology and 21<sup>st</sup> Century Agriculture (AC21), as evidenced by their November 2012 report, “Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture”. In the introduction to that report, AC21’s mandate was to answer the following questions:<sup>1</sup>

1. What types of compensation mechanisms, if any, would be appropriate to address economic losses by farmers in which the value of their crops is reduced by unintended presence of genetically engineered (GE) material(s)?
2. What would be necessary to implement such mechanisms? That is, what would be the eligibility standard for a loss and what tools and triggers (e.g., tolerances, testing protocols,

<sup>1</sup> “Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture”, November 2012, [http://www.usda.gov/documents/ac21\\_report-enhancing-coexistence.pdf](http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf)

etc.) would be needed to verify and measure such losses and determine if claims are compensable?

3. In addition to the above, what other actions would be appropriate to bolster or facilitate coexistence among different agricultural production systems in the United States?

In one of the report's conclusions, it states:

“In its examination of the charge provided by the Secretary, the members of the AC21 have concluded that the responses to all three elements of that charge are linked. No member of the AC21 believes that simply putting in place a compensation mechanism to address economic losses to farmers arising from unintended presence of GE or other material would completely eliminate such unintended presence and strengthen relations between neighboring farmers.”

As evidenced by this report, the issues of coexistence are clearly complex. The NOSB urges the Administration to continue to show leadership by facilitating further discussion on these issues. In particular, many organic stakeholders believe the USDA's actions on genetically engineered crops have been insufficient to protect the organic industry. The NOSB urges you to prioritize the protection of the integrity of the organic industry, which as of 2015 has reached over \$43.3 billion in annual domestic sales (*Organic Trade Association survey*)<sup>2</sup>.

Specifically, the NOSB urges you and your agency to:

- Develop policies to address shared responsibilities for GMO contamination.
- Strengthen farming best management practices guidance to prevent incursion of biotech seeds, pollen and products into conventionally and organically managed acreages.
- Support funding for research and data collection on threshold testing of organic and non-GMO seeds.

The NOSB appreciates that a cornerstone of your administration has been the growth of Organic agriculture. We urge you to continue to champion organic integrity through support of concrete steps – including vigorous, targeted regulatory action – to ensure the concept of coexistence is implemented in an effective, balanced and fair manner.

Sincerely,  
NATIONAL ORGANIC STANDARDS BOARD

Tracy Favre, Chair

Motion to accept this report to the Secretary of Agriculture on the progress to keep GMOs out of organic.

Motion: Zea Sonnabend

Second: Tracy Favre

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recusals: 0

<sup>2</sup> OTA's 2016 Organic Industry Survey was conducted and produced on behalf of OTA by Nutrition Business Journal (NBJ). The survey was conducted from January 7, 2016, through March 25, 2016. More than 200 companies responded to the survey. - See more at: <https://www.ota.com/news/press-releases/19031#sthash.nSfl5VtA.dpuf>



**Sunset 2018 Review Summary**  
**Meeting 2 – Subcommittee Review**  
**Crops Substances**  
**November 2016**

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

**Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.**

[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

**Subcommittee Review**

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](#). . The listings currently under review, 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 copper sulfate is used in aquatic systems the current annotations include specific requirements for application rates.

During the first posting, the NOSB asked for public comment on the viability of alternatives to the use of copper sulfate in rice, and whether ACAs had noticed an increase in baseline soil test values for copper in rice fields. No new information was provided about alternatives. The few ACAs who did respond did not report any concerns with increasing levels of copper in rice fields.

Until the 1990s the need for copper sulfate use in rice was unique to the California rice growing systems. Subsequently, algae, and then tadpole shrimp started to be of concern in the Missouri rice culture. Seeding rice into already flooded fields (water seeding) is what leads to the need for control of these pests. In California all rice is grown this way for a number of reasons, while in Missouri it is becoming increasingly popular. For this reason, rice research in other parts of the world is not relevant because of different growing systems, except in Australia where the rice is susceptible to snail pests.

In the California rice system, the tail water is very carefully monitored and ponds are usually used to collect tail water and allow settling to occur before the water is released back into the canals. This, combined with the current practice of leaving rice straw in the fields from the previous crop, very much stops any copper from being released into the surrounding ecosystem since it binds quickly to the soil sediment and the rice straw.

Annual reports from the California Rice Research Board were consulted from as far back as 2006 (<http://www.carrb.com/>) in preparing this review because they research all possible alternatives as they emerge for both the scum algae and the tadpole shrimp. They studied several microbial products, zinc sulfate, using barley straw, and withholding phosphorus fertilizer as techniques during that time. The zinc sulfate was somewhat promising but had to be used at about 5 times the rate of copper sulfate and the synthetic zinc may be similarly toxic as copper so no further research could be found. The microbial products and barley straw were not effective. Withholding phosphorus worked with synthetic chemical phosphorus somewhat, but not enough to pursue more research since 2010.

The reports from the CA Rice Research Board and from Cooperative Extension in Colusa County ([http://cecolusa.ucanr.edu/newsletters/Rice\\_Briefs\\_Newsletter34775.pdf](http://cecolusa.ucanr.edu/newsletters/Rice_Briefs_Newsletter34775.pdf)) indicate that tadpole shrimp are becoming an increasing problem in recent years. The hypothesis is that more operations are incorporating rice straw into the fields rather than removing it or burning it as was done in the past. This creates the conditions for tadpole shrimp eggs, which can lay dormant for up to 10 years before hatching. . These conditions include warm temperatures in between the seeding of the rice and its emergence from the water (about a 6 to 12 day period).

Since 2012, the NOSB has included in its research priorities document, a request for research into alternatives to copper sulfate. It will remain a priority with the hope that more promising alternatives may arise in the future. Public comment strongly supported the need for such research.

### **Motion to Remove**

The Subcommittee proposes removal of copper sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: availability of alternatives.

## Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harriet Behar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

## 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

### Subcommittee Review

Ozone is a strong oxidant and works by oxidizing plant tissue and bacterial membranes. Originally, 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.

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 November 2003. 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 recommended for relisting by a vote of 14 to 0. At sunset in December 2011 ozone was recommended for relisting by a vote of 13 to 0.

For the first round of public comments, the Crops Subcommittee asked for information on the scope of use of ozone in irrigation system cleaning. Comments from producers and organizations that work with organic producers indicated that there is quite a bit of use of ozone for irrigation system cleaning. One producer indicated that ozone is the least expensive option for irrigation cleaning. Others said they preferred ozone because its breakdown product is oxygen, leaving no toxic residues in the environment. Some organizations commented that a technical review is needed to learn if ozone could pose a hazard for workers or the environment, or if there are better alternatives.

The Crops Subcommittee supports relisting of ozone as an irrigation system cleaner.

### Motion to Remove

The Subcommittee proposes removal of ozone from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None.

## Vote in Subcommittee

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

## 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

### Subcommittee Review

**Specific Uses of the Substance:** In organic crop production, peracetic acid is used to disinfect equipment. It can also be used as a disinfectant to treat seeds or asexually propagated planting material. It can be used to disinfect pruning equipment to help prevent the spread of the fire blight bacterium and is also 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. Peracetic acid was relisted during the 2016 Sunset review for Handling and the 2017 Sunset listing for Livestock.

Peracetic acid is an unstable oxidizing agent, which is what makes it such an effective sanitizer. According to the 2016 TR, solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Most commercially available peracetic acid solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1, 1-diphosphonic acid) or dipicolinic acid (2, 6-dicarboxypyridine) to slow the rate of oxidation or decomposition.

International uses:

- **Canada** – permits the use of peracetic (peroxyacetic) acid at paragraph 4.3 (Crop Production Aids and Materials) with the following annotation: “Permitted for: a) controlling fire blight bacteria; and b) disinfecting seed and asexually propagated planting material”. This allowance is consistent with NOP regulations.
- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008** - Peracetic acid is not listed in Annex II – Pesticides – plant protection products. Nonetheless, as of June 1, 2012, the European Union and the United States have an equivalency agreement whereby organic products certified to the USDA or European Union (EU) organic standards may be sold and labeled as organic in both the U.S.A. and the EU.
- **Codex** - Not listed.
- **Japan** - Not listed in the Japanese Agricultural Standard for Organic Production. However, the United States entered into an equivalency agreement with Japan, effective on January 1, 2104. The scope of the arrangement is limited to plants and plant-based products which undergo final processing, packaging, or labeling within the boundaries of those two countries.
- **IFOAM** - The IFOAM norms permit the use of peracetic acid for cleaning equipment and/or disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), for pest and disease control, and for disinfection of livestock housing and equipment (IFOAM Appendix 5).

**Technical Report:** The Crops Subcommittee received a new Technical Evaluation Report on March 3, 2016. This was not received by the Subcommittee in time to submit a proposal for the Spring 2016 meeting. New TRs were also provided to both the Livestock and Handling Subcommittees, to provide consistency and also from a cost management perspective as well, even though peracetic acid is not currently under review in either of those subcommittees. Peracetic acid was relisted during the 2016 Sunset review for Handling and the 2017 Sunset listing for Livestock.

**Discussion:** Peracetic acid appears to be a straightforward material in that it is made from, and decomposes back to, acetic acid, oxygen, and water. Peracetic acid is a very strong oxidizing agent. First developed in 1950, it has historically 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 two 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 percent limit was too low compared to percentages in use at the time. This point of concern was discussed at the Spring NOSB meeting and it was decided that this slight increase in the percentages was necessary to adequately accommodate use rates in comments provided in public comments during the last sunset review cycle and no further action was needed by the NOSB on this at this time.

While there do appear to be other materials that could be used as a possible alternative to peracetic acid, this material is selected for use by many organic crop producers for many reasons: It is a strong oxidizing compound, works well in colder conditions, does not give off chlorine into the environment, used as part of a rotation process in fire blight disease control, and is the more benign of the sanitizers and disinfectants, since it reverts back to acetic acid, oxygen, and water in the environment. This is according to information provided during public comment and also contained in information found in the latest TR.

Concerns were raised during public comment submitted for the Spring NOSB meeting regarding the various forms of peracetic acid mentioned in the TR. This was discussed during the meeting and determined that the majority of those other sources (that were raising a concern) would not be allowed for use in organic crop production or other currently allowed uses, as currently shown on the National List. Several commenters also mentioned that they felt that all sanitizers and disinfectants should be looked at for a determination of need and prioritization of allowed uses. It was determined that request was outside of the scope of this specific Sunset Review and would need to be addressed as a separate issue/topic.

Other public comment mentioned that the implementation of the Food Safety Modernization Act (FSMA), to oversee an enhanced approach to food safety both at the farm and at the handling levels, places an even higher degree of necessity in having this material and/or other sanitizers available for use in organic crop production.

There was overwhelming support for the continued (re)listing of peracetic acid for use in organic crop production. While a few commenters took a neutral position, there were no commenters either during the written or oral public comment periods that were specifically opposed to the relisting of peracetic acid.

Based on the information provided (comments, new TR, etc.), discussion during public comment periods (in-person, webinar, and written), and Subcommittee review and discussion: it was determined this material satisfies the OFPA Evaluation criteria and the Crops Subcommittee supports the relisting of peracetic acid.

### **Motion to Remove**

The Subcommittee proposes removal of peracetic acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None.

### **Vote in Subcommittee**

Motion by: Harold V. Austin IV

Seconded by: Emily Oakley

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

## **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](#); [08/2015 recommendation to change annotation at 7 CFR 205.601\(m\)](#)

**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.

### **Subcommittee Review**

The Crops Subcommittee supports moving the separate listing for this category into the changed annotation that will cover all inert ingredients, with the ones in pheromone twist ties mentioned as a subheading of inerts. We feel that these materials are an essential component of passive dispensers and have a history of use in organic farming which has reduced the use of many other pest control products. We have seen no new information that would cause us to question their safety to human health or the environment.

### **Additional information requested by NOSB:**

None

### **Motion to Remove**

The Subcommittee proposes removal of EPA List 3 - Inerts of unknown toxicity - for use only in passive pheromone dispensers, from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

### **Vote in Subcommittee**

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

## **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

### **Subcommittee Review**

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 non-synthetic and was not included on §205.601 or §205.602. Calcium chloride was subsequently petitioned and added to National List §205.602 as a non-synthetic 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.” Calcium chloride is commonly used in organic production; there are currently 20 registered OMRI products and 10 WSDA registered products.

This material has historically not been allowed for direct soil applications due to high chloride and high solubility concerns. The Board received petitions in both 2005 and 2015 requesting removal of the prohibition. The 2005 petition was declined by the Board for failing all three OFPA criteria. The 2015 petition contested these concerns and argued the contrary; however, no new substantive information was presented to warrant reconsideration of the petition. Because natural substitutes like limestone, gypsum, rock phosphate, and bone meal are unable to supply calcium in sufficient quantities when faced with limited calcium uptake conditions, targeted foliar sprays are appropriate.

The NOSB did not ask any questions of the public during the first posting, however, written public

comment supported the relisting of calcium chloride. The Subcommittee has no concerns regarding the continued listing of calcium chloride at §205.602.

**Motion to Remove**

The Subcommittee proposes removal of calcium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none.

**Vote in Subcommittee**

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0



**National Organic Standards Board  
Crops Subcommittee  
Discussion Document on Strengthening the Organic Seed Guidance  
September 6, 2016**

**Introduction**

For several years now the Materials/GMO subcommittee of the NOSB has been studying the issue of how to keep seeds used in organic systems from being contaminated with GMO content. One point that comes up repeatedly from the organic community is that the progress towards full adoption of organically grown seed in organic systems is too slow. While there is more and more organic seed available, there has been inconsistent progress in the proportion of organic seed in use by many growers.

It became clear that one key way to help keep GMOs out of organic systems is to strengthen the provisions in the rule and the NOP Guidance 5029 for the use of organic seed. The current state of the organic seed industry has changed since 2011 when the draft guidance was circulated, and even 2013 when the final guidance became official. The final guidance does not reflect the progress that has been made in the organic seed sector since the regulations and the 2005 and 2008 NOSB recommendations were written.

Therefore this Discussion Document will collect public input on the areas in which the seed guidance could be strengthened. Along with it may be recommendations about training for Accredited Certifying Agents (ACAs) and enforcement. The framework for the suggestions discussed here was already solicited at the Spring 2016 NOSB meeting in response to the discussion document on Next Steps for Seed Purity.

Seed is much more than just an input. It is the fundamental starting point for transforming the food system through nutritious ecologically grown food, especially when coupled with the principles behind organic production of building healthy soils, using non-toxic inputs, and stewarding the soil and environment. As the foundation for organic farming systems, it deserves continuous attention, from protecting its genetic resources, to preventing contamination, to building a strong organic seed sector to supply the needs of a diverse and resilient agriculture.

**Background**

The NOSB has worked on organic seed policies since its formation in 1992. This has enabled an organic seed industry to rise to fill the need for high quality organic seed since the USDA organic rule was implemented in 2002. After the NOSB made additional recommendations on the need for guidance on how the organic seed requirements should be explained and enforced, the NOP published the **Guidance on Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production** in 2013. The guidance adopted many of the NOSB recommendations but not all of them, and many stakeholders felt they were not strong or specific enough to make sure that organic seed was the primary form used in organic systems.

Since that time there has been continuing pressure from genetically engineered seeds on at-risk crops leading to contamination of the seed supply, and organic seed companies are struggling to stay viable when the adoption of organic seed is not growing at the same rate as the organic products market. Therefore it seems like a good time for the NOSB to re-visit the important topic of organic seed.

**Relevant Areas of the Rule and Guidance**

From the NOP Rule:

#### **§205.204 Seeds and planting stock practice standard.**

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except, That,*

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except, that,* organically produced seed must be used for the production of edible sprouts;

Excerpts from the **Guidance on Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production** published March 4, 2013 (NOP 5029).

#### **4. Policy**

Producers should develop and follow procedures for procuring organic seeds, annual seedlings, and planting stock and maintain adequate records as evidence of these practices in their organic system plan (OSP).

#### **4.1 Sourcing of Seeds, Annual Seedlings, and Planting Stock**

4.1.3 The following considerations could be acceptable to justify use of non-organic seeds and planting stock as not commercially available. These considerations must be described by the operation in their organic system plan (OSP), pursuant to § 205.201(a)(2), and approved by the certifying agent.

Form Considerations: Examples of forms may include, but are not limited to, treated or non-treated seeds or planting stock, use of pelleted seed.....

Quality Considerations: Examples may include, but are not limited to, germination rate of the seed; presence of weed seeds in the seed mix; shelf life and stability of the seeds; and disease and pest resistance.

Quantity Considerations: Producers may provide evidence that quantities are not available in sufficiently large or small amounts given the scale of the operation.

#### **4.2 Recordkeeping for Organic Producers**

4.2.1 The following records should be maintained by organic producers:

A list of all seed and planting stock, indicating any non-organic seeds or stock used, and the justification for their use including lack of equivalent variety, form, quality or quantity considerations. Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.

The search and procurement methods used to source organic seed and planting stock varieties, including:

1. Evidence of efforts made to source organic seed, including documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. Sources should include companies that offer organic seeds and planting stock.....

#### **4.4 Role of Certifying Agents**

4.4.1 Certifying agents must verify the procedures that certified operations utilize to obtain and plant organic varieties suitable for their operations as part of their annual review of the OSP.

.....

- 4.4.3 Certifying agents shall verify the commercial availability requirements on an annual basis, in their review of the OSP, pursuant to § 205.402(a)(1).
- 4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years.

### **Discussion**

One of the main criticisms of the final guidance 5029 was that there was a failure to provide a framework for what continuous improvement looks like and how to achieve it in the context of seed. Many stakeholders were concerned that the guidance was not strong enough and ignored some of the input that was given to the NOP in the comment period for the draft guidance. Over time we have seen some of the adoption of organic seed stay flat or decline.

The recently published State of Organic Seed Report<sup>1</sup> provides some concrete statistics about the trends in organic seed usage over the past five years. One of the main findings is that organic farmers produce food in many different ways and in many different locations, soil types, and marketing strategies. Therefore organic seed needs to be particularly adapted to organic systems in very diverse ways. While organic farmers are using more organic seed than five years ago, the biggest producers are still using relatively little and this has an impact on overall acreage planted to organic seed. The report also points to inconsistency among certifiers in enforcing organic seed requirements.

When it comes to at-risk crops from GMO contamination, the situation is more fragile and yet important to address. Stakeholders gave compelling input that they needed a greater use of organic seed, and enforcement of the organic seed provisions, if they are to stay ahead of the risks posed by GMO encroachment. Some of these reasons to encourage more organic seed use include:

- Increased sales of certified organic seeds increases field sizes and reduces edge effects at the field-scale of organic seed production, thus minimizing GMO pollen drift.
- Increased revenues to companies producing certified organic seeds reduces the impact of additional fixed costs like seed testing and potential loss of seed yields due to unexpected pollen flooding or higher than anticipated test results.
- Increased demand for organic seed spurs breeding and development of biological blocking mechanisms to GM influx in organic varieties (e.g. Gametophytic incompatibility in corn).
- Any consideration of a testing protocol or threshold will not work well if it only focusses on conventional seed used in organic systems. It appears that minimal contamination from seed can accumulate to significant levels in the finished crop, and therefore organic seed will need to reach the same standard as non-organic seed.

#### Key Points to strengthen the guidance:

- Additional guidance specific to the use of "at-risk" non-organic seed. NOP's Guidance should reiterate that certified operators may only use non-GMO, non-organic seed or planting stock. It's suggested that language is added to 4.1 of the guidance about sourcing seeds that are organic and produced without excluded methods.
- Increase the number of sources required to make an exception for a non-organic untreated variety (especially in at-risk crops).
- Limit the number of seasons the "3 sources" exception could be used on at-risk crops.

<sup>1</sup> Organic Seed Alliance, 2016. State of Organic Seed 2016. <http://stateoforganicseed.org/>

- Establish organic seed usage as a specific Organic System Plan goal, including plans for transitioning to organic varieties and reviewing increases by percentage used or acreage planted. A complete seed list of requests for exempted varieties and documented efforts to source and trial organic seed should be required at inspection.
- NOP should add the following language under section 4.2.1(b) of its final guidance: Records showing whether, from year to year, the operation has, through continuous improvement, increased the overall use of organic seed and planting stock. For example:
  - For row crops/field crops and specialty crops grown on substantial amounts of acres, the percentage of total crop acreage planted with organic seed and/or planting stock year after year would be an appropriate measure of improvement.
  - For specialty crops grown in diverse varieties on smaller acreages, an appropriate measure of improvement would be the number of organic varieties of seed and/or planting stock used year after year, rather than the acreage.
- Track efforts and demonstrate reasonable, measurable increases in the use of organic seed over time. Create a framework for methodically “closing the loophole”, using the percentage of total varieties available in organic form as the metric & threshold. (Made-up example: 51% of available broccoli varieties are available in organic form, therefore all broccoli seed must be organic).
- Encourage certifiers to require producers who do not demonstrate continuous improvement in the context of seed to do additional research in the form of consulting more than three sources and conducting on-farm organic variety trials, including providing the results to certifiers.
- NOP should provide examples of noncompliances through certifier trainings so that consistent and uniform adherence to reinforcing the present organic seed requirements must be enacted by ACAs.
- Address handlers that source seed for contractual growing purposes.
- The NOP should proactively work to encourage organic seed companies to participate in Organic Seed Finder and should include in the guidance an explicit reference for certifiers, inspectors, and producers to use this database as a seed-sourcing tool.

### Discussion Questions

1. Please provide input on the key points above.
2. Are there additional areas of the Seed Guidance in NOP 5029 that could be strengthened?
3. Are there ways to encourage increased organic seed use among larger producers?

### Subcommittee Vote

Motion to adopt the Discussion Document on Strengthening the Organic Seed Guidance

Motion by: Zea Sonnabend

Second: Harriet Behar

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Aluminum Sulfate  
July 19, 2016**

**Summary of [Petition](#):**

Chemtrade Chemical US LLC has petitioned for the inclusion of aluminum sulfate on the National List at §205.601 (Synthetic substances allowed for use in organic crop production) and §205.603 (Synthetic substances allowed for use in organic livestock production). The petition for inclusion on §205.603 was addressed by the Livestock Subcommittee. This proposal will address the petition for listing aluminum sulfate at §205.601. A [technical review](#) of aluminum sulfate was received in May, 2015.

Aluminum sulfate, commonly referred to as alum, is used in conventional livestock production as a litter amendment to reduce volatilized ammonia in livestock facilities. Ammonia is naturally produced in litter as manure decomposes: bacteria hydrolyze uric acid to urea, and then to ammonia. Ammonia is a gas, which is detrimental to animal health and performance, and to the health of workers in livestock production facilities.

Aluminum sulfate hydrolyzes water contained in the litter, producing aluminum hydroxide (precipitate) and sulfuric acid. The sulfuric acid supplies acid ions ( $H^+$ ) which react with ammonia ( $NH_3$ ) to form ammonium cations ( $NH_4^+$ ).

Ammonium cations combine with nitrate, sulfate and phosphate anions in the litter to form non-volatile salts that remain in the litter. This reduces ammonia volatilization, improving the atmosphere in livestock facilities, and also helps retain the nitrogen in the manure/litter, making the litter a higher nitrogen-containing soil amendment.

Aluminum also binds with phosphorus, producing an aluminum-phosphate complex, reducing the presence of soluble phosphorus. The petitioner presents this as an important feature of adding aluminum sulfate to livestock litter—as an environmental aid—to reduce the amount of soluble phosphorus in the litter in order to reduce phosphorus loss to water resources when the litter is applied to soils.

**Summary of Review:**

The Livestock Subcommittee, in its consideration of the petition to add aluminum sulfate at §205.603, did not think aluminum sulfate was necessary as a litter amendment in organic livestock production because other nonsynthetic materials that perform the same function of reducing ammonia volatilization from livestock litter are currently available and in use. The Livestock Subcommittee voted unanimously to not add ammonium sulfate at §205.603.

The rationale presented in the petition to add aluminum sulfate to §205.601, stated that aluminum sulfate could be considered an environmental aid, because aluminum will adsorb and bind phosphorus, potentially reducing phosphorus loss to water resources when litter is applied to soils. Excess phosphorus in the environment is a problem today, and when too much phosphorus gets into water bodies it causes algal growth and eutrophication.

In regions with many Concentrated Animal Feeding Operations (CAFOs) manure is sometimes applied to fields surrounding the CAFOs frequently, and at high rates, in order to dispose of excess manure. Also, for high nutrient-demanding crops (like corn), when manure is applied at rates needed to supply the nitrogen needs of the crop, the amount of phosphorus also added in the manure is often much higher than crop needs, resulting in the buildup of soil phosphorus in those fields over time.

Soluble phosphorus is naturally adsorbed and complexed with calcium, iron, aluminum and organic matter in soils, limiting soluble phosphorus levels and thereby reducing leaching losses to water resources. However, as phosphorus levels in soils increase beyond sufficiency levels for optimum crop yields, the solubility of phosphorus begins to increase exponentially. Under those conditions, a material to bind phosphorus to reduce its solubility can reduce leaching of phosphorus to water resources.

Organic crop producers are often challenged to be able to procure enough plant nutrients to meet their crop production needs, and are generally not motivated to build soil phosphorus up to levels that would result in excessive levels of soluble phosphorus. The National Organic Standards, Section 205.203(c), requires that “The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that **does not contribute to contamination of crops, soil, or water by plant nutrients**, pathogenic organisms, heavy metal, or residues of prohibited substances.” [Emphasis added.] Therefore, organic farmers are already required to manage their farming systems to prevent phosphorus contamination of water resources.

Aluminum can be phytotoxic in low pH soils. It is well documented that in low pH soils aluminum becomes more soluble and toxic to plants. Aluminum toxicity to plants results in reduced root systems, a variety of nutrient-deficiency symptoms, and reduced yields. Caution should be used in applying materials containing aluminum to soils with low pH. The acidic conditions of low-pH soils will solubilize aluminum hydroxide to  $Al_3^+$ .

In summary, the Crops Subcommittee does not think that aluminum sulfate is needed in organic crop production because: 1) Nonsynthetic alternatives to aluminum sulfate are available to control ammonia volatilization in livestock facilities. 2) Organic crop producers normally do not apply phosphorus at levels beyond sufficiency levels for optimum crop production, so excessive soluble phosphorus should not be a problem, 3) Adding aluminum to low-pH soils could contribute to phytotoxicity.

### Category 1: Classification

1. **For CROP use:** Is the substance Non-synthetic or Synthetic? Substance is synthetic. **Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.**

The manufacturing process for all the forms of aluminum sulfate included in the petition involves reacting liquid sulfuric acid with either bauxite ore containing aluminum hydroxide ( $Al(OH)_3$ ) and hydrated aluminum ( $Al_2O_3 \cdot 3H_2O$ ), or synthetic hydrated aluminum previously refined from bauxite. Bauxite ore is the main source of aluminum for the world and contains various aluminum minerals and two iron minerals (Amethyst Galleries 2014). The process creates hydrated aluminum sulfate per the following reactions:

From bauxite:  $3 H_2SO_4 + 2 Al(OH)_3 + 12 H_2O \rightarrow Al_2(SO_4)_3 \cdot 18 H_2O$  52

From hydrated aluminum:  $3 H_2SO_4 + Al_2O_3 \cdot 3H_2O + 12 H_2O \rightarrow Al_2(SO_4)_3 \cdot 18 H_2O$  53

The acidified formulation also contains synthetically produced sulfuric acid.

**2. Reference to appropriate OFPA category:**

**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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?**

The substance contains sulfur. The substance is not an inert ingredient. The substance aluminum sulfate is **not** classified by the EPA as an inert of toxicological concern (it is on EPA List 4 (2004)). The substance is, however, approved as an adjuvant, used pre-harvest, and is exempted from the requirement of a tolerance (40 CFR 180.920).

**Category 2: Adverse Impacts**

**1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

TR LINES 435-478:

Aluminum sulfate is being petitioned as an amendment to poultry litter for consideration in organic livestock application. Aluminum sulfate undergoes various chemical interactions with the poultry litter, altering several key chemical characteristics of the litter:

- The pH of the litter is reduced; however it is unlikely to fall below pH 7.0 in litter collected after the final grow out flock. Initially the treated litter pH does fall to about 5.7 and that pH is maintained for about 3-4 weeks (Moore et al. 2000) (Table 2).
- Aluminum sulfate reacts with water and naturally-occurring NH<sub>3</sub> in the litter to form NH<sub>4</sub><sup>+</sup>, thus stabilizing nitrogen and reducing NH<sub>3</sub> gas volatilization to the atmosphere. In the soil environment, NH<sub>4</sub><sup>+</sup> is transient and is either rapidly taken up by plants, microbially transformed to NO<sub>3</sub><sup>-</sup> which can be taken up by plants or lost to leaching, or anaerobically transformed by microorganisms to N<sub>2</sub> and N<sub>2</sub>O which are lost to the atmosphere (Halvin et al. 2005).
- Poultry litter is a significant source of NH<sub>3</sub> in the atmosphere, which causes formation of aerosol particles. It is also a source of nitric acid deposition to land or water bodies where it causes land and water acidification and nitrate pollution (NOAA 2000). Aluminum sulfate decreases atmospheric pollution of NH<sub>3</sub> by reducing litter pH, which converts NH<sub>3</sub> to water-soluble NH<sub>4</sub><sup>+</sup> (Shah et al. 2006). Incubation studies estimate approximately 14 g N / kg litter is lost from non-treated litter as NH<sub>3</sub>, while ammonia loss from litter treated with aluminum sulfate ranges between 0.7 to 4.07 g N / kg litter between the high and low application rates (Moore et al. 2000. Assuming 40,000 lbs. of litter for a 16,000 square foot poultry house containing 20,000 broilers (Moore and Watkins 2012), this represents a reduction of about 400 lbs. of NH<sub>3</sub>-N lost to the atmosphere over a 42-day period with low rates of aluminum sulfate, and about 560 lbs. of NH<sub>3</sub>-N at high rates of aluminum sulfate.

- Litter treated with aluminum sulfate contains less soluble phosphate ( $\text{PO}_4^{3-}$ ) than non-treated litter, as  $\text{Al}^{3+}$  reacts with  $\text{PO}_4^{3-}$  to form insoluble  $\text{AlPO}_4$  (Table 2). Although the total phosphorous concentration in the litter does not change greatly, phosphorous becomes less plant-available, and likelihood of phosphorous transport to surface water is reduced. Aquatic ecosystems tend to be phosphorous-limited, and phosphorous eutrophication of natural water bodies is reduced when land-applied litter is treated with aluminum sulfate. The insoluble aluminum phosphate is not available to plants as nutrients and instead stays in the soil as a mineral (Moore and Edwards 2005).
- Litter treated with aluminum sulfate contains both higher total aluminum and higher soluble aluminum than non-treated litter (Table 2); however, runoff from fields where aluminum sulfate-treated litter is applied does not contain significantly higher levels of aluminum than fields where non-treated litter is applied (Moore et al. 1998).
- Litter treated with aluminum sulfate contains higher total sulfur and higher soluble sulfur than non-treated litter (Table 2).
- Concentration of soluble arsenic is reduced by aluminum sulfate treatment due to arsenic co-precipitation by aluminum (Violante et al. 2006) (Table 2).

**2. What is 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?**  
**[\$6518(m)(2)]**

TR LINES 356-387:

**Toxicity:** Aluminum sulfate is considered a dry acid, and is an irritant to the skin and eyes (UN-LIO 2012). However, acidity created by the substance is neutralized by the litter, and litter applied to land generally has a near-neutral pH (Sims and Luka-McCafferty 2002).

**Mode of action:** Aluminum sulfate reacts with water to create acid, which reduces ammonia losses from litter in confined poultry operations. Furthermore, aluminum causes precipitation of phosphates, reducing phosphorus solubility in the land-applied litter (Moore and Watkins 2012).

**Breakdown products:** Breakdown products of aluminum sulfate include  $\text{Al}^{3+}$ ,  $\text{Al}(\text{OH})_2^+$ ,  $\text{Al}(\text{OH})_3$ ,  $\text{SO}_4^{2-}$ ,  $\text{HSO}_4^-$ , and  $\text{H}_2\text{SO}_4$ , and  $\text{H}_3\text{O}^+$  (McBride 1996). Aluminum phosphate ( $\text{Al}(\text{PO}_4)$ ) precipitate is also formed via reaction of  $\text{Al}^{3+}$  with phosphates in the litter (Warren et al. 2008).

**Toxicity of breakdown products:** Free  $\text{Al}^{3+}$  is a toxic species that increases in concentration as pH decreases, and typically reaches phytotoxic levels when pH falls below 5.0 (Havlin et al. 2005). Poultry litter without aluminum sulfate typically ranges in pH from 8.0 to 8.9 (Sims and Luka-McCafferty 2002). Shortly after aluminum sulfate application, pH of the litter decreases to about 5.7, but becomes neutralized (near pH 7.0) after 3-4 weeks due to reaction with  $\text{NH}_3$  in the poultry guano (Moore et al. 2000). Thus, although adding aluminum sulfate increases total concentration of aluminum, persistence of the toxic  $\text{Al}^{3+}$  species is not enhanced. In contrast, application of litter near pH 7.0 to acidic soils decreases solubility of toxic  $\text{Al}^{3+}$  (Moore and Edwards 2005).

**Persistence of the breakdown products:** Aluminum hydroxide and phosphates from aluminum sulfate addition to poultry litter are persistent in the soil after land application due to low solubility (Warren et al. 2008). Sulfates, however, are more soluble, serve as a source of sulfur for crop plants, or are lost to leaching (Havlin et al. 2005).

**Contaminants:** The primary contaminants present in the  $Al_2O_3$  precursor to aluminum sulfate include  $SiO_2$ ,  $Fe_2O_3$ , and  $Na_2O$ , and could carry through into the final aluminum sulfate product, however do not pose toxicological concerns (Carter and Norton 2007)

**3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

TR LINES 392-429:

Aluminum sulfate is a dry acid, and can create zones of high acidity if accidentally spilled. Acid damage severity from a concentrated spill is dependent on the quantity spilled, and also on the moisture available for reacting. If the spilled material does not come into contact with moisture, the majority of the material could be cleaned up before significant acidification occurs. . But, surfaces of most soils are typically fissured and loose, and sometimes moist, making complete soil cleanup unlikely. Aluminum sulfate is designated as a hazardous substance under the CERCLA (superfund), and discharges exceeding 5,000 lbs (2,270 kg) require notification to the U.S. Environmental Protection Agency (TABLE 302.4 40 CFR).

Localized environmental acidification has a profound impact on chemical equilibrium regulating biological systems. In the soil, acidic conditions cause enhanced solubility of the  $Al^{3+}$  species, which is toxic to plant roots. Furthermore, both  $H^+$  and  $Al^{3+}$  are more strongly adsorbed to soil cation exchange sites than calcium, magnesium, and potassium and cause potential soil depletion of these nutrients via leaching. Soil remediation of large aluminum sulfate spills can be accomplished with a liming agent to neutralize the acidity and reduce solubility of  $Al^{3+}$  (NIH 2014).

Aluminum sulfate is sometimes deliberately added to water bodies impaired by phosphorus eutrophication, but accidental discharge of large quantities could cause excessive water acidification and subsequent solubilization of  $Al^{3+}$  which is toxic to aquatic organisms (UN-ILO 2012).

Personal protective equipment should be used when applying aluminum sulfate in the poultry house, but no specific precautions are needed for handling spent litter treated with aluminum sulfate due to the high level of dilution in the litter. In the poultry house, any aluminum sulfate spills should be incorporated into the litter to prevent ingestion by the birds (Walker and Burns 2000). Applications of liquid ammonium sulfate are typically made by certified applicators due to transport restrictions (Moore and Watkins 2012).

Aluminum sulfate reduces environmental contamination of phosphorus in natural water bodies from surface litter applications, compared to non-treated litter. Moore and Edwards (2005) measured 340% greater cumulative phosphorus load in runoff water from non-treated litter than from treated litter in a paired watershed study.

The process of extracting bauxite ore has a deleterious impact on the environment through habitat degradation and fragmentation by roads, and through carbon emissions (Cooke 1999). After extraction, regulations in some countries require replacement of topsoil and other

remediation measures; however quality of land after remediation is unlikely to be equivalent to before-extraction parameters (Cooke 1999). Most of the bauxite extraction worldwide is for the production of aluminum oxide, and less than 5% of bauxite imported into the U.S. is used for other purposes including aluminum sulfate production (USGS 2014)

4. **Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].**

TR LINES 544-563:

Aluminum sulfate reacts with water to form sulfuric acid, which is an irritant. Aluminum sulfate is corrosive to the eyes; skin contact causes a rash and burning feeling, and inhalation causes throat and lung irritation (New Jersey Department of Health 2009). The magnitude of the toxic response to aluminum sulfate is completely dose-dependent, and the substance is permitted as a food additive in small quantities. Minor ingestion of dilute solutions causes stomach upset, while substantial ingestion can rarely cause hemorrhagic gastritis, circulatory collapse and multi-organ failure (United Kingdom National Poisons Information Service 1996).

Aluminum is a subject of medical contention with suspected links to Alzheimer's disease. Implications of a link between Alzheimer's disease and aluminum have been made for approximately 40 years. The current large body of research has not concluded specific roles of aluminum in contributing to Alzheimer's disease, but also has not dismissed aluminum as a non-contributor to the disease (Agency for Toxic Substances and Disease Registry 2008; Exeley 2001). Under FDA regulations, aluminum sulfate is generally recognized as safe (GRAS) as a food additive when used in accordance with good manufacturing or feeding practice (CFR 182.1125(b)).

Although aluminum sulfate has chronic toxicity for human exposure, use of the substance as petitioned should not have negative effects on human health. Use of the substance as petitioned decreases ammonia concentration in the atmosphere of poultry houses, which has a positive impact on both health of the birds and health of workers (Moore et al., 2000).

5. **Discuss any effects the substance may have 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. [§6518(m)(5)]**

TR LINES 485-522:

Aluminum sulfate is not applied while birds are in the poultry house. The substance is not applied before the first flock grow-out; however, it is systematically applied thereafter before every flock is exposed to the litter. Any spills or concentrations of the product should be dispersed into the litter to avoid consumption by young chicks (Walker and Burns 2000). As stated in the petition, aluminum sulfate is not applied to feed. In the event of accidental ingestion, aluminum sulfate is corrosive and irritating to the digestive system and kidneys of birds (Dumoncaux and Harrison 2013). In one study, Japanese quail fed aluminum sulfate as >0.10% of their diet reduced body weight accumulation, eggshell strength, plasma inorganic phosphorous, feed consumption, and egg production (Hussein et al. 1988). Physiological effects of aluminum sulfate intake by broiler chickens occurs at higher intake levels than quail, with decreases in weight gain when consumed at >0.93% of the diet. Higher concentrations of aluminum sulfate in the diet cause more severe depressions in weight gain, decreased bone strength, and serum phosphorous. At application rates of 100 g / kg litter, birds would need to

ingest 10% of total dietary intake as litter to exceed 0.93% aluminum sulfate in the diet, and the aluminum would need to be in the original non-reacted aluminum sulfate crystalline form which does not persist in the presence of moisture. Typical observed litter ingestion rates are below this threshold, ranging from 2% to 5% of daily dietary intake. Aluminum sulfate is toxic to poultry if directly ingested in large quantities, but not at levels expected from litter consumption (Huff et al. 1996). When aluminum sulfate is used, mortality decreases and poultry weight gain increases, indicating the birds are likely not suffering toxic effects from incidental aluminum sulfate ingestion from the litter (Walker and Burns 2000).

Deleterious effects of aluminum sulfate on the head, skin, feathers, or feet of poultry were not revealed in the literature review, but the material is an irritant (UN-LIO 2012). If aluminum sulfate remains in its original non-reacted dry form, there is potential for foot irritation. Producers can mitigate the potential of bird exposure by rototilling aluminum sulfate into the litter after application, and before birds are placed back in the poultry house. Liquid formulations are less likely to expose birds to concentrations of the chemical due to greater dispersal in the litter compared to dry formulations (Moore and Watkins 2012). Aluminum sulfate tends to dry out the litter, and in turkeys the use of aluminum sulfate decreased the incidence of foot pad dermatitis, which is associated with wet litter (Wu and Hocking 2011).

In addition to the phosphorous-fixing properties of aluminum sulfate, litter treated with aluminum sulfate inhibits microbial phosphorous mineralization from organic matter (Warren et al. 2008). Although the literature review did not reveal problems associated with salinity of litter treated with aluminum sulfate, treated litter contains higher levels of soluble  $\text{NH}_4^+$ , and sulfur; thus, the salinity is likely higher than non-treated litter. However, salt damage to crops at normal agronomic application rates is likely low due to dilution factors (Sims and Luka-McCafferty 2002). Effects on bird health are positive, as ammonia accumulation causes lung irritation to poultry (Walker and Burns 2000). Pathogen loads in the broiler house are reduced with aluminum sulfate, which combined with lower ammonia concentration in the air causes increased bird weight gain (Shah et al. 2006).

## **6. Are there any adverse impacts on biodiversity? (§205.200)**

Aluminum sulfate reacts with water and naturally-occurring  $\text{NH}_3$  in the litter to form  $\text{NH}_4^+$ , thus stabilizing nitrogen and reducing  $\text{NH}_3$  gas volatilization to the atmosphere. In the soil environment,  $\text{NH}_4^+$  is transient and is either rapidly taken up by plants, microbially transformed to  $\text{NO}_3^-$  which can be taken up by plants or lost to leaching, or anaerobically transformed by microorganisms to  $\text{N}_2$  and  $\text{N}_2\text{O}$  which are lost to the atmosphere (Halvin et al. 2005). Although nitrogen is more persistent in the litter, there is no effect on cumulative soil nitrogen accumulation compared to non-treated litter, as aluminum sulfate does not alter the organic fraction of the total nitrogen. (TR 443-449)

Litter treated with aluminum sulfate contains less soluble phosphate ( $\text{PO}_4^{3-}$ ) than non-treated litter, as  $\text{Al}^{3+}$  reacts with  $\text{PO}_4^{3-}$  to form insoluble  $\text{AlPO}_4$  (Table 2). Although the total phosphorous concentration in the litter does not change greatly, phosphorous becomes less plant-available, and likelihood of phosphorous transport to surface water is reduced. Aquatic ecosystems tend to be phosphorous-limited, and phosphorous eutrophication of natural water bodies is reduced when land-applied litter is treated with aluminum sulfate. The insoluble aluminum phosphate is not available to plants as nutrients and instead stays in the soil as a mineral (Moore and Edwards 2005). (TR 462-468)

Litter treated with aluminum sulfate contains both higher total aluminum and higher soluble aluminum than non-treated litter (Table 2); however, runoff from fields where aluminum sulfate-treated litter is applied does not contain significantly higher levels of aluminum than fields where non-treated litter is applied (Moore et al. 1998). (TR 469-472)

### **Category 3: Alternatives/Compatibility**

**1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

Alternatives to litter amendments include management practices such as proper air exchange in barns, removing caked areas and keeping litter areas dry.

TR LINES 569-581:

Clinoptilolite is a naturally-occurring aluminosilicate zeolite which can absorb ammonia, reducing volatilization to the atmosphere. The literature contains results of mixed efficacy for this material, with some reports of decreased ammonia in broiler house air, and other reports of increased atmospheric ammonia (Amon et al. 1997; Karamanlis et al. 2008; Shah 2006).

Agricultural lime can be applied to litter between flocks to increase litter pH, chemically inducing volatilization of large quantities of ammonia. The volatilized ammonia can then be removed by ventilation before birds are placed back in the poultry house. Removal of ammonia from litter in between flocks reduces ammonia concentration in air for the subsequent grow-out, but does not mitigate ammonia production during the grow-out compared to acidification products. Although lime does not decrease total atmospheric ammonia pollution like aluminum sulfate, phosphorous in the litter is stabilized by complexation with calcium at high pH to reduce eutrophication of natural water bodies after land application of the litter (Shah 2006).

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC the board did receive one public comment that stated there are OMRI listed poultry litter amendments currently in use and was provided information from a currently listed OMRI poultry litter amendment product on concerns they had with the TR on all litter amendments being brought forward in 2016. The commenter felt that the board should not approve additional poultry litter amendments when there are already OMRI-certified products being used in the marketplace.

**2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

No. This substance requires the use of sulfuric acid in its manufacture. Also, the proposed use of this substance to reduce soluble phosphorus in organic cropping systems assumes the presence of excessive phosphorus levels in soils on organic farms, which is not in keeping with the National Organic Standards or with a system of sustainable agriculture. Further, use of this substance in soils with low pH could result in aluminum toxicity to plants. Also, nonsynthetic alternatives exist to control ammonia volatilization in livestock facilities.

**Classification Motion:**

Motion to classify aluminum sulfate as synthetic  
Motion by: Francis Thicke  
Seconded by: Harriet Behar  
Yes: 6 No: 1 Abstain: 0 Absent: 1 Recuse: 0

**National List Motion:**

Motion to add aluminum sulfate at §205.601  
Motion by: Francis Thicke  
Seconded by: Harriet Behar  
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Soywax  
July 5, 2016**

**Summary of [Petition](#):**

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 saprophytic mushrooms grown on logs.

**Summary of Review:**

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 when it is hydrogenated, it undergoes a chemical change that does not happen naturally. Hydrogenation is the process whereby the poly- and mono-unsaturated oils are turned into saturated oils, solidifying them 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.

A proposal to add soy wax to §205.601 was considered at the April 2016 meeting in Washington, D.C., but was referred back to the Crops Subcommittee for further discussion.

The Crops Subcommittee supports the addition of soy wax made from non-GMO soybeans to the National List as an alternative to microcrystalline cheesewax, which is made from petroleum.

**Category 1: Classification**

1. For CROP use: Is the substance Non-synthetic or Synthetic? Substance is synthetic  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Yes, the soybean oil is hydrogenated, a process in which double bonds between carbon and hydrogen atoms in the oil are converted into single bonds to make saturated fats. This is a chemical (synthetic) process that is accomplished by the reaction of hydrogen with the oil at elevated temperature (140-225° C) in the presence of a nickel catalyst.

2. Reference to appropriate OFPA category:  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in

production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inert or of toxicological concern?

Yes, soy wax is used as a production aid

### **Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Vegetable oils are not very reactive chemically and they biodegrade readily in the soil.

2. What is 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? [§6518(m)(2)]

There should not be any because vegetable oils are not toxic and fully biodegrade in the soil. The breakdown products are carbon dioxide and water.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The process of hydrogenation involves dissolving hydrogen in soybean oil in the presence of heat and a nickel catalyst. No other chemical inputs are required or need to be disposed of.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

Hydrogenated soy oil is considered a trans-fatty acid, which has been shown to increase the risk of heart disease, so nutritionists recommend avoiding it in human diets. However, little--if any--soy wax is expected to be consumed in edible mushrooms that have been grown on logs treated with soy wax.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

Soy wax is hydrogenated soybean oil and is non-toxic and biodegradable in soil. Soybean oil is commonly used in livestock feeds.

6. Are there any adverse impacts on biodiversity? (§205.200)

There should not be any adverse impacts on biodiversity because soybean oil is nontoxic and readily degraded by soil organisms.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The currently used alternative is microcrystalline cheesewax, a synthetic made from petroleum, which is on the National List.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, it is more compatible than the petroleum-based material currently being used for mushroom production.

**Classification Motion:**

Motion to classify soy wax as synthetic

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National List Motion:**

Motion to add 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 soybeans grown without excluded methods if soy wax from organic soybeans is not commercially available.

Motion by: Francis Thicke

Seconded by: Emily Oakley

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
1-Methylcyclopropene (1-MCP)**

**July 5, 2016**

**Summary of Petition**

The NOSB Crops Subcommittee received a proposal for 1-Methylcyclopropene (1-MCP) to add to the National List at §205.601. The proposed use is as a post-harvest treatment for apples to delay fruit ageing and slow down ripening so that the apples can be stored for a longer period. It was noted that the condition of the fruit was improved after it is removed from storage until it reaches consumers. The product, as petitioned, is used in sealed storage rooms. A technical report was not requested for this material because there was sufficient information in the petition for the review.

1-Methylcyclopropene (1-MCP) binds to ethylene receptor sites and slows ethylene activity, thus slowing ripening. 1-MCP is a hydrocarbon gas with a similar structure to ethylene although it does not occur in nature. The ethylene receptor sites have a higher affinity for 1-MCP than ethylene. The generic material is always formulated with a natural sugar (alpha cyclodextrin) to stabilize the gas.

**Summary of Review:**

The Subcommittee notes that while the manufacturing process of this substance is proprietary, enough information was provided in the petition, including a link to the patent, that the NOSB can clearly determine that it is a synthetic material that does not occur in nature.

The Subcommittee discussion revolved around the points listed in the Category 3 compatibility section below. First, it is a synthetic substance that does not fit in the categories for exemptions given in OFPA [§6517(c)(1)(B)(i)]. Second, extending the storage life of a crop is not one of the criteria in OFPA [§6518(m)] that is used to evaluate materials. Lastly, there are alternative practices that can help with storage. The NOSB does not support the addition of synthetic materials to the National List in an effort to make a seasonal crop available year round.

**Category 1: Classification**

1. For CROP use: Is the substance Non-synthetic or Synthetic? This substance is synthetic. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.
2. Reference to appropriate OFPA category: NONE  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The substance is not used in the environment but in a closed room, so no potential to interact.

2. What is 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? [§6518(m)(2)]

1-MCP competes with ethylene for the ethylene receptor sites and due to its higher affinity selectively binds to the sites. According to the petition, 1-MCP is non-toxic and non-persistent, and this is cited by a reference to TOXNET. It is a gas in the atmosphere and has a half-life of 4.4 hours.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

A closed system is used for manufacture and the manufacturing facility meets all industry safety standards for environmental controls, recycling waste, and employee exposure.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

1-MCP has been used for more than 15 years. There are no residues in the fruit when it reaches the consumer.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

Not used in soil or environment.

6. Are there any adverse impacts on biodiversity? (§205.200)  
No. Not used in environment.

## Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are alternatives in the broad sense, although there are no other non-synthetic or allowed synthetic materials with a similar function. A key point in the petition is that no other practices or materials work as well once the fruit has left the storage room until it is sold. For this issue there is not alternative other than rapidly getting the fruit to market.

Alternatives noted by the Crops subcommittee include:

- Crop nutritional approaches to enable apples to store longer, such as increased calcium in the fruit.
  - Excellent harvest and post-harvest handling practices such as picking at the right time for storage, timely handling to get fruit into storage, and optimal storage conditions.
  - Use of varieties that store better than others, such as Goldrush, Enterprise, Granny Smith, and numerous heirloom apples.
  - For consumers, choosing fresh organic apples from the southern hemisphere in the apple off season.
2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

The substance is not compatible for a number of reasons. First, it is a synthetic substance that does not fit in the categories for exemptions given in OFPA [§6517(c)(1)(B)(i)]. Second, extending the storage life of a crop is not one of the criteria in OFPA [§6518(m)] that the NOSB must use to evaluate materials. Furthermore, there are alternative practices that can help apples store longer and the NOSB has been of the opinion that having a seasonal crops available year round is not a sufficient reason to add a synthetic material to the National List.

**Classification Motion:**

Motion to classify 1-Methylcyclopropene (1-MCP) as synthetic

Motion by: Zea Sonnabend

Seconded by: Emily Oakley

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National List Motion:**

Motion to add 1-Methylcyclopropene (1-MCP) at 205.601

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Ammonium Citrate  
September 6, 2016**

**Summary of [Petition](#):**

Alpha Chelates has petitioned for the inclusion of Ammonium citrate on the National List at §205.601 (synthetic substances allowed for use in organic crop production). Ammonium citrate is used as a chelating agent. Ammonium glycinate was petitioned at the same time for an equivalent use and will be addressed in a separate proposal.

Ammonium citrate, or citrate ammonium salt, is an amino acid. As an organic chemistry salt, it is reacted with trace metal salts of copper, iron, manganese, or zinc to form a chelate. The petitioner manufactures liquid micronutrient chelates using ammonium citrate as the chelating agent. Chelates are used to provide micronutrients that are readily available to plants in deficient soils.

Ammonium citrate is manufactured through a reaction of ammonium hydroxide and citric acid. The petition argues that approval of ammonium hydroxide is understood in the listing of ammonium carbonate in §205.601(e)(1) since it is a salt of ammonium hydroxide and carbonic acid (ammonium carbonate is listed for use “in insect traps only, no direct contact with crop or soil”). Further, the petitioner claims that since lignin sulfonate is listed as a chelating agent in §205.601(j)(4) and because OMRI approves the use of ammonium lignosulfonate, ammonium citrate should be allowed.

The petition states that chelated trace minerals are necessary in high pH soils because the simple metal micronutrient salts allowed in §205.601(j)(6)(ii) otherwise need to be applied at four to five times the rate of plant up-take because unchelated micronutrients precipitate quickly when they come into contact with soils high in pH. Additionally, the petitioner claims that although nonsynthetic chelating agents can be produced, they are incompatible with the manufacturing of chelates as a result of unpredictable variations in species and composition.

In addition to the information on ammonium citrate, the petition puts forth a case that the use of the term “chelating agent” in the regulations needs to be revisited. The petitioner contends that both the cation and anion of a salt approved for use as a chelating agent should be on National List. The petitioner requests that the NOP define which bases can be used to neutralize acids used to synthesize chelating agents. However, these claims and request are beyond the purview of this Subcommittee whose role in this case is the review of substances petitioned for inclusion on the National List.

**Summary of Review:**

Upon review of the petition, the Subcommittee determined that there was insufficient information in the justification statement regarding the necessity of the material for organic crop production. The Subcommittee sent a request to the petitioner, asking why the petitioned materials would be better than the nonsynthetic and/or synthetic chelating agents that are already allowed. The petitioner submitted an [addendum](#) but still did not completely address the question of alternatives. The addendum claims that there are no nonsynthetic substances, nor any substances already on the National List, that could be used in place of ammonium citrate. The petitioner subsequently volunteered a [second addendum](#).

Despite the submission of the second addendum, the petitioner did not make a convincing case that the permitted products already on the market are inadequate to meet farmers' needs. The petitioner does not provide evidence that chelates made with synthetic citrate are needed to replace lignin sulfonate and nonsynthetic chelating agents such as fulvic acids, humic acids, and nonsynthetic citrate currently in use by organic growers.

The Subcommittee did not request a technical review after determining that the petitioned material was not necessary for organic production.

The Subcommittee has concluded that the petitioned substance does not meet the OFPA criteria and therefore should not be added to the National List.

### **Category 1: Classification**

1. For CROP use: Is the substance Non-synthetic or synthetic? This substance is synthetic. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

No

2. Reference to appropriate OFPA category:  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No

### **Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Chelates occur in nature and are used at low rates in organic farming, so there should be no detrimental chemical interactions with other materials used in organic farming systems.

2. What is 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? [§6518(m)(2)]

Ammonium hydroxide and citric acid are introduced in a reaction vessel to produce ammonium citrate, a salt. The amino acid citric acid is neutralized by the alkali ammonium hydroxide. Ammonium citrate is reacted in a solution with copper, iron, manganese, or zinc salt to form a

liquid chelate of the given metal. Chelates are applied in low dosages; application rates for the chelates manufactured by the petitioner are 1.2-2.5 kg/ha.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The petition states that there is minimal chance of environmental or human contamination during the manufacturing process as the reaction takes place inside a sealed vessel. As stated above, the petitioned substance is an ingredient in a finished product and is converted into a metal salt chelate and is therefore not subject to questions of disposal. However, ammonium hydroxide is used in the manufacture of the substance, and ammonium hydroxide is produced by the reaction of ammonia with water. Ammonia can be harmful to human health and aquatic life if spilled or improperly handled.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

The petition states that “in the unlikely event of contact of reaction vessel contents with human skin, there is a very low level of hazard as the substance is at a low concentration, is not toxic, and can be easily washed off with water”.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

The Subcommittee is not aware of negative effects of the petitioned material on biological and chemical interactions in the agroecosystem.

6. Are there any adverse impacts on biodiversity? (§205.200)

None known.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as nonsynthetic and synthetic available materials. [§6518(m)(6)]

Alternatives to the petitioned substance exist and are currently in use, including lignin sulfonate, humic acids, fulvic acids, and nonsynthetic citrate.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Chelates occur naturally in soils, so chelates, *per se*, are not incompatible with a system of sustainable agriculture. However, overreliance on synthetic materials is not compatible with a system of sustainable agriculture. The subcommittee has determined that there are insufficient grounds for adding this substance to the National List as there are natural alternatives and one allowed synthetic already available.

**Classification Motion:**

Motion to classify Ammonium Citrate as synthetic  
Motion by: Emily Oakley  
Seconded by: Francis Thicke  
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National List Motion:**

Motion to add Ammonium Citrate as petitioned at §205.601  
Motion by: Emily Oakley  
Seconded by: Francis Thicke  
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Ammonium Glycinate  
September 6, 2016**

**Summary of the [Petition](#):**

Alpha Chelates has petitioned for the inclusion of Ammonium glycinate on the National List at §205.601 (synthetic substances allowed for use in organic crop production). Ammonium glycinate is used as a chelating agent. Ammonium citrate was petitioned at the same time for an equivalent use and will be addressed in a separate proposal.

Ammonium glycinate, or glycine ammonium salt, is an amino acid. As an organic chemistry salt, it is reacted with trace metal salts of copper, iron, manganese, or zinc to form a chelate. The petitioner manufactures liquid micronutrient chelates using ammonium glycinate as the chelating agent. Chelates are used to provide micronutrients that are readily available to plants in deficient soils.

Ammonium glycinate is manufactured through a reaction of ammonium hydroxide and glycine. The petition argues that approval of ammonium hydroxide is understood in the listing of ammonium carbonate in §205.601(e)(1) since it is a salt of ammonium hydroxide and carbonic acid (ammonium carbonate is listed for use “in insect traps only, no direct contact with crop or soil”). Further, the petitioner claims that since lignin sulfonate is listed as a chelating agent in §205.601(j)(4) and because OMRI approves the use of ammonium lignosulfonate, ammonium glycinate should be allowed.

The petition states that chelated trace minerals are necessary in high pH soils because the simple metal micronutrient salts allowed in §205.601(j)(6)(ii) otherwise need to be applied at four to five times the rate of plant up-take because unchelated micronutrients precipitate quickly when they come into contact with soils high in pH. Additionally, the petitioner claims that although nonsynthetic chelating agents can be produced, they are incompatible with the manufacturing of chelates as a result of unpredictable variations in species and composition.

In addition to the information on Ammonium glycinate, the petition puts forth a case that the use of the term “chelating agent” in the regulations needs to be revisited. The petitioner contends that both the cation and anion of a salt approved for use as a chelating agent should be on National List. The petitioner requests that the NOP define which bases can be used to neutralize acids used to synthesize chelating agents. However, these claims and request are beyond the purview of this Subcommittee whose role in this case is the review of substances petitioned for inclusion on the National List.

**Summary of Review:**

Upon review of the petition, the Subcommittee determined that there was insufficient information in the justification statement regarding the necessity of the material for organic crop production. The Subcommittee sent a request to the petitioner, asking why the petitioned materials would be better than the nonsynthetic and/or synthetic chelating agents that are already allowed. The petitioner submitted an [addendum](#) but still did not completely address the question of alternatives. The addendum claims that there are no nonsynthetic substances, nor any substances already on the National List, that could be used in place of Ammonium glycinate. The petitioner subsequently volunteered a [second addendum](#).

Despite the submission of the second addendum, the petitioner did not make a convincing case that the permitted products already on the market are inadequate to meet farmers' needs. The petitioner does not provide evidence that chelates made with synthetic glycinate are needed to replace lignin sulfonate and nonsynthetic chelating agents such as fulvic acids, humic acids, and nonsynthetic citrate currently in use by organic growers.

The Subcommittee did not request a technical review after determining that the petitioned material was not necessary for organic production.

The Subcommittee has concluded that the petitioned substance does not meet the OFPA criteria and therefore should not be added to the National List.

### **Category 1: Classification**

1. For CROP use: Is the substance Non-synthetic or Synthetic? Substance is synthetic.  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

No

2. Reference to appropriate OFPA category:  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No

### **Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Chelates occur in nature and are used at low rates in organic farming, so there should be no detrimental chemical interactions with other materials used in organic farming systems.

2. What is 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? [§6518(m)(2)]

Ammonium hydroxide and glycine are introduced in a reaction vessel to produce ammonium glycinate, a salt. The amino acid glycine is neutralized by the alkali ammonium hydroxide. Ammonium glycinate is reacted in a solution with copper, iron, manganese, or zinc salt to form a liquid chelate of the given metal. Chelates are applied in low dosages; application rates for the chelates manufactured by the petitioner are 1.2-2.5 kg/ha.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The petition states that there is minimal chance of environmental or human contamination during the manufacturing process as the reaction takes place inside a sealed vessel. As stated above, the petitioned substance is an ingredient in a finished product and is converted into a metal salt chelate and is therefore not subject to questions of disposal. However, ammonium hydroxide is used in the manufacture of the substance, and ammonium hydroxide is produced by the reaction of ammonia with water. Ammonia can be harmful to human health and aquatic life if spilled or improperly handled.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

The petition states that “in the unlikely event of contact of reaction vessel contents with human skin, there is a very low level of hazard as the substance is at a low concentration, is not toxic, and can be easily washed off with water”.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

The Subcommittee is not aware of negative effects of the petitioned material on biological and chemical interactions in the agroecosystem.

6. Are there any adverse impacts on biodiversity? (§205.200)

None known.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as nonsynthetic and synthetic available materials. [§6518(m)(6)]

Alternatives to the petitioned substance exist and are currently in use, including lignin sulfonate, humic acids, fulvic acids, and nonsynthetic citrate.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Chelates occur naturally in soils, so chelates, *per se*, are not incompatible with a system of sustainable agriculture. However, overreliance on synthetic materials is not compatible with a system of sustainable agriculture. The subcommittee has determined that there are insufficient grounds for adding this substance to the National List as there are natural alternatives and one allowed synthetic already available.

**Classification Motion:**

Motion to classify Ammonium glycinate as synthetic

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National List Motion:**

Motion to add Ammonium glycinate as petitioned at §205.601

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Potassium Cellulose Glycolate  
August 30, 2016**

**Summary of [Petition](#):**

Lamberti USA, Incorporated has petitioned for the inclusion of potassium cellulose glycolate on the National List at 7 CFR 205.601 (synthetic substances allowed for use in organic crop production) as a synthetic inert ingredient.

Potassium Cellulose glycolate, or Potassium Carboxymethylcellulose (CMC), is a chemically modified polymer derived from natural cellulose. The petition proposes to utilize Potassium CMC as a water filtration aid during irrigation and in combination with liquid fertilizers and nutrients.

Potassium CMC is manufactured from naturally occurring cellulose by replacing one or more reactive hydroxyl groups with carboxymethyl groups through etherification. This is achieved by treating cellulose with caustic soda to attain the alkali-cellulose complex. This is further reacted with Mono Chloroacetic Acid (MCA), and the result is CMC and Sodium Chloride. Sodium Glycolate is formed through a side reaction by the caustic soda on MCA. Pure grade CMC is obtained by removing impurities with an aqueous solvent treatment.

Potassium CMC is being petitioned for its water holding properties, delivering water more effectively to the plant's root zone. The petition claims that the material increases drip irrigation efficiency by approximately 30-40%.

**Summary of Review:**

The Subcommittee determined that water usage is not a criteria under OFPA, and there was insufficient information justifying the need for this material in an organic production system. Soil organic matter serves to naturally increase water holding capacity and retention. Managing for and fostering soil organic matter is a key element in a good organic system plan.

The Subcommittee did not request a technical review after deciding that the petitioned material was not necessary for organic production. The Subcommittee determined that the petitioned substance fails to meet the OFPA criteria and therefore should not be added to the National List.

**Category 1: Classification**

1. For CROP use: Is the substance Non-synthetic or synthetic? Substance is synthetic. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Potassium CMC is manufactured from naturally occurring cellulose and undergoes a synthetic chemical change.

2. Reference to appropriate OFPA category:  
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; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Potassium CMC is a List 4 Inert approved for food and nonfood uses. It is a low-risk polymer (40 CFR 723.250) and is exempted from a requirement of tolerance under FFDC section 408 when used in accordance with good agricultural practices.

### Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The petition states that potassium salt is petitioned to avoid increasing soil sodium content. As a component of plants, cellulose would not be expected to have detrimental interactions with other materials used in organic farming systems

2. What is 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? [§6518(m)(2)]

The petition relied on test results of carboxymethylcellulose, sodium salt (structurally identical to Potassium CMC except for the cation of the salt) as there are no test results available for the petitioned material. Average biodegradation rates were above 73%.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The petition presented results from EcoToxicological studies on fish and crustacean toxicity for carboxymethylcellulose, sodium salt with no toxicity detected.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

Results from acute toxicity tests on rats, short-term studies on rats, guinea pigs, rabbits, and dogs, and long-term and teratogenicity studies on mice and rats for carboxymethylcellulose, sodium salt were shown with minimal or no effects found. The safety data sheet supplied in the petition lists no hazard or precautionary statements but does note a European Union special provision that the substance may produce an allergic reaction.

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

The petition presents results from terrestrial toxicity studies measuring bean and corn seed exposure to applications carboxymethylcellulose, sodium salt in natural soil media with no reported effects.

6. Are there any adverse impacts on biodiversity? (§205.200)

None known.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

A primary goal of an organic system plan is maintaining or improving soil organic matter content through strategic management practices. Conservative tillage and no-till practices increase soil organic matter, decrease compaction, minimize water evaporation, and increase rain and irrigation water infiltration. Plant, mulch, and cover crop residues can increase water infiltration by preventing crusting and conserving water. Incorporated residues and compost improve soil fauna, whose activity increases aeration, opens pores, and decreases compaction. In turn, these attributes increase water penetration.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Synthetic water filtration materials are incompatible with a system of sustainable agriculture. Natural alternatives and good soil management practices exist, and water use is not an OFPA criteria. The subcommittee does not recommend adding this substance to the National List.

### **Classification Motion:**

Motion to classify potassium cellulose glycolate as synthetic

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

### **National List Motion:**

Motion to add potassium cellulose glycolate as petitioned at §205.601

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0



**National Organic Standards Board  
Crops Subcommittee Proposal  
Hydroponic/Aquaponics/Biaponics  
September 6, 2016**

**Introduction**

The National Organic Program (NOP) established a Hydroponic/Aquaponic Task Force (referred to as Task Force throughout) in 2015 to write a report to the National Organic Standards Board (NOSB) on whether hydroponic/aquaponic production should be allowed under the current organic regulations; and if not, how the regulations could or should be changed. The report was completed in July 2016<sup>1</sup> and now it is up to the NOSB to formulate the input from the report into recommendations.

The issues involved are complicated, not only because of lack of clarity in current regulations, but because of a continuum of growing methods for plants in containers and the lack of a clear set of definitions around containers, growing media, soil, and other terms both in the regulations and in general. Also, there have been contradictory statements from the NOSB in the past and gaps in the NOSB recommendations, which have resulted in gray areas that the NOP does not know how to address in rulemaking.

All of the ramifications are going to take time to sort through and work out by the NOSB Crops Subcommittee, with stakeholder input along the way. We have chosen to break this into three potential components or sections so that we can take a systematic approach to this complex issue. Two of the components will be presented at the Fall 2016 NOSB meeting while the third may be drafted in pending the outcome of the Part 1 proposal. For the purposes of moving forward with uniform terminology, from here on we will use the term "Biaponics," as suggested by the Task Force, to refer to the combined term "Hydroponic/Aquaponic" systems currently employed by organic hydroponic/aquaponics producers.

- Part 1 (this part) is whether Biaponics fits into the Organic Foods Production Act (OFPA) and the USDA organic regulations in CFR Part 205 (referred to throughout as the NOP rule). This is a proposal that will go before the NOSB in Fall 2016.
- Part 2 is a Discussion Document on container systems for solid substrates, including which ones could or should be allowed under the existing NOP Rule and/or which would require a change in the Rule, along with suggestions for what changes need to be made.
- Part 3 will be a Discussion Document on the standards needed for biaponic systems to be allowed under the NOP organic rules, along with possible limits on what sort of systems would qualify as Biaponics. This will occur for spring 2017 if the proposal in part 1 passes.

**Background**

The NOSB has made several past recommendations on the subject of greenhouse production, which have relevance to this discussion. In a 1995 *Standards for Greenhouses* recommendation, the following statement is made:

“Hydroponic production in soilless media to be labeled organically produced shall be allowed if all provisions of the OFPA have been met.”

This was before there was an NOP rule so the NOSB only had OFPA to guide them.

<sup>1</sup> [Hydroponic and Aquaponic Task Force Report, July 2016](#)

In 2010 the NOSB issued a recommendation titled *Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses)*. While this mostly focused on greenhouse production in containers with solid growing media, the following statement is made:

"Observing the framework of organic farming based on its foundation of sound management of soil biology and ecology, it becomes clear that systems of crop production that eliminate soil from the system, such as hydroponics or aeroponics, cannot be considered as examples of acceptable organic farming practices. Hydroponics" "...cannot be classified as certified organic growing methods due to their exclusion of the soil-plant ecology intrinsic to organic farming systems and USDA/NOP regulations governing them."

Furthermore, in 2009 a document titled *Soil-less Growing Systems Discussion Item* contains the following statement:

"In previous Crops Committee discussion documents, the question has been asked: "Should container culture based growing media (typically utilized in greenhouse systems) that are predominately compost and compostable plant materials be considered 'soil'?" As highlighted in earlier portions of this document, a foundational principle of organic farming is the practice of maintaining and nurturing soil health so as to foster the proliferation of the proper soil biology with their accompanying ecologies. Since all typical soil dwelling organisms, such as earthworms, insects, arachnids, protozoa, fungi, bacteria, and actinomycetes can thrive in a properly designed compost based growing media, producing the beneficial symbiotic ecological relationships found in soil, such growing media should be rightfully considered soil."

At the first meeting of the Hydroponic/Aquaponic Task Force in January 2016, the NOP presented information on where they thought there were gaps and inconsistencies in the past NOSB recommendations, both for hydroponics and for greenhouse growing systems in general. Their presentation included the following statement: "Further analysis and clarification is necessary because regardless of what position the NOSB ultimately takes on the issue of hydroponics and aquaponics, the NOP will likely need to undertake rulemaking. Rulemaking requires a comprehensive recommendation from the NOSB that addresses grey (*sic*) areas left by past recommendations."

The gray areas and gaps include the following (paraphrased from original):

- A clear explanation of the basis for each recommendation made.
- Acknowledging the continuum of production methods from field/soil to hydroponic and the role of compost or other biological growing media. Recommendations on each type of production and reasons for allowing or prohibiting.
- Guidelines are needed on exactly how different production types comply with provisions in regulations for soil fertility, rotation, and cover cropping.
- Definitions of vague terms including container, hydroponics, soil-less media, "compost-based", and soil ecology.
- How are OFPA and the NOP rule able to be consistent on other soilless production such as mushrooms, sprouts, aquatic plants and greenhouse in-ground systems?
- What is the justification for requiring soil (as opposed to cycling of resources, promoting ecological balance, and conserving biodiversity) but making an exception for cover crops, crop rotation, etc. when soil is not explicitly required in the regulations, but crop rotation is mandatory?
- Aquaponic systems are not specifically addressed in previous NOSB recommendations.

The lengthy report from the Task Force contains a lot more background information which is too extensive to cover here. Selected portions will be referenced below in the discussion section.

## **Relevant areas in the Rule**

### **Organic Food Production Act (OFPA)**

#### **§6504. National standards for organic production**

To be sold or labeled as an organically produced agricultural product under this chapter, an agricultural product shall—

- (1) Have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this chapter;
- (2) Except as otherwise provided in this chapter and excluding livestock, not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products; and
- (3) Be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

#### **§6512. Other production and handling practices**

If a production or handling practice is not prohibited or otherwise restricted under this chapter, such practice shall be permitted unless it is determined that such practice would be inconsistent with the applicable organic certification program.

#### **§6513. Organic plan**

... (b) Crop production farm plan

(1) Soil fertility

An organic plan shall contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring. ...

.... (g) Limitation on content of plan

An organic plan shall not include any production or handling practices that are inconsistent with this chapter.

#### **§6519. Recordkeeping, investigations, and enforcement**

(c) Violations of chapter

(1) Misuse of label.... (2) False statement.... (3) Ineligibility

### **National Organic Program Rule**

## **§205.2 Terms defined.**

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

*Field.* An area of land identified as a discrete unit within a production operation.

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

## **§205.202 Land requirements.**

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “organic,” must: (a) Have been managed in accordance with the provisions of §205.203 through 205.206;

## **§ 205.203 Soil fertility and crop nutrient management practice standard.**

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.
- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances....

## **§205.205 Crop rotation practice standard.**

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

- (a) Maintain or improve soil organic matter content;
- (b) Provide for pest management in annual and perennial crops;

## **§205.208 - 205.235 [Reserved]**

## Discussion

First and foremost, a standardized set of definitions must be adopted to discuss this successfully. Therefore a glossary is appended here of some of the most common definitions taken from the NOSB 2010 Recommendation and the Task Force Report, amended for this proposal.

The writers of OFPA were wise enough to leave many issues somewhat open-ended so that regulations could evolve over time. OFPA also contains several statements that can be perceived to conflict with each other. It then falls to the writers of the regulations to sort through the provisions to develop specific standards. Such is the case with §6512 cited above. This implies that since soil is not specifically mandated, and lack of soil is not specifically prohibited, such practices could be permitted if regulations were written to support them. This is in part what led to the 1995 NOSB statement that hydroponics could potentially be allowed if OFPA requirements were met, and this would be, through regulations, specific to how hydroponic systems are consistent with the rest of organic production. The 1995 NOSB realized that, at that time, hydroponics could not meet the requirements of OFPA, but wanted to leave the door open for future discussions.

The NOP rules as written do not have specific provisions for many specialized areas of production, including mushrooms, aquatic plants, greenhouse, container growing, apiary, or fish. Some of these have been promised for a long time. All of them involve alternative provisions to some of the current clauses in the regulation. In anticipation of this, sections 205.208 - 205.235 were put in as reserved. Under the umbrella of OFPA, such regulations could be recommended by the NOSB and then regulations written by the NOP (*in the future*). In the meantime there are certifiers who have figured out how to certify these operations, presumably with NOP oversight.

The 2010 NOSB made it very clear that they did not believe that hydroponic systems, as they understood them, were compatible with organic production and therefore they recommended that rules be written for "Terrestrial Plants in Containers and Enclosures" but not for hydroponics. They based this decision on the opinion that soil-plant ecology is intrinsic to organic farming systems and USDA/NOP regulations. However there were key gaps in their position:

- Using the parameter of a compost-based growing media without definition of how much compost or how much growing media. Also, there was no definition of soil provided.
- Not recognizing the similarities between crops grown to maturity in containers and hydroponic systems. There is a continuum in container production from plants getting nutrition from the growing media to plants solely getting nutrition from liquid sources. There needs to be specific parameters for growing media components and liquid-based nutrition in organic container systems.
- Not giving adequate reasons for why other soilless productions, such as aquatic plants, mushrooms or sprouts could be organic but not hydroponics.
- Proposing to exempt greenhouse production from crop rotations and cover cropping but not exempt hydroponics with enough reasons.

The decision before the NOSB now is whether to uphold the 2010 recommendation and fill in the gaps so that rulemaking can proceed on greenhouses and/or containers for solid growing media, or to make recommendations that would lead to rulemaking regarding what types of "bioponic" systems might be compatible with organics and what standards are needed to assure that they are.

Since either decision means that there is still a lot of work to do, we are putting forward a discussion document on how to "fill the gaps" by: justifying greenhouse production in the regulations, defining

containers and compliant growing media, discussing provisions of the NOP rule regarding natural resources, land use, rotations and nutrition, and where to draw the line in the continuum for containers.

It is worth noting that in 2016 there are 52 certified organic hydroponic/aquaponic operations and 69 certified operations who grow crops in containers.

### Advantages of Bioponics

As is pointed out in the Task Force report, bioponics has a long history in agriculture from societies that worked with limited resources in changing conditions. It has always involved innovation and shares many of the same principles behind organic farming such as recycling, water efficiency, and eliminating the use of toxic pesticides. It is an appropriate way to address challenges in farming as a whole, such as drought, food safety, limited arable land, and climate change. Practitioners have developed some wonderful systems that are fully integrated, use only materials on the National List and depend extensively on microbial action to provide plant health and nutrition. The introduction of fish to create an aquaponic system is especially creative, since it can address production of a protein source and integrate in situ fertilizer production to an integrated system.

In the Organic Integrity Quarterly from May 2014, a publication from NOP, they note that organic hydroponic production is allowed as long as the producer can demonstrate compliance with the USDA organic regulations. The Bioponics proponents of the Task Force cited this and the fact that certifiers are accepting Organic System Plans for such operations as approval. However the article does state that there may be additional guidance issued in the future for these methods.

The Task Force elaborated on the advantages of these systems, focusing on water conservation, increased food safety, disease suppression, nutrient conservation and retention, and soil conservation (because of not using any). They point out that most areas of the rules can be followed as written, including writing and implementing an Organic System Plan, keeping records, preserving natural resources, and using compliant inputs.

The justifications for how bioponic systems comply with §205.203 (soil fertility and crop nutrients) and §205.205 (rotations) are as follows (see rule wording above):

- §205.203 (a) – the lack of tillage and extraction of nutrients from soil is also a way to improve or maintain soil.
- §205.203 (b) – crop nutrient management and growing media fertility can be maintained without contributing to contamination by allowing proliferation of active biology which is equivalent to rotation, or cover crops.
- §205.203 (c) – contamination is avoided by growing in a controlled system and having compliant practices in place for discharges.
- §205.205 – rotation is accomplished by renewal of growing media at the end of each crop cycle or as appropriate for each crop. "As bioponic systems do not impact the soil organic matter below the system as would an in-ground crop, it is expected that the requirement of rotations and cover crops to maintain or improve such surrounding soil organic matter would be inapplicable to bioponic production." (Task Force report, p. 149).

The bioponics proponents of the Task Force have supplied language for a suggested rule change to §205.2 Terms defined and a new section §205.208 Bioponic Production Standard. Depending on the outcome of the vote below, we may need another discussion document on bioponic production,

including justification for it to be written into the rules and consistency with the "applicable organic certification program" (§6512 OFPA), as well as specific parameters and standards that apply regarding systems, growing media, "crop rotation", and possibly labelling.

#### Arguments against Hydroponics/Biaponics

Natural soils are generally about 95% (plus or minus) mineral matter by weight. Soil mineral particles (clay, silt and sand) are intimately intertwined and complexed with soil organic matter. This mineral/organic matter soil system provides habitat and food sources for soil microorganisms and creates pore spaces in soils for storing water and for air exchange with the atmosphere. The clay/humus complexes also serve a primary function of holding soil nutrients in reserve for plant uptake.

The maintenance and regeneration of this complex, living soil system is a biological process that requires continual recycling of organic materials within the soil system. Crop rotations and cover crops are also important to create and maintain healthy soils, which contribute to healthy plants. It is this complex soil system that pioneer organic farmers learned to work with and optimize, in contrast to the prevalent industrial, input-based model of agriculture that they rejected. Early organic certification standards reflected this system and required on-farm practices and use of materials that fostered soil health by means of managing crop residue, using livestock manures, composting, cover cropping and adding natural rock powders. (Task Force report p. 14). For this reason, many organic producers reject hydroponic and bioponic systems that are input-based rather than soil-based. Also, when bioponic operations pave over soil with cement or gravel, soil conservation goals are not met.

Loss of arable land and the need to feed a growing world population are also cited by the pro-bioponic advocates. Organic agriculture, with its focus on soil building and protection or enhancement of natural resources, offers the opportunity to continually improve land and other natural resources while producing crops, as well as transform land, which has been degraded by poor farming practices or is of low productive capability, to sustainable farming systems. While production of the crop in a bioponic system can require less water to grow the crop than field growing, this ignores the earth's water cycle, where "excess" water is not lost or wasted, but is continually recycled either by recharging the ground water resource or evaporating into vapor to produce rain, snow or fog. Lastly, unless there is careful attention paid to managing water runoff when siting and building hoop houses or greenhouses, the potential for soil erosion can be extreme. There are some areas of the United States, specifically California, which have experienced severe soil loss problems where many hoop houses are present.

#### **Recommendation**

The USDA/NOP regulations require proper stewardship toward improving and maintaining the soil ecology within an organic farming system for terrestrial plant production. Therefore the NOSB supports the decisions by previous boards by recommending that hydroponics, aeroponics, biaponics or aquaponics are not consistent with organic production due to their exclusion of the soil-plant ecology intrinsic to organic farming systems. We believe that action from this board would be needed to overturn the previous recommendation of the NOSB in 2010, and therefore the motion as worded would require a 2/3 majority.

The NOSB plans to work further on defining the systems and practices that are allowed, and delineating what is not allowed with regard to containers for solid substrate and growing media.

### **Committee Vote**

Motion to allow bioponics (including hydroponics, aeroponics, or aquaponics) as consistent with organic production under the provisions and recommendations to be developed by the NOSB in 2017.

Motion by: Zea Sonnabend

Seconded by: Emily Oakley

Yes: 2 No: 5 Absent: 0 Abstain: 0 Recuse: 0

## **Glossary of terms**

*Source in (Parentheses)*

**Aquaponics** – A system in which plants are grown in waste water from aquatic organisms, which in turn purifies the water. *(Task Force Report)*

**Aeroponics** – A variation of hydroponics in which plant roots are suspended in air and misted with nutrient solution. *(2010 NOSB Recommendation)*

**Bioponics** – A contained and controlled growing system in which plants in growing media derive nutrients from natural animal, plant and mineral substances that are released by the biological activity of microorganisms and delivered in water. *(Task Force Report with slight modification by CS)*

**Compost** – The product of a managed process through which microorganisms break down plant and animal materials, including allowed feedstock materials (either nonsynthetic substances not prohibited at § 205.602, or synthetics approved for use as plant or soil amendments), into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1 and processes it to a low final C:N ratio (in the range of 5:1 to 20:1). Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times. *(USDA organic rule)*

**Compost Tea** – A water extract of compost produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase, intending to maintain or increase (it may be brewed) the living, beneficial microorganisms extracted from the compost. *(Task Force Report)*

**Container** – Any vessel and associated equipment used to house growing media and the complete root structure of terrestrial plants and to prevent the roots from contacting the soil or surface beneath the vessel, such as, but not limited to, pots, troughs, plastic bags, floor mats, etc. *(Task Force Report)*

**Greenhouse** – Permanent enclosed structure that allows for an actively controlled environment used to grow crops, annual seedlings or planting stock. *(2010 NOSB Recommendation)*

**Hydroponics** – The growing of normally terrestrial vascular plants in mineral nutrient solutions with or without an inert growing media to provide mechanical support. *(Hybrid definition adopted by CS from Task Force report)*

**Growing media** – Material which provides sufficient support for the plant root system and enables the plant to extract water and nutrients. Used interchangeably with the term "substrate". *(Adopted by CS from Task Force and internet sources)*

**Microbial solution** – Growing solution used in bioponic production which is commonly composed of organic substances and a diverse ecosystem of beneficial microorganisms in water. *(Task Force Report)*

**Nutrient solution** – Growing solution used in traditional hydroponic production which is commonly composed of immediately plant-available soluble synthetic mineral salts in water *(Task Force Report)*

**Soil** – The outermost layer of the earth comprised of minerals, water, air, organic matter, and living organisms, in which plants grow. (Modified from *Task Force Report*)

**Soil Ecology** – A term used to describe the incredible diversity of organisms that live in the soil and the complex interactions between them that contribute to plant nutrition and plant and soil health. They range in size from the tiniest one-celled bacteria, algae, fungi, and protozoa, to the more complex nematodes and microarthropods, to the visible earthworms, insects, small vertebrates, and plants. (Hybrid definition adopted by CS from *Task Force report*)

**National Organic Standards Board  
Crops Subcommittee  
Discussion Document  
Container and greenhouse production: further clarifications  
September 6, 2016**

**Introduction**

Regardless of how a recommendation on bioponic comes out, the NOP has said that they do not have enough clarity to write rules for crops grown in greenhouses or containers with solid substrate. This Discussion Document will look at the gaps and inconsistencies in the 2010 NOSB recommendation on Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses) to fill in those gaps and justify the unresolved points.

The goal is to examine what is needed for growing plants to maturity in containers in order to be consistent with the organic regulations, to create definitions and standards for terms that were not precisely spelled out in the 2010 recommendation, and to create a stage for further rulemaking efforts if needed.

Each point below has a discussion section in which options and opinions from the Task Force report are mentioned. The Discussion Questions posed request public comment on which policy option or standards are preferred and why.

**Background**

The NOSB has made several past recommendations on the subject of greenhouse production which have relevance to this discussion. In a 1995 Standards for Greenhouses recommendation, the following statement is made:

Hydroponic production in soilless media to be labeled organically produced shall be allowed if all provisions of the OFPA have been met.

This was before there was an NOP rule so the NOSB only had OFPA to guide them.

In 2010 the NOSB issued a recommendation titled Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses). While this mostly focused on greenhouse production in containers with solid growing media, the following statement is made:

Observing the framework of organic farming based on its foundation of sound management of soil biology and ecology, it becomes clear that systems of crop production that eliminate soil from the system, such as hydroponics or aeroponics, cannot be considered as examples of acceptable organic farming practices. Hydroponics" "...cannot be classified as certified organic growing methods due to their exclusion of the soil-plant ecology intrinsic to organic farming systems and USDA/NOP regulations governing them.

Furthermore, in 2009 a document titled Soil-less Growing Systems Discussion Item contains the following statement:

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with their accompanying ecologies. Since all typical soil dwelling organisms, such as earthworms, insects, arachnids, protozoa, fungi, bacteria, and actinomycetes can thrive in a properly designed compost-based growing media, producing the beneficial symbiotic ecological relationships found in soil, such growing media should be rightfully considered soil.

At the first meeting of the Hydroponic/Aquaponic Task Force in January 2016, the NOP presented information on where they thought there were gaps and inconsistencies in the past NOSB recommendations, both for hydroponics and for greenhouse growing systems in general. Their presentation included the following statement, "Further analysis and clarification is necessary because regardless of what position the NOSB ultimately takes on the issue of hydroponics and aquaponics, the NOP will likely need to undertake rulemaking. Rulemaking requires a comprehensive recommendation from the NOSB that addresses grey (*sic*) areas left by past recommendations."

The gray areas and gaps include the following (paraphrased from original):

- A clear explanation of the basis for each recommendation made.
- Acknowledging the continuum of production methods from field/soil to hydroponic and the role of compost or other biological growing media. Recommendations on each type of production and reasons for allowing or prohibiting.
- Guidelines are needed on exactly how different production types comply with provisions in regulations for soil fertility, rotation, and cover cropping.
- Definitions of vague terms including container, hydroponics, soil-less media, "compost-based", and soil ecology.
- How are OFPA and the NOP rule able to be consistent on other soilless production such as mushrooms, sprouts, aquatic plants and greenhouse in-ground systems?
- What is the justification for requiring soil (as opposed to cycling of resources, promoting ecological balance, and conserving biodiversity) but making an exception for cover crops, crop rotation, etc. when soil is not explicitly required in the regulations, but crop rotation is mandatory?
- Aquaponic systems are not specifically addressed in previous NOSB recommendations.

The lengthy report from the Task Force contains a lot more background information which is too extensive to cover here. Selected portions will be referenced below in the discussion section.

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- (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

## **§6512. Other production and handling practices**

If a production or handling practice is not prohibited or otherwise restricted under this chapter, such practice shall be permitted unless it is determined that such practice would be inconsistent with the applicable organic certification program.

## **§6513. Organic plan**

... (b) Crop production farm plan

(1) Soil fertility

An organic plan shall contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring. ...

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An organic plan shall not include any production or handling practices that are inconsistent with this chapter.

## **§6519. Recordkeeping, investigations, and enforcement**

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Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must: (a) Have been managed in accordance with the provisions of §205.203 through 205.206;

### **§ 205.203 Soil fertility and crop nutrient management practice standard.**

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
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- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter

content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances....

#### **§205.205 Crop rotation practice standard.**

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

- (a) Maintain or improve soil organic matter content;
- (b) Provide for pest management in annual and perennial crops;

.....

#### **§205.208 - 205.235 [Reserved]**

### **Discussion**

First and foremost, a standardized set of definitions must be adopted in order to have a successful discussion. Therefore a glossary is appended here of some of the most common definitions taken from the NOSB 2010 Recommendation and the Task Force Report. Definitions taken from these two documents may be slightly amended for this discussion.

#### **1. Consistency with mushrooms, aquatic plants, seedlings, and other "soilless" culture.**

The Task Force report points out the following:

From this subcommittee's perspective, the recommendation could be bettered, and more easily accepted by the NOP, if it explained how each of these exceptions to the premise that crops be grown in soil; 1) are linked to soil, or 2) are not naturally living or growing in soil so there is no reason for farming them in soil. Furthermore, how each meets the Principles of Organic Production and Handling (NOSB, 2001) should be made clear.

They continue by pointing out that sprouts and wild harvest aquatic plants are addressed in the current organic regulations, and that the preamble to the final rule specifically states that additional standards would be needed for mushrooms and greenhouses.

The CS concurs with this analysis. Sprouting seeds is similar to a processing step for an organic product. Therefore the ingredient (seeds) must be certified organic. There are no inputs to the seeds to make them grow besides water which is an exempt handling ingredient. . The essential elements otherwise needed for plants to complete their lifecycle are not added because all the nutrition they need to the point of harvest is provided by the seed.

Wild Aquatic plants are covered under the wild crop section of the rules and the preamble specifically points out that the term "site" was used to replace "from land" in the proposed rule. This clarifies that wild aquatic plant certification was intended. However, there is now a large amount of aquatic plant farming occurring that would not be considered wild, and this is not covered in the current rules.

Seedlings, or transplants, are also specifically mentioned in the organic rules and must be certified organically grown, but are considered acceptable if raised in soil-less media. These are future crops that will spend most of their time growing in soil and the time to produce the transplant is short compared to the time in the ground.

Mushrooms are fungi, not plants, and that justifies that they don't have a direct link to soil. They are more similar to yeasts and microorganisms that may be grown on substrate that does not depend on minerals from soil. The parameters of their production may eventually need additional rulemaking but so far many mushrooms are able to be certified organic under the existing rules.

Cultivated plants in aquatic systems do not appear to be specifically allowed in the existing rules. This is true for both bioptic systems and cultivated aquatic plants in bodies of water.

## **2. Land Considerations and Natural Resources**

Regardless of where the container production is occurring, the land underneath the containers and the surrounding environment must be considered. The land underneath an outdoor operation must comply with the same provisions of the rule regarding land history and transition as other land. It must also be maintained or improved with respect to avoiding contamination. Land that has a building on top of it with an impermeable floor must comply with whatever practices are adopted for greenhouse or enclosure production.

The Task Force asked the NOSB to consider limiting the use of land where crops could be grown in the soil from being converted to container production. It also recommended limiting the conversion of non-organic container plants to organic by re-potting them in organic growing media.

Natural Resource conservation includes the resources of soil and water and wildlife. This must be addressed in an Organic System plan for a container growing system. This includes maintaining the condition of land underneath the container production, fate of any water or nutrient run-off from container production, and any positive actions taken to encourage biodiversity such as installing hedgerows, planting insectary plants amongst the containerized crop plants, and other similar techniques.

## **3. Rotation**

The NOSB 2010 recommendation noted that the intent of the rotation and cover cropping clauses in the rule could be met by similar practices with the same functions or goals as the crop rotation that are applicable to the operation. Such techniques might include mulching, replacing growing media (thus replenishing the soil system), planting hedgerows, adding microbial inoculants to stimulate existing populations, and recycling and composting used growing media. It was noted by the Task Force that the crop rotation requirement is already not enforced by some certifiers on greenhouse crops grown in soil and on perennial crops with limited water.

Canadian standards 7.5.12: "Soil regeneration and recycling procedures shall be practiced. The following alternatives to crop rotation are permitted: grafting of plants onto disease-resistant rootstock, freezing the soil in winter, regeneration by incorporating biodegradable plant mulch (for example, straw or hay), and partial or complete replacement of greenhouse soil or container soil, provided it is re-used outside the greenhouse for another crop."

## **4. Containers & Growing Media**

The 2010 NOSB recommendation on Terrestrial Plants in Containers does partially address production in containers. It specifies that the substrate in the container be based on compost and re-iterates the previous NOSB opinion that compost was equivalent to soil (see Background section from Bioptics proposal).

The weakness of the 2010 recommendation was that it didn't quantify "compost-based", nor did it put any limits on the volume of solid material that would be sufficient in a container in order for there to be an equivalent amount of biological activity occurring to the activity occurring in the ground. There was also no recognition of whether non-synthetic, carbon-based materials such as coir or peat moss could serve the same functions as soil in a container, especially over time and if inoculated with a diverse biological microbial population.

The statement from OFPA that fertility come "primarily through the management of the organic content of the soil" has been interpreted to mean that soluble fertilizers should not be the primary source of nutrients, but only a supplement to an overall program focused on crop rotations and amending with compost or manure. This is reflected consistently throughout NOSB recommendations from the past, from limitations on sodium nitrate or potassium chloride, to many rejected petitions that were requesting the addition of more soluble forms of nutrients to the National List.

In order to specify an appropriate size of container or characteristics of the growing media that are appropriate for organic production, there needs to be a comparison of the characteristics of container system vs. the soil system. The Task Force uses Bulk Density as a viable comparison factor. Mineral soils have a bulk density of 1.3 grams per cubic centimeter ( $\text{g}/\text{cm}^3$ ), while peat or coir-based media have a bulk density of only  $0.13 \text{ g}/\text{cm}^3$ , or one-tenth the bulk density of mineral soils. As compost or other high organic matter materials are added to peat or coir, the bulk density of the media will typically increase, along with the nutrient holding capacity.

A raised bed which has a liner between it and the ground is considered a container, even if the growing media is a foot deep. However, containers as referred to in this discussion are limited to those containing a solid substrate only. Liquid substrate containers are covered by the overall bioponics proposal/recommendation.

By making the containers large enough, the nutrients in the organic matter fraction will be able to supply the majority of nutrition for the plant. What is large enough? And how can it be explained in a way that is appropriate for different plants? The Task Force cites the work of Dr. Martine Dorais of Laval University and the Agassiz Research and Development Centre. At a volume of 100 to 180 liters of soil per  $\text{m}^2$ , Dr. Dorais has demonstrated that no liquid feeding is necessary, and fertility can be provided by the biological activity of the growing medium in the beds.

Both Canada and Sweden permit container growing while requiring minimum soil volumes based on growing area. Canada requires a minimum soil volume of 70 liters<sup>1</sup> per  $\text{m}^2$  of growing area. For staked crops like tomatoes and peppers they require at least 10% compost at the start of production and containers must be at least 30 cm (12 inches) high. They state in section 7.5.4: "Soil used in a container system, with the exception of transplants, shall provide nutrients to plants continuously. The soil (growth media) shall contain a mineral fraction (sand, silt or clay) and an organic fraction; it shall support life and ecosystem diversity."

The Canadian standards do not specify an amount of compost or soil for other crops such as lettuce or blueberries. They do not account for breakdown and settling of soil volume, it is unclear how certifiers can measure the soil volume, and the term "growing area" is not well defined.

In Sweden they require at least 30 liters of soil per  $\text{m}^2$  for annual crops with long seasons and 0.2 liters per pot for other plants such as herbs, lettuce and strawberries.

<sup>1</sup> For reference a 5-gallon pot holds 25 liters and a 10-gallon pot holds 40 liters.

The Task Force report states, "(t)ransplant and container growing methods would have more clarity if container growing media had a defined initial and temporal water and nutrient holding capacity and biology carrying capacity." It is possible to have a compost- or soil-based growing media with adequate aeration and water holding capacity that can provide enough fertility for production of annual plant crops or a season in the growth of perennial plants.

The Task Force Subcommittee that reviewed the 2010 NOSB recommendation is recommending that organic growing media must have a minimum of 20% compost.

In presentations given to the Task Force, it was mentioned that coir-based media amended with compost or compost tea can partially decompose into substrate with a high nutrient holding capacity similar to compost. No research on this has been presented, but over time, the bulk density of the media could increase along with microbial diversity. It might be appropriate to require only 5 or 10% compost in a coir-based media for perennial plants, which would more closely mimic a soil system that rarely has as much as 10% organic matter.

## **5. Nutrition**

The Task Force Report states, "(t)he key distinction between organic fertility management and conventional fertility management is that in organic the source of the bulk of the crop nutrients are from the biological activity decomposing complex organic molecules (compost, manures, seed meals, etc.) and the mineral fractions." Soil is important due to the interactions of the physical, chemical and biological properties together.

While the bioponics systems are sustainable in regards to nutrient recycling and water conservation, they do not have the complex interactions found in an organic soil-based system. The backbone of organic production is the complex interactions between soils, plants, animals and humans.

It would seem logical to assess the continuum between grown in the ground and fully liquid based systems by determining where the plant nutrition is coming from. If the nutrients are primarily coming from the "soil" or approved growing media and solid amendments, then they would be considered equivalent to in-ground production. Whereas a container production system that relies primarily on liquid fertilizers would not be within the requirement for soil-based systems.

The NOSB recognizes that some soils contain very little inherent fertility and crops are being grown and certified organic which rely in large part on liquid fertilizers. While this is an area that should perhaps be enforced more vigorously, this is outside the scope of this attempt to set standards for crops grown in containers. In order for container production to be certified organic, there may have to be greater efforts made than for growing crops in soil.

If there is a minimum soil volume requirement created to provide most nutrition from the soil, there may still need to be a limit set to how much of the plant's needs can be supplied by soluble liquid nutrients. For instance, the Soil Association in Britain limits the amount of nutrients that can be added after planting to no more than 50% of the total nutrients required. This applies to crops grown in the ground. Other standards for greenhouses limit liquid nutrients to 25% of the total nutrients supplied. A brand new revision to the Canadian standards<sup>2</sup> also proposes limits on liquid fertilizers by stating that

<sup>2</sup> 2016 amended draft of Canada Organic Standards, pp 44-45: [General Principles and Management Standards](#)

for small soil volumes there must be 70% of the nitrogen and phosphorus supplied by solid organic soil amendments that require an active soil ecosystem.

The Task Force Subcommittee that reviewed the 2010 recommendation is recommending that liquid nutrients be limited to 20% of the total nutrients supplied. No reasoning is given for being lower than the international standards in use.

The bioponics proponents claim that the mineralization of nutrients into forms that plants can take up is performed by microbial digestion in a bioponic system and that the microbial population and dynamics are equivalent to a "diverse soil ecology". The Crops Subcommittee questions this statement because no solid information was provided about the specific microbes and their roles, and because saying that "soil biology" can happen without soil is not substantiated by definition or data.

## 6. Other issues

The Task Force report included information about production in controlled indoor environments and electric vs. natural lighting. Some of the other international standards take up issues such as the use of energy and the sustainability of peat moss. At other times the issue of supplementing carbon dioxide in greenhouses through heating or adding an input have been brought up. We are not going to take up these topics until the others are worked out.

### Discussion Questions

1. For container production of crop plants which of the suggestions made in the discussion above should be recommended as standards? Why?  
For example, container size, amount of compost or soil in growing media, stipulation about liquid vs. solid nutrition sources, and varying requirements for different crop types.
2. Do you have other suggestions about certified organic container production?

Motion to accept the discussion document on container-based growing.

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

### Glossary of terms

*Source in (Parentheses)*

**Aquaponics** – A system in which plants are grown in waste water from aquatic organisms, which in turn purifies the water. (*Task Force Report*)

**Aeroponics** – A variation of hydroponics in which plant roots are suspended in air and misted with nutrient solution. (*2010 NOSB Recommendation*)

**Bioponics** – A contained and controlled growing system in which plants in growing media derive nutrients from natural animal, plant and mineral substances that are released by the biological activity of microorganisms and delivered in water. (*Task Force Report with slight modification by CS*)

**Compost** – The product of a managed process through which microorganisms break down plant and

animal materials, including allowed feedstock materials (either nonsynthetic substances not prohibited at § 205.602, or synthetics approved for use as plant or soil amendments), into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1 and processes it to a low final C:N ratio (in the range of 5:1 to 20:1). Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times. (*USDA organic rule*)

**Compost Tea** – A water extract of compost produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase, intending to maintain or increase (it may be brewed) the living, beneficial microorganisms extracted from the compost. (*Task Force Report*)

**Container** – Any vessel and associated equipment used to house growing media and the complete root structure of terrestrial plants and to prevent the roots from contacting the soil or surface beneath the vessel, such as, but not limited to, pots, troughs, plastic bags, floor mats, etc. (*Task Force Report*)

**Greenhouse** – Permanent enclosed structure that allows for an actively controlled environment used to grow crops, annual seedlings or planting stock. (*2010 NOSB Recommendation*)

**Hydroponics** – The growing of normally terrestrial vascular plants in mineral nutrient solutions with or without an inert growing media to provide mechanical support. (*Hybrid definition adopted by CS from Task Force report*)

**Growing media** – Material which provides sufficient support for the plant root system and enables the plant to extract water and nutrients. Used interchangeably with the term "substrate". (Adopted by CS from Task Force and internet sources)

**Microbial solution** – Growing solution used in bioponic production which is commonly composed of organic substances and a diverse ecosystem of beneficial microorganisms in water. (*Task Force Report*)

**Nutrient solution** – Growing solution used in traditional hydroponic production which is commonly composed of immediately plant-available soluble synthetic mineral salts in water (*Task Force Report*)

**Soil** – The outermost layer of the earth comprised of minerals, water, air, organic matter, and living organisms, in which plants grow. (Modified from *Task Force Report*)

**Soil Ecology** – A term used to describe the incredible diversity of organisms that live in the soil and the complex interactions between them that contribute to plant nutrition and plant and soil health. They range in size from the tiniest one-celled bacteria, algae, fungi, and protozoa, to the more complex nematodes and microarthropods, to the visible earthworms, insects, small vertebrates, and plants. (*Hybrid definition adopted by CS from Task Force report*)



**National Organic Standards Board  
Policy Development Subcommittee Proposal  
Policy and Procedures Manual Revision  
September 13, 2016**

**Introduction and Background**

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 NOSB. During public comment at the April 2016 NOSB meeting several additional suggested changes to the PPM were raised that were not directly addressed by that revision. The PDS has reviewed these additional suggested changes and proposes the following changes as listed in the table below. Not all items raised by the public or the Board have been addressed by the Subcommittee. Outstanding items will be forwarded to the PDS for ongoing consideration.

**Summary Table of Changes**

<b>Section</b>	<b>Change</b>
III.D	Role of the Administrative team is clarified.
III.I	Recordkeeping sections are clarified and include updated reference to relevant section of the general records scheduled 6.2 applicable to FACA committees as well as the GSA memo to CMO's on FACA disclosures.
IV.H	Revised sections on petitions and proposals to allow the NOSB to remove National List items by adding a proposal to remove to the work agenda. Former process was via public petition only.
VIII.C	Clarified order of procedures of rules under which the NOSB operates.
VIII.F	Clarified election of officers to require majority voting.
Appendix 2	Specified goal of publishing the next NOSB meeting docket as soon as possible after previous NOSB meeting to create an "open docket" for public input.

**Attachments**

Redlined version of the Policy and Procedure Manual comparing the draft September 13, 2016 to the April 26, 2016 version

**Proposal**

The NOSB moves to adopt the September 13, 2016 draft version of the Policy and Procedures Manual.

**Subcommittee Vote**

The NOSB Policy Development Subcommittee approves the three sections of this proposal as stated above.

Motion to accept the Policy and Procedures Manual (PPM) as edited

Motion by: Tom Chapman

Seconded by: Tracy Favre

Additional discussion: none

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

## NATIONAL ORGANIC STANDARDS BOARD

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### 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  
Revised April 26, 2016  
[Draft September 13, 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. This team is not a subcommittee and makes no decisions. All items needing further discussion or action are placed on the Executive Subcommittee agenda and are recorded in the Executive Subcommittee notes.

### **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 defined and handled in accordance with General Records Schedule ~~26, Item 2-6.2~~ or other approved agency records disposition schedule. This schedule is available online at: <https://www.archives.gov/records-mgmt/grs/grs06-2.pdf>. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Requests for records should be handled in accordance with the GSA March 14, 2000 memo that is available online here: <http://www.gsa.gov/portal/content/100785>. 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, documents provided to the board, a complete and accurate description of matters discussed and conclusions, and the outcome of voting. If not included in the minutes, a voting summary will be published that contains votes by member.

**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 Subcommittee's 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 [and NOP 3011, Procedure- National List Petition Guidelines, effective March 11, 2016.](#)

[In lieu of a formal petition, a subcommittee \(Livestock, Crops, Handling\) of the NOSB may propose to remove a material from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518\(m\) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H-2 in this PPM.\(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, classification of materials, or proposal to remove.**

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-, a reclassification of the substance, or removal of a 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 or proposal 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 or proposal 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**

No procedures or business of the NOSB shall be taken in conflict with OFPA, FACA or other pertinent laws (herein referred to as governing legislation). For parliamentary procedure, all motions and votes not covered under the governing legislation shall be governed by this Policy and Procedure Manual if directly addressed. If procedures, motions and votes are not directly addressed in the Policy and Procedures Manual, they shall be governed by Robert’s Rules of Order Newly Revised. 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 comment:** All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. 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.

- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. 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.
- 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 first nominee to receive a majority candidate receiving the greatest number of votes will be elected. If no nominee receives the majority of votes, the nominee with the least votes will be eliminated and a revote will occur with the remaining candidates. This process will be repeated until a nominee obtains a majority.
- 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.
- A nominee may withdraw at their discretion at any time.
- In the event of only one nominee for office, the vote may be by acclamation.

## 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
  - The NOP will strive to publish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" in which public comment can be received by the NOP and NOSB. Notwithstanding the above, the NOP will 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

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# POLICY AND PROCEDURES MANUAL

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**Draft Feb. 29, 2016**

# NATIONAL ORGANIC STANDARDS BOARD (NOSB) POLICY AND PROCEDURES MANUAL

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## XI. 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

## **XII. 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."

## **XIII. 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:

8. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
9. 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;
10. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
11. the effect of the substance on human health;
12. 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;
13. the alternatives to using the substance in terms of practices or other available materials; and
14. 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:

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

Work agenda items should be prioritized accordingly:

5. Substance evaluations (e.g., 5-year sunset review, petitions)
6. NOP requests to the NOSB
7. NOSB requests to NOP
8. 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.

### **4) 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.

#### **5) 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.

#### **6) 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:

- 8.** 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.
- 9.** 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).
- 10.** 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.
- 11.** 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.
- 12.** 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).”
- 13.** 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.

14. 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.

#### **XIV. 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:**

**8. The new NOSB Chair takes Office**

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

**9. Appointment of Subcommittee Chairs**

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

**10. Appointment of Subcommittee Vice Chair**

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

**11. 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.

**12. Review of Subcommittee Files**

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

**13. 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.

**14. 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**

#### **4. 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.

## 5. 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

## 6. 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:

7. **Introduction:** A brief summary of the issue or statement of the problem.
8. **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.
9. **Proposal:** A concise explanation of the recommended action.
10. **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.
11. **Public Comment:** A brief summary of the public comments
12. **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]).

#### **8. Steps in the material review process for a new petition:**

2. 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.
9. Subcommittee (SC) determines if a Technical Review (TR) is needed.
10. Technical Report is completed and sent to the Subcommittee for review.
11. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
12. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
13. The NOSB members analyze comments and votes on the proposal at the public meeting.
14. 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.

## **5. 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.

## **6. 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>

## 7. 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.

## XV. 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.

#### **XVI. 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.

#### **XVII. 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

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.

## XVIII. 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 comment:** All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. 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.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. 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.
- 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:
  4. Chair
  5. Vice Chair
  6. 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**

**3. 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.

#### **4. 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.

### **XIX. 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.

## xx. APPENDICES

### A. Appendix 1: FOUNDATIONS

#### 4. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

1.3 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.

1.4 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.

**5. 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?

**6. 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

### **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.
  - The NOP will strive to publish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" in which public comment can be received by the NOP and NOSB. Notwithstanding the above, the NOP will 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>

**National Organic Standards Board  
Policy Development Subcommittee Proposal  
Sunset Review - Efficient Work Load Reorganization  
August 9, 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 occurs in the 2/7 review cycle<sup>1</sup> (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) which has only 1 material set for review. The sum of materials for all years other than the 2/7 cycle is 31 (estimated). Reviewing 196 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 (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, often 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; i.e. materials that “sunset” in 2018 are being considered in 2016 by the NOSB.

<sup>1</sup> A Note of terminology used to talk about sunset review cycles. Sunset review cycles occur every five years in 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.

<b>Terminology used</b>	<b>Current Sunset Cycle</b>	<b>Next Sunset Review year</b>
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)

The advantages of a more even distribution of this work include:

- More balanced attention for individual materials, regardless of the date it was 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 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)).”

#### **DISCUSSION:**

The following will be observed to complete early review of 2/7 sunset items:

3/8 cycle excluded – Items will not be moved from the 2/7 to the 3/8 due to timing - items would need to be included in the 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 the sunset review date, 2018 materials need to be reviewed prior to 3/17/2017.

Only materials on the 2/7 cycle are subject to early review- Only items from the 2/7 cycle are being evaluated for an early review. Items on other cycles will remain where they are even if an 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.

Early Review – A list of the materials to be reviewed early are listed below as part of attachment A. 2/7 cycle materials will be added to the work agenda in spring of each year prior to the review year by request of the PDS. All other materials will remain on their current timelines. The materials will then be referred to the respective subcommittees. Work will cease for any material whose sunset date is modified from the 2/7 sunset cycle due to rulemaking, until such rulemaking, the subcommittees shall continue to work against the earlier review date. An early review of materials will be based on current information and known alternatives that are commercially available in the year they will be reviewed, and not on alternatives that may be available in 2022. If not mentioned below, sunset review shall occur along with the normal sunset materials for that cycle.

Material Removals – Farmers, livestock operations and handling operations need to operate under a predictable business environment. These businesses are planning operations and researching new

alternative materials on a 5-year cycle. 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 evenly distributed amongst the 4 years. Materials should be split by subcommittee 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. Similar items are grouped together (i.e. chlorine materials) as best as can be keeping in mind the restrictions above, and then sequentially distributed into each of the 4 years. Any grouping will be put in the year where the first item in the group is numbered. The PDS believes this proposal achieves efficiency by grouping like items for review, allowing for TRs 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.

### **Vote in Subcommittee**

Motion to accept this proposal on Sunset review efficient work load reorganization

Motion by: Tom Chapman

Seconded by: Jean Richardson

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Attachment A**

<b>NL Section</b>	<b>Substance</b>	<b>Current Sunset Date</b>	<b>Sub Committee</b>	<b>Next Projected Sunset Year</b>	<b>Proposed Sunset Review Year</b>
205.601(a)	Calcium hypochlorite	6/27/2017	CS	2022	2019
205.601(a)	Chlorine dioxide	6/27/2017	CS	2022	2019
205.601(a)	Ethanol	6/27/2017	CS	2022	2020
205.601(a)	Hydrogen peroxide	6/27/2017	CS	2022	2021
205.601(a)	Isopropanol	6/27/2017	CS	2022	2020
205.601(a)	Sodium hypochlorite	6/27/2017	CS	2022	2019
205.601(b)	Herbicides, soap-based	6/27/2017	CS	2022	2019
205.601(b)	Newspaper or other recycled paper	6/27/2017	CS	2022	2020
205.601(b)	Plastic mulch and covers (petroleum-based other than polyvinylchloride (PVC))	6/27/2017	CS	2022	2020
205.601(c)	Newspaper or other recycled paper	6/27/2017	CS	2022	2020
205.601(d)	Soaps, ammonium	6/27/2017	CS	2022	2021
205.601(e)	Boric acid	6/27/2017	CS	2022	2019
205.601(e)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(e)	Lime sulfur	6/27/2017	CS	2022	2020
205.601(e)	Oils, horticultural	6/27/2017	CS	2022	2021
205.601(e)	Sticky traps/barriers	6/27/2017	CS	2022	2019
205.601(e)	Sucrose octanoate esters	6/27/2017	CS	2022	2020
205.601(f)	Pheromones	6/27/2017	CS	2022	2021
205.601(i)	Copper sulfate	6/27/2017	CS	2022	2019
205.601(i)	Coppers, fixed	6/27/2017	CS	2022	2019
205.601(i)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(i)	Hydrated lime	6/27/2017	CS	2022	2020
205.601(i)	Hydrogen peroxide	6/27/2017	CS	2022	2021

205.601(i)	Lime sulfur	6/27/2017	CS	2022	2020
205.601(i)	Oils, horticultural	6/27/2017	CS	2022	2021
205.601(i)	Potassium bicarbonate	6/27/2017	CS	2022	2021
205.601(j)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(j)	Humic acids	6/27/2017	CS	2022	2019
205.601(j)	Liquid fish products	6/27/2017	CS	2022	2020
205.601(j)	Magnesium sulfate	6/27/2017	CS	2022	2021
205.601(j)	Soluble boron products	6/27/2017	CS	2022	2019
205.601(j)	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt	6/27/2017	CS	2022	2019
205.601(j)	Vitamin B1	6/27/2017	CS	2022	2019
205.601(j)	Vitamin C	6/27/2017	CS	2022	2019
205.601(j)	Vitamin E	6/27/2017	CS	2022	2019
205.601(k)	Ethylene	6/27/2017	CS	2022	2020
205.601(l)	Lignin sulfonate	6/27/2017	CS	2022	2021
205.601(o)	Microcrystalline cheesewax	3/15/2017	CS	2022	2020
205.602(a)	Ash from manure burning	6/27/2017	CS	2022	2021
205.602(d)	Lead salts	6/27/2017	CS	2022	2019
205.602(e)	Potassium chloride	6/27/2017	CS	2022	2020
205.602(f)	Sodium fluoaluminatate	6/27/2017	CS	2022	2021
205.602(i)	Tobacco dust (nicotine sulfate)	6/27/2017	CS	2022	2019
205.603(a)	Aspirin	6/27/2017	LS	2022	2020
205.603(a)	Atropine	6/27/2017	LS	2022	2021
205.603(a)	Calcium hypochlorite	6/27/2017	LS	2022	2019
205.603(a)	Chlorhexidine	6/27/2017	LS	2022	2019
205.603(a)	Chlorine dioxide	6/27/2017	LS	2022	2019

205.603(a)	Electrolytes	6/27/2017	LS	2022	2020
205.603(a)	Ethanol	6/27/2017	LS	2022	2020
205.603(a)	Fenbendazole	5/16/2017	LS	2022	2021
205.603(a)	Glucose	6/27/2017	LS	2022	2019
205.603(a)	Glycerine	6/27/2017	LS	2022	2020
205.603(a)	Hydrogen peroxide	6/27/2017	LS	2022	2021
205.603(a)	Iodine	6/27/2017	LS	2022	2021
205.603(a)	Isopropanol	6/27/2017	LS	2022	2020
205.603(a)	Ivermectin	6/27/2017	LS	2022	2021
205.603(a)	Magnesium sulfate	6/27/2017	LS	2022	2021
205.603(a)	Moxidectin	5/16/2017	LS	2022	2021
205.603(a)	Oxytocin	6/27/2017	LS	2022	2019
205.603(a)	Peracetic acid	6/27/2017	LS	2022	2021
205.603(a)	Phosphoric acid	6/27/2017	LS	2022	2020
205.603(a)	Sodium hypochlorite	6/27/2017	LS	2022	2019
205.603(a)	Tolazoline	6/27/2017	LS	2022	2019
205.603(a)	Vaccines	6/27/2017	LS	2022	2020
205.603(a)	Xylazine	6/27/2017	LS	2022	2021
205.603(b)	Copper sulfate	6/27/2017	LS	2022	2019
205.603(b)	Hydrated lime	6/27/2017	LS	2022	2020
205.603(b)	Iodine	6/27/2017	LS	2022	2021
205.603(b)	Lidocaine	6/27/2017	LS	2022	2019
205.603(b)	Mineral oil	6/27/2017	LS	2022	2020
205.603(b)	Procaine	6/27/2017	LS	2022	2019
205.603(b)	Sucrose octanoate esters	6/27/2017	LS	2022	2020
205.603(d)	Methionine	10/2/2017	LS	2022	2021
205.603(d)	Trace minerals	6/27/2017	LS	2022	2021
205.603(d)	Vitamins	6/27/2017	LS	2022	2021
205.605(a)	Alginate acid	6/27/2017	HS	2022	2021
205.605(a)	Attapulgate	8/3/2017	HS	2022	2019
205.605(a)	Bentonite	6/27/2017	HS	2022	2019
205.605(a)	Calcium carbonate	6/27/2017	HS	2022	2020
205.605(a)	Calcium chloride	6/27/2017	HS	2022	2021
205.605(a)	Citric acid	6/27/2017	HS	2022	2021
205.605(a)	Dairy cultures	6/27/2017	HS	2022	2021
205.605(a)	Diatomaceous earth	6/27/2017	HS	2022	2019
205.605(a)	Enzymes	6/27/2017	HS	2022	2021
205.605(a)	Flavors	6/27/2017	HS	2022	2020

205.605(a)	Lactic acid	6/27/2017	HS	2022	2021
205.605(a)	Magnesium sulfate	6/27/2017	HS	2022	2021
205.605(a)	Nitrogen	6/27/2017	HS	2022	2019
205.605(a)	Oxygen	6/27/2017	HS	2022	2020
205.605(a)	Perlite	6/27/2017	HS	2022	2021
205.605(a)	Potassium chloride	6/27/2017	HS	2022	2020
205.605(a)	Potassium iodide	6/27/2017	HS	2022	2021
205.605(a)	Sodium carbonate	6/27/2017	HS	2022	2019
205.605(a)	Yeast	10/21/2017	HS	2022	2021
205.605(b)	Acidified sodium chlorite	3/15/2017	HS	2022	2019
205.605(b)	Alginates	6/27/2017	HS	2022	2020
205.605(b)	Ascorbic acid	6/27/2017	HS	2022	2021
205.605(b)	Calcium citrate	6/27/2017	HS	2022	2021
205.605(b)	Calcium hydroxide	6/27/2017	HS	2022	2020
205.605(b)	Calcium hypochlorite	6/27/2017	HS	2022	2019
205.605(b)	Carbon dioxide	6/27/2017	HS	2022	2019
205.605(b)	Chlorine dioxide	6/27/2017	HS	2022	2019
205.605(b)	Diglycerides	6/27/2017	HS	2022	2020
205.605(b)	Ethylene	6/27/2017	HS	2022	2020
205.605(b)	Ferrous sulfate	6/27/2017	HS	2022	2021
205.605(b)	Hydrogen peroxide	6/27/2017	HS	2022	2021
205.605(b)	Magnesium chloride	6/27/2017	HS	2022	2019
205.605(b)	Magnesium stearate	6/27/2017	HS	2022	2020
205.605(b)	Monoglycerides	6/27/2017	HS	2022	2020
205.605(b)	Nutrient vitamins and minerals	10/21/2017	HS	2022	2021
205.605(b)	Phosphoric acid	6/27/2017	HS	2022	2020
205.605(b)	Potassium acid tartrate	6/27/2017	HS	2022	2019
205.605(b)	Potassium carbonate	6/27/2017	HS	2022	2020
205.605(b)	Potassium citrate	6/27/2017	HS	2022	2021
205.605(b)	Potassium phosphate	6/27/2017	HS	2022	2021

205.605(b)	Sodium citrate	6/27/2017	HS	2022	2021
205.605(b)	Sodium hypochlorite	6/27/2017	HS	2022	2019
205.605(b)	Sodium phosphates	6/27/2017	HS	2022	2019
205.605(b)	Sulfur dioxide	6/27/2017	HS	2022	2020
205.605(b)	Tocopherols	6/27/2017	HS	2022	2021
205.605(b)	Xanthan gum	6/27/2017	HS	2022	2020
205.606	Arabic gum	6/27/2017	HS	2022	2020
205.606	Carob bean gum	6/27/2017	HS	2022	2020
205.606	Casings	6/27/2017	HS	2022	2019
205.606	Celery powder	6/27/2017	HS	2022	2021
205.606	Fish oil	6/27/2017	HS	2022	2021
205.606	Fructooligosaccharides	6/27/2017	HS	2022	2020
205.606	Gelatin	6/27/2017	HS	2022	2021
205.606	Guar gum	6/27/2017	HS	2022	2020
205.606	Konjac flour	6/27/2017	HS	2022	2019
205.606	Lecithin—deoiled	3/15/2017	HS	2022	2020
205.606	Locust bean gum	6/27/2017	HS	2022	2020
205.606	Orange pulp, dried	3/15/2017	HS	2022	2021
205.606	Pectin (non-amidated forms only)	6/27/2017	HS	2022	2019
205.606	Seaweed, Pacific kombu	3/15/2017	HS	2022	2021
205.606	Wakame seaweed (Undaria pinnatifida)	6/27/2017	HS	2022	2021

**National Organic Standards Board (NOSB)**  
**Livestock Subcommittee**  
**Proposal to remove ivermectin (CAS # 70288-86-7) from the National List**  
**July 19, 2016**

**I SUMMARY:**

This proposal to remove ivermectin from §205.603 of the National List of Allowed and Prohibited Substances is made pursuant to the Organic Foods Production Act (OFPA), Section 6518, in accordance with NOP 3011 effective March 11, 2016, and in response to a petition to remove ivermectin submitted to NOP on June 26, 2016.

The NOSB finds that new information indicates that ivermectin should be removed from the National List, pursuant to Section 6518(m) of the OFPA, with particular reference to Criteria 2, 5, 6, and 7 at Section 6518(m) as cited below:

*(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;*

*(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) Its compatibility with a system of sustainable agriculture.*

**II BACKGROUND:**

The USDA standards prohibit the use of parasiticides in slaughter stock.

The use of synthetic parasiticides in organic production is strictly confined to emergencies. Synthetic 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 recently reviewed as part of the regular five-year Sunset process. All three materials have annotations and other language limiting usage.

In 2015 a comprehensive technical evaluation report (TR) on parasiticides was requested by the NOSB as part of its regular five year review of materials. A research bibliography is included in the technical report dated June 3, 2015. This research information is comprehensive in nature and reviews all aspects of use of ivermectin and comparisons with alternative herbal and synthetic parasiticides as well as management techniques on farms and ranches which can be used to reduce or eliminate use of parasiticides.

During 2015 the NOSB received public comment on ivermectin as part of the five year review for materials scheduled to Sunset in 2017. New information was provided which indicated that ivermectin was not always effective, that both moxidectin and fenbenzadole were also available for use, and that dung beetles, a critical component of good pasture management, are negatively impacted by use of ivermectin.

With strong stakeholder support from all sectors the Subcommittee recommended removing ivermectin from the National List by a vote of 5 yes, 1 no and 2 absences. However, during the second posting of this material, public comment from a sector of producers, notably in western states, indicated that ivermectin was their preferred parasiticide, in part because fenbenzadole requires veterinarian prescription. Therefore the final NOSB vote at the October 2015 NOSB Meeting was to reluctantly continue to list ivermectin, but to immediately review all the parasiticides as a group. This additional review resulted in a Recommendation to make some changes to the parasiticide annotations as follows:

- \* *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.*

This parasiticide recommendation of April 27 2016 passed unanimously, 15:0.

At that meeting the NOSB was again urged by a broad sector of stakeholders to petition to Remove ivermectin from the National List, based on the expectation that the April 27, 2016 Recommendation on parasiticides is approved by the NOP and is successful in the rulemaking process.

**Reference is also made to the following:**

**Technical Report:** 1999 Technical Advisory Panel Report (TAP)(fenbendazole, ivermectin); 2015 Technical Evaluation Report on parasiticides; fenbenzadole, ivermectin, moxidectin.

**Past NOSB Actions:** 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation.

4/27/16 Parasiticide Recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12

**Sunset Date:** 06/27/17

### III RELEVANT AREAS OF THE RULE:

#### **Section 205.603(a) – with language as recommended to NOP on April 27, 2016**

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 harvest of fleece or wool that is to be sold, labeled or represented as organic. 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)—milk or milk products from a treated animal cannot be labeled as approved for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats and sheep.

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

(iii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as approved for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats and sheep.

#### **Section 205.238 – with language as recommended to NOP on April 27, 2016**

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of parasiticides and regulate the use of 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.
  - (2) Dairy animals, as allowed under §205.603.
  - (3) Fiber bearing animals, as allowed under §205.603

#### **IV DISCUSSION:**

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures. Moxidectin and ivermectin are both in one class of parasiticides, and fenbendazole is in a separate class, relative to their modes of action. Some commenters suggested that it may be beneficial to keep one parasiticide from each class on the National List to allow rotation of parasiticides, prevent the development of resistance, and have alternatives in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas ivermectin and moxidectin are both approved for topical, subcutaneous and oral administration.

Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Ivermectin is not approved for use in dairy animals, and no milk withdrawal time has been established for ivermectin.<sup>1,2</sup>

Moxidectin is approved for use in cattle and sheep.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only ivermectin had sufficient votes 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.”* According to the meeting notes, *“It was the committee’s opinion, that (moxidectin) failed on Criteria 1, and that was the reason for the proposed annotation because of concern about the half-life of the material and impact on soil organisms.”* However, the Board noted then that moxidectin *“is also less problematic”* than ivermectin. Further, it should be noted that just before the NOSB vote on moxidectin, a board member corrected an error that had been part of the discussion leading to the annotation: it was brought up that the

<sup>1</sup><http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=128-409>

<sup>2</sup> <http://www.accessdata.fda.gov/scripts/animaldrugsatfda/>

2003 TAP review indicated the half-life of moxidectin in soil is two months, not six months as reported in the evaluation criteria document (which had led to support for the annotation).

Although the NOSB approved the addition of moxidectin to the National List in 2004, the US Department of Agriculture Secretary did not initially accept NOSB's recommendation because moxidectin was labeled as a macrolide antibiotic. However, subsequent clarification found that moxidectin belongs to the polyene class of macrolides, "which unlike their erythromycin counterparts do not possess antibiotic properties" (2015 TR lines 100 – 111). Moxidectin was then added to the National List.

In May 2008, fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when fenbendazole was added to the List, ivermectin (and possibly moxidectin) should come off the List (meeting notes, page 207).

Ivermectin is considered to be the most harmful to soil life of the three parasiticides listed. The 2015 TR indicates that the half-life for degradation of ivermectin is 127 days in soil. However, other sources indicate that the half-life of can be quite variable, depending on temperature and soil conditions. For example, the half-life of ivermectin in a soil/feces mixture was found to be 91 to 217 days during winter weather conditions and 7 to 14 days during the summer period.<sup>3</sup>

The 2015 TR includes the following: *"Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. Excreted ivermectin does delay the disappearance of dung pats, but does not affect earthworm populations or health. The delay in ivermectin treated soils may be the result of its toxicity to insects"* (2015 TR lines 580 – 583).

Ivermectin is more toxic to dung-dwelling insects than moxidectin: "The macrocyclic lactones (the class of parasiticides to which ivermectin and moxidectin belong) can be ranked in decreasing order of toxicity to dung-dwelling insects as abamectin>doramectin ≥ ivermectin > eprinomectin>>moxidectin" (TR 2015 Table 7).

Although ivermectin is not labeled for use in dairy animals of breeding age, it may be used under veterinary order under provisions of AMDUCA (TR line 321).

In its initial request for public comment, the Livestock Subcommittee asked the public: *"Are the three parasiticides (ivermectin, moxidectin and fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?"*

<sup>3</sup> Fate of Pharmaceuticals in the Environment and in Water Treatment Systems. 2008. Diana S. Aga ed., p. 128. CRC Press.

In the public response the most common comment received was that ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Recent research indicates that ivermectin has a negative impact on the agro-ecosystem in a number of ways, but especially on its impact on dung beetles which are critical for healthy pastures.

Ivermectin is rapidly adsorbed to soil and sediment. Up to 98% of the administered dose of ivermectin may be excreted as non-metabolized drug in feces (Horvat et al., 2012). Ivermectin does not appreciably leach from soil sediment (Krogh et al., 2008). Radio-chromatographic studies have shown the ivermectin half-life for degradation to be 127 days in soil and less than 6 hours in water (Prasse et al., 2009). The environmental burden on fields manured with feces from ivermectin treated animals ranges from 0.001 to 0.09 parts per billion (ppb) depending on animal species (Halley et al., 1989) (TR 2015, 568-573)

Ivermectin has very little solubility in water. The only route for entry into the environment is through animal excretion. Ivermectin has limited mobility in soil because it is lipophilic and tightly binds to soil particles. The half-life for degradation of ivermectin in soil can be as long 240 days in natural soil depending on the soil type. Degradation in water is much faster with a half-life as short as 2.9 days. Ivermectin is hydrolytically unstable at pH 6.3. Predicted environmental concentrations based on the introduction of manure to field is relatively low and on the order of 100 parts per billion (ppb).

Ivermectin is toxic to fish at concentrations between 3 and 17 ppb.

Generally, since its introduction, no risks from appropriate use of ivermectin have been established for the environment or for human health. However, it has been consistently shown that ivermectin is unacceptably toxic for larval forms of arthropod insects (dung organisms) and daphnids (Liebig et al., 2010; Oh et al., 2006). (TR 2015, 665-574)

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelmintic 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.

Ivermectin is no longer necessary as there are two synthetic parasiticides, fenbendazole and moxidectin which can be used in emergencies when preventive management practices have failed to control parasite load.

Further, the negative impacts of ivermectin on dung beetles in pastures and on rangelands is not compatible with a system of sustainable agriculture.

Grazing management and the use of safe pastures for calves and sheep after weaning is an important component of helminth control in organic farming. It is important to have (1) preventive grazing management such as delayed turn-out, change of pastures between seasons, (2) diluting grazing management: mixed or alternate grazing with other host species, (3) evasive grazing management like changing the pasture within the season, and (4) supplementary feeding in the spring.

Pasture management which includes grazing management using both goats and cattle has been found effective.

Organic farmers have found that there is a biological interdependence between animals and plants with the use of a “mixed farming” approach to grazing where (1) animals succeeded one another on the field to avoid species specific transfer of disease, i.e. dairy cattle, then sheep and goats, then beef cattle; (2) only composted animal wastes for fertilizer were used to avoid transfer of known disease agents to the soil and back to their livestock and (3) overcrowding and over grazing were avoided to prevent contact with potentially parasitic worms in various stages of development naturally following bacteria and fungus into specific plants and decomposing material (Sykes, 1949; Ingham, 1999). (TR 2015 932-938)

Organic farms tend to have a higher diversity of nematodes, since animals are not normally treated with anthelmintic drugs. Helminth diversity has been related to a lower intensity of infection in extensive goat breeding and in meat cattle (Caberet et al., 2002). (TR 2015, 924-931)

Identifying and treating animals that are severely affected by parasites while leaving healthy animals that are coping with the disease untreated and maintaining a reservoir of susceptible parasites has also been effective for reducing the use of parasiticides and suppressing the development of anthelmintic resistance. This is called the FAMACHA system. It provides for a method of identifying diseased sheep using the color of their conjunctiva from deep red in healthy sheep to white in sick sheep as a guide (van Wyk and Bath, 2002). (TR 2015 lines 905-913)

Many holistic products are available and effective for worming. Anthelmintic resistance is in part the result of improper use, e.g., the consequence of under dosing, mass therapy and the use of the same class of anthelmintics for prolonged periods of time (Villalba et al., 2014). Resistance to synthetic parasiticides is not a problem, if synthetic parasiticides are not used. Livestock production based on grazing and browsing systems is directly related to the use of plant resources (Alonzo-Diaz, 2014). 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 (Brunetti and Karreman, 2006). (TR 939-946).

**In Summary:**

When evaluating ivermectin with reference to the OFPA Criteria at 6518(m), this material clearly demonstrates:

- That it is toxic in the environment – Criteria 2;
- That it has a negative impact on dung beetles which are a critical component of good pasture management (pasture management is a requirement of organic farming) – Criteria 5;
- That there are two alternative synthetic parasiticides which can be used as alternative medications during an emergency; that high quality pasture and range management grazing techniques can reduce the need to use any parasiticide; and that there are many alternative herbal remedies – Criteria 6;
- That use of ivermectin is incompatible with a system of sustainable agriculture – Criteria 7.

**V RECOMMENDATION - MOTION TO REMOVE:**

That ivermectin (CAS # 70288-86-7) be removed from the National List §205.603.

**Vote in Subcommittee:**

Motion by: Jean Richardson

Seconded by: Harriet Behar

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Aluminum Sulfate  
June 21, 2016**

**Summary of [Petition](#):**

In August 2013 the NOP received a petition to add Aluminum Sulfate to the National List of synthetic substances allowed for use in organic livestock production 7 CFR 205.603 as a poultry litter treatment.

**Summary of Review:**

**Manufacture and Uses of the Substance:**

The intended and current use of aluminum sulfate is to be used as a poultry and livestock bedding amendment. Aluminum sulfate has been used in poultry, turkeys and livestock production for decades to safely and effectively protect animals and caretakers from volatilized ammonia that is generated from poultry and livestock manure, which accumulates in poultry and livestock bedding. For the sake of clarification, the term litter will be used synonymously with bedding and mixtures of used bedding and manure. Volatilized ammonia that occurs from the natural decomposition process in litter is the result of bacterial enzyme hydrolysis of uric acid to urea which is further hydrolyzed to ammonia (NH<sub>3</sub>). Ammonia has been shown to be detrimental to animal health, livability, well-being and overall live performance. Aluminum sulfate reacts with ammonia by donating acid ions, converting ammonia (NH<sub>3</sub>) to ammonium (NH<sub>4</sub><sup>+</sup>), a highly reactive ion that bonds with nitrates, phosphates and sulfates forming stable non-volatile ammonium salts that are retained in the litter, which improve the litter's nutrient value as a natural fertilizer. In addition to litter treatment in the poultry house, aluminum sulfate is being petitioned for use in organic crop production as a poultry litter additive. Litter treated with aluminum sulfate differs from non-treated litter, as it contains more total nitrogen and less soluble phosphorous, which increases the nitrogen fertilizer value and reduces phosphorous pollution of surface waters (Moore and Watkins 2012).

By retaining nitrogen in the litter through the conversion of NH<sub>3</sub> to NH<sub>4</sub><sup>+</sup>, and by binding soluble phosphorus, the fertilizer nutrient value of alum treated litter is improved. When land applied, litter that has been treated with alum contains bound soluble phosphorus that is utilized by plants on an as need basis. Plants have the ability to secrete acid from their roots to break the aluminum phosphate bonds re-solubilize phosphorus, making the essential nutrient available to plants. Aluminum sulfate in water treatment is classified as a flocculent and its function is to precipitate silica, minerals and organic material out of suspension. It is incorporated as one of the initial steps in municipal water purification. Aluminum sulfate based products have also been used for decades in municipal water treatment and lake restorations in the US and Canada. Over 50% of the municipal water in the US is treated with Chemtrade aluminum sulfate, the sponsor for this petition and aluminum sulfate is the most widely used water clarification chemical in the world.

Dry aluminum sulfate is applied using drop spreaders, and centrifugal (slinger) spreaders, varying in size and complexity depending on application demand. Liquid aluminum sulfate is applied using a vehicle designed with a storage tanks, a pump and a PVC spray wand equipped with stainless steel nozzles. Typical dry product application rates range from 50 to 200 lbs/1000 ft<sup>2</sup>. Typical liquid product application rates range from 20 to 55 gal/1000 ft<sup>2</sup>. Dry aluminum sulfate is either applied by the poultry

farmer or by custom applicators. Liquid aluminum sulfate and acidified aluminum sulfate products are applied by custom applicators.

The manufacturing process for all the forms of aluminum sulfate included in the petition involves reacting liquid sulfuric acid with either bauxite ore containing aluminum hydroxide (Al(OH)<sub>3</sub>) and hydrated aluminum (Al<sub>2</sub>O<sub>3</sub>·3H<sub>2</sub>O), or synthetic hydrated aluminum previously refined from bauxite. Bauxite ore is the main source of aluminum for the world and contains various aluminum minerals and two iron minerals (Amethyst Galleries 2014). The process creates hydrated aluminum sulfate per the following reactions:

From bauxite:  $3 \text{H}_2\text{SO}_4 + 2 \text{Al}(\text{OH})_3 + 12 \text{H}_2\text{O} \rightarrow \text{Al}_2(\text{SO}_4)_3 \cdot 18 \text{H}_2\text{O}$  52

From hydrated aluminum:  $3 \text{H}_2\text{SO}_4 + \text{Al}_2\text{O}_3 \cdot 3\text{H}_2\text{O} + 12 \text{H}_2\text{O} \rightarrow \text{Al}_2(\text{SO}_4)_3 \cdot 18 \text{H}_2\text{O}$  53

The acidified formulation also contains synthetically produced sulfuric acid.

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the board received one public comment that stated that there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not approve synthetic poultry litter amendments when there are already effective OMRI listed products being used in the marketplace.

### Category 1: Classification

1. **Substance is used for:** Livestock
2. **For LIVESTOCK use:**
  - a. Is the substance agricultural or non-agricultural? This substance is non-agricultural
  - b. If the substance is non-agricultural, is the substance: non-synthetic or synthetic. This substance is synthetic

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From hydrated aluminum:  $3 \text{H}_2\text{SO}_4 + \text{Al}_2\text{O}_3 \cdot 3\text{H}_2\text{O} + 12 \text{H}_2\text{O} \rightarrow \text{Al}_2(\text{SO}_4)_3 \cdot 18 \text{H}_2\text{O}$  53

The acidified formulation also contains synthetically produced sulfuric acid.

- 3. For LIVESTOCK:** This product would be listed at 205.603 Livestock Production-Synthetic. The substance contains sulfur. The substance is not an inert ingredient. Aluminum sulfate is **not** classified by the EPA as an inert of toxicological concern (it is on EPA List 4 (2004)). The substance is, however, approved as an adjuvant, used pre-harvest, and is exempted from the requirement of a tolerance (40 CFR 180.920).

## Category 2: Adverse Impacts

- 1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

TR LINES 435-478

Aluminum sulfate is being petitioned as an amendment to poultry litter for consideration in organic livestock application. Aluminum sulfate undergoes various chemical interactions with the poultry litter, altering several key chemical characteristics of the litter:

1. The pH of the litter is reduced; however it is unlikely to fall below pH 7.0 in litter collected after the final grow out flock. Initially the treated litter pH does fall to about 5.7 and that pH is maintained for about 3-4 weeks (Moore et al. 2000) (Table 2).
2. Aluminum sulfate reacts with water and naturally-occurring NH<sub>3</sub> in the litter to form NH<sub>4</sub><sup>+</sup>, thus stabilizing nitrogen and reducing NH<sub>3</sub> gas volatilization to the atmosphere. In the soil environment, NH<sub>4</sub><sup>+</sup> is transient and is either rapidly taken up by plants, microbially transformed to NO<sub>3</sub><sup>-</sup> which can be taken up by plants or lost to leaching, or anaerobically transformed by microorganisms to N<sub>2</sub> and N<sub>2</sub>O which are lost to the atmosphere (Halvin et al. 2005). Although nitrogen is more persistent in the litter, there is no effect on cumulative soil nitrogen accumulation compared to non-treated litter, as aluminum sulfate does not alter the organic fraction of the total nitrogen.

Poultry litter is a significant source of NH<sub>3</sub> in the atmosphere, which causes formation of aerosol particles. It is also a source of nitric acid deposition to land or water bodies where it causes land and water acidification and nitrate pollution (NOAA 2000). Aluminum sulfate decreases atmospheric pollution of NH<sub>3</sub> by reducing litter pH, which converts NH<sub>3</sub> to water-soluble NH<sub>4</sub><sup>+</sup> (Shah et al. 2006). Incubation studies estimate approximately 14 g N / kg litter is lost from non-treated litter as NH<sub>3</sub>, while ammonia loss from litter treated with aluminum sulfate ranges between 0.7 to 4.07 g N / kg litter between the high and low application rates (Moore et al. 2000). Assuming 40,000 lbs. of litter for a 16,000 square foot poultry house containing 20,000 broilers (Moore and Watkins 2012), this represents a reduction of about 400 lbs. of NH<sub>3</sub>-N lost to the atmosphere over a 42-day period with low rates of aluminum sulfate, and about 560 lbs. of NH<sub>3</sub>-N at high rates of aluminum sulfate.

3. Litter treated with aluminum sulfate contains less soluble phosphate (PO<sub>4</sub><sup>3-</sup>) than non-treated litter, as Al<sup>3+</sup> reacts with PO<sub>4</sub><sup>3-</sup> to form insoluble AlPO<sub>4</sub> (Table 2). Although the total phosphorous concentration in the litter does not change greatly, phosphorous becomes less plant-available, and likelihood of phosphorous transport to surface water is reduced. Aquatic ecosystems tend to be phosphorous-limited, and phosphorous eutrophication of natural water

bodies is reduced when land-applied litter is treated with aluminum sulfate. The insoluble aluminum phosphate is not available to plants as nutrients and instead stays in the soil as a mineral (Moore and Edwards 2005).

4. Litter treated with aluminum sulfate contains both higher total aluminum and higher soluble aluminum than non-treated litter (Table 2); however, runoff from fields where aluminum sulfate-treated litter is applied does not contain significantly higher levels of aluminum than fields where non-treated litter is applied (Moore et al. 1998).

5. Litter treated with aluminum sulfate contains higher total sulfur and higher soluble sulfur than non-treated litter (Table 2).

6. Concentration of soluble arsenic is reduced by aluminum sulfate treatment due to arsenic co-precipitation by aluminum (Violante et al. 2006) (Table 2).

**2. What is 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?  
[§6518(m)(2)]**

TR LINES 356-387

**Toxicity:** Aluminum sulfate is considered a dry acid, and is an irritant to the skin and eyes (UN-LIO 2012). However, acidity created by the substance is neutralized by the litter, and litter applied to land generally has a near-neutral pH (Sims and Luka-McCafferty 2002).

**Mode of action:** Aluminum sulfate reacts with water to create acid, which reduces ammonia losses from litter in confined poultry operations. Furthermore, aluminum causes precipitation of phosphates, reducing phosphorus solubility in the land-applied litter (Moore and Watkins 2012).

**Breakdown products:** Breakdown products of aluminum sulfate include  $Al^{3+}$ ,  $Al(OH)_2^+$ ,  $Al(OH)_3$ ,  $SO_4^{2-}$ ,  $HSO_4^-$ , and  $H_2SO_4$ , and  $H_3O^+$  (McBride 1996). Aluminum phosphate ( $Al(PO_4)$ ) precipitate is also formed via reaction of  $Al^{3+}$  with phosphates in the litter (Warren et al. 2008).

**Toxicity of breakdown products:** Free  $Al^{3+}$  is a toxic species that increases in concentration as pH decreases, and typically reaches phytotoxic levels when pH falls below 5.0 (Havlin et al. 2005). Poultry litter without aluminum sulfate typically ranges in pH from 8.0 to 8.9 (Sims and Luka-McCafferty 2002). Shortly after aluminum sulfate application, pH of the litter decreases to about 5.7, but becomes neutralized (near pH 7.0) after 3-4 weeks due to reaction with  $NH_3$  in the poultry guano (Moore et al. 2000). Thus, although adding aluminum sulfate increases total concentration of aluminum, persistence of the toxic  $Al^{3+}$  species is not enhanced. In contrast, application of litter near pH 7.0 to acidic soils decreases solubility of toxic  $Al^{3+}$  (Moore and Edwards 2005).

**Persistence of the breakdown products:** Aluminum hydroxide and phosphates from aluminum sulfate addition to poultry litter are persistent in the soil after land application due to low solubility (Warren et al. 2008). Sulfates, however, are more soluble, serve as a source of sulfur for crop plants, or are lost to leaching (Havlin et al. 2005).

**Contaminants:** The primary contaminants present in the Al<sub>2</sub>O<sub>3</sub> precursor to aluminum sulfate include SiO<sub>2</sub>, Fe<sub>2</sub>O<sub>3</sub>, and Na<sub>2</sub>O, and could carry through into the final aluminum sulfate product, however do not pose toxicological concerns (Carter and Norton 2007)

**3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

TR LINES 392-429

Aluminum sulfate is a dry acid, and can create zones of high acidity if accidentally spilled. Acid damage severity from a concentrated spill is dependent on the quantity spilled, and also on the moisture available for reacting. If the spilled material does not come into contact with moisture, the majority of the material could be cleaned up before significant acidification occurs. . But, surfaces of most soils are typically fissured and loose, and sometimes moist, making complete soil cleanup unlikely. Aluminum sulfate is designated as a hazardous substance under the CERCLA (superfund), and discharges exceeding 5,000 lbs (2,270 kg) require notification to the U.S. Environmental Protection Agency (TABLE 302.4 40 CFR).

Localized environmental acidification has a profound impact on chemical equilibrium regulating biological systems. In the soil, acidic conditions cause enhanced solubility of the Al<sup>3+</sup> species, which is toxic to plant roots. Furthermore, both H<sup>+</sup> and Al<sup>3+</sup> are more strongly adsorbed to soil cation exchange sites than calcium, magnesium, and potassium and cause potential soil depletion of these nutrients via leaching. Soil remediation of large aluminum sulfate spills can be accomplished with a liming agent to neutralize the acidity and reduce solubility of Al<sup>3+</sup> (NIH 2014).

Aluminum sulfate is sometimes deliberately added to water bodies impaired by phosphorus eutrophication, but accidental discharge of large quantities could cause excessive water acidification and subsequent solubilization of Al<sup>3+</sup> which is toxic to aquatic organisms (UN-ILO 2012).

Personal protective equipment should be used when applying aluminum sulfate in the poultry house, but no specific precautions are needed for handling spent litter treated with aluminum sulfate due to the high level of dilution in the litter. In the poultry house, any aluminum sulfate spills should be incorporated into the litter to prevent ingestion by the birds (Walker and Burns 2000). Applications of liquid ammonium sulfate are typically made by certified applicators due to transport restrictions (Moore and Watkins 2012).

Aluminum sulfate reduces environmental contamination of phosphorus in natural water bodies from surface litter applications, compared to non-treated litter. Moore and Edwards (2005) measured 340% greater cumulative phosphorus load in runoff water from non-treated litter than from treated litter in a paired watershed study.

The process of extracting bauxite ore has a deleterious impact on the environment through habitat degradation and fragmentation by roads, and through carbon emissions (Cooke 1999). After extraction, regulations in some countries require replacement of topsoil and other

remediation measures; however quality of land after remediation is unlikely to be equivalent to before-extraction parameters (Cooke 1999). Most of the bauxite extraction worldwide is for the production of aluminum oxide, and less than 5% of bauxite imported into the U.S. is used for other purposes including aluminum sulfate production (USGS 2014)

**4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

TR LINES 544-563

Aluminum sulfate reacts with water to form sulfuric acid, which is an irritant. Aluminum sulfate is corrosive to the eyes; skin contact causes a rash and burning feeling, and inhalation causes throat and lung irritation (New Jersey Department of Health 2009). The magnitude of the toxic response to aluminum sulfate is completely dose-dependent, and the substance is permitted as a food additive in small quantities. Minor ingestion of dilute solutions causes stomach upset, while substantial ingestion can rarely cause hemorrhagic gastritis, circulatory collapse and multi-organ failure (United Kingdom National Poisons Information Service 1996).

Aluminum is a subject of medical contention with suspected links to Alzheimer's disease. Implications of a link between Alzheimer's disease and aluminum have been made for approximately 40 years. The current large body of research has not concluded specific roles of aluminum in contributing to Alzheimer's disease, but also has not dismissed aluminum as a non-contributor to the disease (Agency for Toxic Substances and Disease Registry 2008; Exeley 2001). Under FDA regulations, aluminum sulfate is generally recognized as safe (GRAS) as a food additive when used in accordance with good manufacturing or feeding practice (CFR 182.1125(b)).

Although aluminum sulfate has chronic toxicity for human exposure, use of the substance as petitioned should not have negative effects on human health. Use of the substance as petitioned decreases ammonia concentration in the atmosphere of poultry houses, which has a positive impact on both health of the birds and health of workers (Moore et al., 2000).

**5. Discuss any effects the substance may have 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. [§6518(m)(5)]**

TR LINES 485-522

Aluminum sulfate is not applied while birds are in the poultry house. The substance is not applied before the first flock grow-out; however, it is systematically applied thereafter before every flock is exposed to the litter. Any spills or concentrations of the product should be dispersed into the litter to avoid consumption by young chicks (Walker and Burns 2000). As stated in the petition, aluminum sulfate is not applied to feed. In the event of accidental ingestion, aluminum sulfate is corrosive and irritating to the digestive system and kidneys of birds (Dumoncaux and Harrison 2013). In one study, Japanese quail fed aluminum sulfate as >0.10% of their diet reduced body weight accumulation, eggshell strength, plasma inorganic

phosphorous, feed consumption, and egg production (Hussein et al. 1988). Physiological effects of aluminum sulfate intake by broiler chickens occurs at higher intake levels than quail, with decreases in weight gain when consumed at >0.93% of the diet. Higher concentrations of aluminum sulfate in the diet cause more severe depressions in weight gain, decreased bone strength, and serum phosphorous. At application rates of 100 g / kg litter, birds would need to ingest 10% of total dietary intake as litter to exceed 0.93% aluminum sulfate in the diet, and the aluminum would need to be in the original non-reacted aluminum sulfate crystalline form which does not persist in the presence of moisture. Typical observed litter ingestion rates are below this threshold, ranging from 2% to 5% of daily dietary intake. Aluminum sulfate is toxic to poultry if directly ingested in large quantities, but not at levels expected from litter consumption (Huff et al. 1996). When aluminum sulfate is used, mortality decreases and poultry weight gain increases, indicating the birds are likely not suffering toxic effects from incidental aluminum sulfate ingestion from the litter (Walker and Burns 2000).

Deleterious effects of aluminum sulfate on the head, skin, feathers, or feet of poultry were not revealed in the literature review, but the material is an irritant (UN-LIO 2012). If aluminum sulfate remains in its original non-reacted dry form, there is potential for foot irritation. Producers can mitigate the potential of bird exposure by rototilling aluminum sulfate into the litter after application, and before birds are placed back in the poultry house. Liquid formulations are less likely to expose birds to concentrations of the chemical due to greater dispersal in the litter compared to dry formulations (Moore and Watkins 2012). Aluminum sulfate tends to dry out the litter, and in turkeys the use of aluminum sulfate decreased the incidence of foot pad dermatitis, which is associated with wet litter (Wu and Hocking 2011).

In addition to the phosphorous-fixing properties of aluminum sulfate, litter treated with aluminum sulfate inhibits microbial phosphorous mineralization from organic matter (Warren et al. 2008). Although the literature review did not reveal problems associated with salinity of litter treated with aluminum sulfate, treated litter contains higher levels of soluble  $\text{NH}_4^+$ , and sulfur; thus, the salinity is likely higher than non-treated litter. However, salt damage to crops at normal agronomic application rates is likely low due to dilution factors (Sims and Luka-McCafferty 2002). Effects on bird health are positive, as ammonia accumulation causes lung irritation to poultry (Walker and Burns 2000). Pathogen loads in the broiler house are reduced with aluminum sulfate, which combined with lower ammonia concentration in the air causes increased bird weight gain (Shah et al. 2006).

## **6. Are there any adverse impacts on biodiversity? (§205.200)**

Aluminum sulfate reacts with water and naturally-occurring  $\text{NH}_3$  in the litter to form  $\text{NH}_4^+$ , thus stabilizing nitrogen and reducing  $\text{NH}_3$  gas volatilization to the atmosphere. In the soil environment,  $\text{NH}_4^+$  is transient and is either rapidly taken up by plants, microbially transformed to  $\text{NO}_3^-$  which can be taken up by plants or lost to leaching, or anaerobically transformed by microorganisms to  $\text{N}_2$  and  $\text{N}_2\text{O}$  which are lost to the atmosphere (Halvin et al. 2005). Although nitrogen is more persistent in the litter, there is no effect on cumulative soil nitrogen accumulation compared to non-treated litter, as aluminum sulfate does not alter the organic fraction of the total nitrogen.

Litter treated with aluminum sulfate contains less soluble phosphate ( $\text{PO}_4^{3-}$ ) than non-treated litter, as  $\text{Al}^{3+}$  reacts with  $\text{PO}_4^{3-}$  to form insoluble  $\text{AlPO}_4$  (Table 2). Although the total

phosphorous concentration in the litter does not change greatly, phosphorous becomes less plant-available, and likelihood of phosphorous transport to surface water is reduced. Aquatic ecosystems tend to be phosphorous-limited, and phosphorous eutrophication of natural water bodies is reduced when land-applied litter is treated with aluminum sulfate. The insoluble aluminum phosphate is not available to plants as nutrients and instead stays in the soil as a mineral (Moore and Edwards 2005).

Litter treated with aluminum sulfate contains both higher total aluminum and higher soluble aluminum than non-treated litter (Table 2); however, runoff from fields where aluminum sulfate-treated litter is applied does not contain significantly higher levels of aluminum than fields where non-treated litter is applied (Moore et al. 1998).

Litter treated with aluminum sulfate contains higher total sulfur and higher soluble sulfur than non-treated litter

### **Category 3: Alternatives/Compatibility**

#### **1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

Alternatives to litter amendments include management practices such as proper air exchange in barns, removing caked areas and keeping litter areas dry.

TR LINES 569-581

Clinoptilolite is a naturally-occurring aluminosilicate zeolite which can absorb ammonia, reducing volatilization to the atmosphere. The literature contains results of mixed efficacy for this material, with some reports of decreased ammonia in broiler house air, and other reports of increased atmospheric ammonia (Amon et al. 1997; Karamanlis et al. 2008; Shah 2006).

Agricultural lime can be applied to litter between flocks to increase litter pH, chemically inducing volatilization of large quantities of ammonia. The volatilized ammonia can then be removed by ventilation before birds are placed back in the poultry house. Removal of ammonia from litter in between flocks reduces ammonia concentration in air for the subsequent grow-out, but does not mitigate ammonia production during the grow-out compared to acidification products. Although lime does not decrease total atmospheric ammonia pollution like aluminum sulfate, phosphorous in the litter is stabilized by complexation with calcium at high pH to reduce eutrophication of natural water bodies after land application of the litter (Shah 2006).

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the board received one public comment that stated there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not approve synthetic poultry litter amendments when there are already OMRI certified listed being used in the marketplace.

**2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

Yes, but it is unclear if this substance is needed in organic agriculture as alternatives exist. The subcommittee would like to pose the following questions:

1. Are there alternatives available to reduce Ammonia in poultry barns?
2. Do the alternatives work in the area of reducing or eliminating Salmonella that could be present in barns?

**Classification Motion:** Move to classify aluminum sulfate as petitioned as synthetic

Motion by: Ashley Swaffar

Seconded by: Harriet Behar

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Listing Motion:** Motion to add aluminum sulfate as petitioned at §205.603

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0



**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Sodium Bisulfate  
June 21, 2016**

**Summary of [Petition](#):**

In April 2014 the NOP received a petition to add Sodium Bisulfate to the National List of synthetic substances allowed for use in organic livestock production 7 CFR 205.603 as a poultry litter treatment.

**Summary of Review:**

Manufacture and Uses of the Substance:

The petitioned purpose for sodium bisulfate, in the form of the commercial product PLT<sup>®</sup>, is to control ammonia in poultry houses for all species of domestic fowl in the Galliformes order (includes chickens, turkeys, quail, pheasant, etc.) and Anseriformes, which includes waterfowl. It is intended as a topical litter and dirt pad treatment. It is not intended for use in feed, food or drinking water. It is being petitioned for addition to §205.603 as a poultry litter additive. According to the petitioner, litter amendments such as sodium bisulfate minimize ammonia volatilization, improve poultry health and maximize the litter's agronomic, environmental, and financial value.

Sodium bisulfate is used as a top dressing to poultry litter to control ammonia in poultry houses. It is widely used in the commercial poultry industry (Blake and Hess 2001). It is also used in the dairy industry to reduce bacterial counts in bedding and ammonia emissions, preventing environmental mastitis and calf respiratory stress (Sun, et al. 2008). Sodium bisulfate has been successfully used in commercial applications in a wide variety of animal housing types, including dry litter in broiler, turkey and layer facilities; deep bedding for horses (Sweeney, Scanlon, et al. 2000), swine and cattle; and free-stall and dry lot dairy housing systems. Specific application rates and application timings are necessary for reduction in environmental ammonia levels, as well as for reduction of food-borne pathogens and fly control purposes. Floor-raised poultry are typically kept on litter that starts out as new bedding and becomes a mixture of decomposing manure, spilled feed, feathers and bedding throughout the life of the flock. For commercial broiler houses in the U.S., bedding is typically placed in the poultry house once per year and then reused repeatedly over several flocks (Moore, et al. 1995). This is known as built-up litter. Built-up litter is a major source of volatilizing ammonia, and litter management is a key factor affecting ammonia levels and emissions. Sodium bisulfate is typically added to poultry litter prior to the placement of chicks. The high temperatures during brooding (28-34°C or 82-93°F) enhance ammonia volatilization at a time when chicks are most susceptible to the health challenges associated with elevated ammonia levels (more than 25 ppm).

Sodium bisulfate application rates of 93-100 lbs. per 1,000 ft<sup>2</sup> controlled ammonia levels for up to 30 day relative to the untreated control (McWard and Taylor 2000). By this time the critical brooding period is over. Multiple applications at the manufacturer's recommended rate in two-week intervals reduced ammonia concentration by 56.6% and 21.8% at days 42 and 57, respectively (Purswell, et al. 2013). Growth rate and feed efficiency were not affected by repeated additions of the sodium bisulfate litter amendment with the birds present.

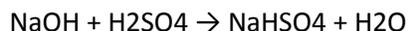
In addition to the control of ammonia levels in poultry houses, litter treatments have also been found to be effective in reducing litter microbial populations. This can be beneficial in controlling food-borne

pathogens such as Campylobacter and Salmonella (Line 2002). Reducing the level of microbial contamination of litter is also important when the litter is removed and used as a fertilizer. Potential contamination of fresh fruits and vegetables grown on fields with applied animal manures is an increasing food safety concern (Hanning, Nutt and Ricke 2009).

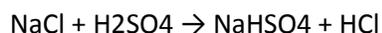
The use of sodium bisulfate as a litter amendment reduces atmospheric ammonia content and reduces the frequency and populations of the human pathogen Campylobacter. A further benefit discovered includes significant reductions in the population of darkling beetles, a common poultry house pest (Terzich 1997).

For many years sodium bisulfate has been used as a pH reducer in a variety of agricultural, industrial, and food applications. The anti-bacterial properties of sodium bisulfate have been exploited in its application as a toilet bowl cleaner (EPA Reg #1913-24-AA) and as a preservative in EPA method #5035 "Closed-System Purge-and-Trap & Extraction for Volatile Organics in Soil and Water samples" to prevent microbial activity leading to release of volatile organic compounds (VOC).

Historically sodium bisulfate is a by-product from the manufacture of nitric acid from sodium nitrate and sulfuric acid. The by-product is referred to as niter cake. Today there are two methods for producing sodium bisulfate. One involves mixing sodium hydroxide with sulfuric acid which will react to form sodium bisulfate and water as shown in the equation below. This method, produced by JOST Chemical® (Jost Chemical 2014), results in a sodium bisulfate monohydrate which is used as a laboratory reagent.



The petitioner states that they use another sodium bisulfate production method that involves reacting sodium chloride (salt) and sulfuric acid at elevated temperatures to produce sodium bisulfate and hydrogen chloride gas as shown in the equation below.



According to the petitioner, the liquid sodium bisulfate is then sprayed and cooled so that it forms solid beads. The hydrogen chloride gas produced is dissolved in water to produce hydrochloric acid, which may be sold as a by-product.

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the board received one public comment that stated there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not approve synthetic poultry litter amendments when there are already effective OMRI listed products being used in the marketplace.

### **Category 1: Classification**

- 1. Substance is used for:** Livestock
- 2. For LIVESTOCK use:**
  - a. Is the substance agricultural or non-agricultural? This substance is non-agricultural

b. If the substance is non-agricultural, is the substance: non-synthetic or synthetic. This substance is synthetic

**3. For LIVESTOCK:**

This product would be listed at 205.603 Livestock Production-Synthetic. Sodium bisulfate is a synthetic substance in that it is manufactured using a chemical process where sodium hydroxide interacts with sulfuric acid.

A) Sodium bisulfate contains sulfur (S) in the form of bisulfate (HSO<sub>4</sub><sup>-</sup>). It is not a toxin produced from bacteria. Sodium bisulfate is not a pheromone, horticultural oil, fish emulsion, treated seed, vitamin or mineral. Although not a soap, sodium bisulfate is a key ingredient in several cleansers. Sodium bisulfate is not a livestock parasiticide or medicine. It is not a physical production aid such as netting, insect trap, sticky barrier, etc. It does function as a production aid in that it is a litter amendment to control ammonia levels in the poultry house.

B) Sodium bisulfate is an inert ingredient which is not listed on EPA List 4 (7 U.S.C. §6517(c)(1)(B)(ii)), but is exempt from a requirement of a tolerance per 40 CFR part 180. An EPA final rule published in the Federal Register (Federal Register 2014) established an exemption from the requirement of a tolerance of residues of sodium bisulfate when used as an inert ingredient in antimicrobial formulations on food contact surfaces. This exemption applies to its use in public eating places, dairy processing equipment and food processing equipment and utensils at no more than 2,000 ppm in final formulation. The regulation was effective June 6, 2014.

**Category 2: Adverse Impacts**

**1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

TR LINES 434-441

Sodium bisulfate should not be mixed with chlorine bleach or ammonia cleansers. In addition, sodium bisulfate should not be mixed with sodium carbonate or sodium hypochlorite, which are both approved substances for use in organic production. Sodium carbonate is a §205.605 (a) nonsynthetic allowed substance, and may be used as a natural cleaning product on organic operations. Sodium hypochlorite is on §205.601 as a synthetic allowed as an algacide, disinfectant and sanitizer. Sodium hypochlorite is also on §205.603 as a synthetic allowed for disinfecting and sanitizing facilities and equipment. Sodium sulfate should not, therefore, be used when sodium hypochlorite has been used for disinfecting and sanitizing poultry facilities.

**2. What is 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? [§6518(m)(2)]**

TR LINES 346-368 and 375-387

Sodium bisulfate is hygroscopic in that it attracts water. Sodium bisulfate dissociates completely in water into sodium (Na<sup>+</sup>), hydrogen (H<sup>+</sup>) and sulfate (SO<sub>4</sub><sup>2-</sup>). As a mineral acid, sodium bisulfate is not expected to contaminate ground water or soil or to accumulate in the food chain (EPA 1993).

Without the addition of the sodium bisulfate, the nitrogen present in the litter would be lost as volatile ammonia. Sodium bisulfate captures this nitrogen, increasing the nitrogen content of the litter (Choi and Moore Jr. 2008). Sodium bisulfate-treated chicken litter also provides a nitrogen source in a form that plants can use immediately (ammonium sulfate). Ammonium sulfate is available to plants as a nitrogen source. In the soil the ammonium ion is released and forms a small amount of acid, lowering the soil pH while contributing nitrogen for plant growth. In commercial fertilizers, nitrogen is supplied in the form of ammonium nitrate. The nitrogen content of ammonium sulfate is lower – 21% nitrogen and 24% sulfur, compared to ammonium nitrate (NH<sub>4</sub>NO<sub>3</sub>) with 34% nitrogen.

Bacterial levels in poultry litter have been shown to decrease as pH decreases. The use of PLT<sup>®</sup> has been shown to reduce survivability of E. coli and Salmonella in broiler house litter (Pope and Cherry 2000). As such, sodium bisulfate may be a beneficial component for pathogen reduction, and could play a role in an on-farm HACCP (Hazard Analysis and Critical Control Points) program, although further research is needed (Pope and Cherry 2000).

PLT<sup>®</sup> is reported to be 93.2% pure, with 6.8% sodium sulfate as an impurity. Sodium sulfate is also produced in the reaction of sodium bisulfate and ammonia, but has not been shown to be a concern for the welfare of the flock or the environment. In fact, sodium sulfate can be used as a source of sodium without chloride in poultry diets (Jankowski, et al. 2011).

The mode of action of sodium bisulfate with ammonia is unrelated to the type of litter used. The only effect of litter type is the amount of moisture and thus the amount of ammonia produced. For example, sand, grass and newspaper litters volatilize greater amounts of ammonia than wood shavings (Garces, Chilundo and Jairoce 2013). Bedding materials help absorb moisture, limiting the production of ammonia gas and growth of harmful pathogens. Historically, pine shavings have been used as poultry bedding and are the standard to which other materials are compared. There are some regional variations in bedding material, with peanut hulls sometimes used in Georgia and Florida, or rice hulls in Arkansas and Mississippi. Other bedding materials studied include, but are not limited to, pine bark, chipped pine, mortar sand, ground hardware pallets, chopped straw, ground door filler, and cotton-gin trash (Bilgili, et al. 2009). While bedding material in poultry houses must be absorbent, it must also dry quickly. Paper products absorb moisture well but do not dry out appropriately. This can lead to caking, especially around the waterers, which can cause increased ammonia production, footpad lesions and breast blisters (Bilgili, et al. 2009).

**3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

TR LINES 393-428

The hydrogen chloride gas produced in the production of sodium bisulfate is absorbed in water to produce hydrochloric acid which can be sold as a co-product. There are no other materials

requiring disposal. Quality control measures used in the manufacturing of sodium bisulfate ensure that all the starting materials are converted to final products so that no waste is generated.

EPA's Envirofacts Master Chemical Integrator (EMCI) (EMCI 2009) references the Environmental Defense Fund's Chemical Score Card for sodium bisulfate (Chemical Scorecard 2011). The chemical scorecard summarizes information about the health effects, hazard rankings, industrial and consumer product uses, environmental releases, risk assessment values and regulatory coverage for different products. They use a three ranking system looking at human health, ecological health and integrated environmental rankings. They rank products from least hazardous to most hazardous in a scale from 0-100. Worker exposure hazard score for sodium bisulfate was 18. The environmental hazard value score was 15, and the total hazard value score was 12. Sodium bisulfate has a safe ranking for EPA's Design for the Environment (DfE) program (DfE 2014).

In general, mineral acids such as ammonium sulfate (by product of sodium bisulfate treated litter) will dissociate and release hydrogen ions in the environment thus decreasing the pH. The extent and duration of this decrease in pH will depend on the amount of neutralizing ions present, the buffering capacity of the medium, and the amount of dilution possibilities. However, ammonium sulfate only exerts a small decrease in pH. For example, the application of an ammonium sulfate fertilizer 21-0-0 at 10 lbs per 1000 square feet changes the soil pH from 7.5 to 7.4 (Mason 2008). There was no literature to suggest that repeated applications of sodium bisulfate treated litter would lead to decreases in soil or water pH. .

Sodium bisulfate is harmful if swallowed in large amounts (ScienceLab.com MSDS 2014). Symptoms of swallowing more than one tablespoon of sodium bisulfate include burning pain in the mouth, diarrhea, vomiting and severe low blood pressure. If sodium bisulfate touches human skin, symptoms may include blisters, burns and painful red skin. If sodium bisulfate gets in eyes there may be decreased vision, eye pain, eye redness and tearing (ScienceLab.com MSDS 2014).

Sodium bisulfate is incompatible with strong bases, strong oxidizing agents, sodium carbonate and sodium hypochlorite. It should not be mixed with chlorine bleach or ammonia cleansers.

The levels at which sodium bisulfate is added to poultry litter in broiler houses has been shown to have no statistically significant effect on the incidence of foot pad lesions (Nagaraj, Wilson and Saenmahayak, et al. 2007). Multiple additions of the product PLT during broiler grow out effectively controlled ammonia volatilization from litter with no reduction in foot pad quality (Purswell, et al. 2013).

**4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

TR LINES 506-511

Sodium bisulfate is typically spread mechanically on litter prior to bird placement. It must be hand applied when birds are in the house. Sodium bisulfate is considered hazardous by the

OSHA Hazard Communication Standard (29 CFR 1910.1200) in that it causes serious eye irritation, may cause respiratory irritation, and may be harmful if swallowed. When handling sodium bisulfate, it is important to use personal protective equipment. Breathing in dust must be avoided. It is important to wash thoroughly after handling sodium bisulfate. The material is hygroscopic and will readily absorb moisture.

**5. Discuss any effects the substance may have 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. [§6518(m)(5)]**

TR LINES 445-484

According to the EPA website (EPA 2014), toxicity tests of sodium bisulfate with mosquitos, green algae and water fleas showed that it is not acutely toxic. The research, however, is very old (Anderson 1946, Dowden and Bennett 1965). More recent data could not be located. Sodium bisulfate is used as a means of chemically preserving soil samples to prevent the microbiological degradation of volatile organic compounds (Hewitt 1995).

Soil pH is an important chemical property because it affects the availability of essential plant nutrients (Lucas and Davis 1961). Most of the common crops have a wide range of pH adaptation. As an example, alfalfa, corn and small grains grow well in soil pH ranging from 5.7 to 8.1. No research could be found on the maximum level of sodium bisulfate that could be added to soil before it would have an adverse effect on soil chemistry. No research showing effects of fertilizing with PLT-treated litter on soil ecosystem could be found, indicating a need for research in this area. The use of PLT-treated litter in the Delmarva Peninsula, a region with heavy broiler production, has not been shown to have negative effects on the soil when applied at levels applicable to the nutrient requirement of the crop being grown (Guo, N. Tongtavee and Labreveux 2009).

The biggest environmental concern with respect to animal manures, including poultry litter, is currently phosphorus runoff (Moore Jr., et al. 1995). Phosphorus is normally the limiting nutrient for eutrophication, which has been identified as an important water problem in United States surface waters. Manure typically has a low nitrogen-to-phosphorus ratio and, if manure is applied to meet the nitrogen requirement of the crops being fertilized, there is a buildup of phosphorus in agricultural soils. Much of this soil phosphorus is lost in runoff from pastures fertilized with manure. As a result, much of the manure must be applied based on crop phosphorus requirement, limiting the potential of poultry manure as an organic fertilizer. Increasing the nitrogen content of the manure, by preventing volatilization, improves its value as an organic fertilizer, thereby reducing phosphorus buildup (Moore Jr., et al. 1995).

To control ammonia levels in animal houses, including poultry houses, sodium bisulfate is added to the bedding or litter. In a study looking at the effect of sodium bisulfate on skin and hooves of horses, it was concluded that sodium bisulfate was safe for use in horse barns (Sweeney, Habecker and Russell 2000). In the study, sodium bisulfate was applied to clipped intact skin after a single and repetitive application. Sodium bisulfate was also applied to the sole of both front hooves and covered with wet gauze. Contact with moistened sodium bisulfate had no effect on pony skin. There were no gross changes, but contact with sodium bisulfate for 6 hours

on 10 consecutive days did cause mild to moderate microscopic changes. However, the duration of contact in the study was in excess of that expected under typical husbandry conditions.

The addition of PLT<sup>®</sup> to poultry litter in broiler houses had no statistically significant effect on the incidence of pododermatitis<sup>4</sup> (Nagaraj, Wilson and Saenmahayak, et al. 2007).

## **6. Are there any adverse impacts on biodiversity? (§205.200)**

TR LINES 346-368

Sodium bisulfate is hygroscopic in that it attracts water. Sodium bisulfate dissociates completely in water into sodium (Na<sup>+</sup>), hydrogen (H<sup>+</sup>) and sulfate (SO<sub>4</sub><sup>-2</sup>). As a mineral acid, sodium bisulfate is not expected to contaminate ground water or soil or to accumulate in the food chain (EPA 1993).

Without the addition of the sodium bisulfate, the nitrogen present in the litter would be lost as volatile ammonia. Sodium bisulfate captures this nitrogen, increasing the nitrogen content of the litter (Choi and Moore Jr. 2008). Sodium bisulfate-treated chicken litter also provides a nitrogen source in a form that plants can use immediately (ammonium sulfate). Ammonium sulfate is available to plants as a nitrogen source. In the soil the ammonium ion is released and forms a small amount of acid, lowering the soil pH while contributing nitrogen for plant growth. In commercial fertilizers, nitrogen is supplied in the form of ammonium nitrate. The nitrogen content of ammonium sulfate is lower – 21% nitrogen and 24% sulfur, compared to ammonium nitrate (NH<sub>4</sub>NO<sub>3</sub>) with 34% nitrogen.

Bacterial levels in poultry litter have been shown to decrease as pH decreases. The use of PLT<sup>®</sup> has been shown to reduce survivability of E. coli and Salmonella in broiler house litter (Pope and Cherry 2000). As such, sodium bisulfate may be a beneficial component for pathogen reduction, and could play a role in an on-farm HACCP (Hazard Analysis and Critical Control Points) program, although further research is needed (Pope and Cherry 2000).

PLT<sup>®</sup> is reported to be 93.2% pure, with 6.8% sodium sulfate as an impurity. Sodium sulfate is also produced in the reaction of sodium bisulfate and ammonia, but has not been shown to be a concern for the welfare of the flock or the environment. In fact, sodium sulfate can be used as a source of sodium without chloride in poultry diets (Jankowski, et al. 2011).

### **Category 3: Alternatives/Compatibility**

#### **1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

Alternatives to litter amendments include management practices such as proper air exchange in barns, removing caked areas and keeping litter areas dry.

TR LINES 517-555

A new type of litter amendment has become available which is based on dried *Yucca schidigera* whole plant. This is Eco-Gest YS® (Nova Microbial Technologies 2014), however it is unknown if it has been approved for use on an organic farm by any certifier or material review organization. Yucca extract products have already been employed as a feed additive for the control of manure odors in organic production (Prince Yuccaplus and Bioliquid 3000®).

There is also a group of litter additives that can be applied to built-up litter to speed the release of ammonia, which is then flushed out of the poultry house before the chicks are placed. This would include such products as agricultural lime (CaCO<sub>3</sub>), the least effective, and burnt lime (CaO), the most effective, with the effectiveness of hydrated lime (Ca(OH)<sub>2</sub>) falling in between. This method for controlling ammonia levels in the poultry house shifts the flux in gaseous nitrogen to outside the poultry facility, which can have associated negative impacts on the surrounding environment (Kelleher, et al. 2002).

Another group of litter amendments that have been used to control ammonia in poultry litter are clay-based products that adsorb odors and reduce ammonia release by absorbing moisture. This would include zeolite (natural clay material). Zeolite from Clean Age Minerals, Inc. (Clean Age Minerals 2014) has been approved by the third party material review organization, OMRI (it is "OMRI Listed"). Additional OMRI Listed products include Barn Fresh Plus and Activated Barn Fresh (Absorbent Products 2012), which are combinations of diatomaceous earth and calcium montmorillonite<sup>6</sup> with added citric acid. These products are possible alternatives for sodium bisulfate for control of ammonia

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the board received one public comment that stated there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not approve synthetic poultry litter amendments when there are already OMRI certified listed being used in the marketplace.

**2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

Yes, but it is unclear if this substance is needed in organic agriculture as alternatives exist. The subcommittee would like to pose the following questions:

1. Are there alternatives available to reduce ammonia in poultry barns?
2. Do the alternatives work in the area of reducing or eliminating Salmonella that could be present in barns?

**Classification Motion:** Move to classify sodium bisulfate as petitioned as synthetic:

Motion by: Ashley Swaffar

Seconded by: Harriet Behar

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Listing Motion:** Move to add sodium bisulfate as petitioned at §205.603

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0



**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Acid Activated Bentonite  
June 21, 2016**

**Summary of [Petition](#):**

In April 2015 the NOP received a petition to add acid-activated bentonite to the National List of synthetic substances allowed for use in organic livestock production 7 CFR 205.603 as a poultry litter treatment.

**Summary of Review:**

**Manufacture and Uses of the Substance:**

The primary use of acid-activated bentonite is to reduce the level of ammonia generated by certain urease producing bacteria commonly found in poultry litter. Additionally, it has been found to reduce populations of darkling beetles and pathogens in poultry litter, but no claims for these properties are being made in the present petition. In its finished form the acid-activated bentonite described here is composed of odorless, virtually dustless, free flowing granular particles which are spread over poultry litter by means of manually operated or tractor propelled broadcast spreaders.

The finished product of the present petition (acid-activated bentonite, CAS# 98561-46-7) is prepared by treating naturally occurring bentonite clay with sulfuric acid. The product is manufactured by spraying 46 weight percent concentrated sulfuric acid (CAS# 7664-93-9) onto a pre-weighed bed of bentonite clay granules (CAS# 1302-78-9) as they are tumbled in a Munsen mixer. After a short period of mixing, the acid-activated granules are transferred to a bagging line where 50 lb. aliquots are loaded into high melt-temperature plastic bags and heat sealed. The petitioner notes that small amounts of crystalline quartz (CAS# 14808-60-7) occur naturally in the bentonite clay used to make the finished product.

The rate of addition to a poultry house is typically about 100 lbs/1000 ft<sup>2</sup> of litter surface area, but can range up to 200 lbs/1000 ft<sup>2</sup> depending on age and depth of litter. The product is added to the poultry litter only once at the beginning of each new grow out cycle. Application is typically done three days prior to bird placement in the house, but can be done up to the day of placement. The product can also be applied to bare ground after old litter is removed and before new litter is added at a rate of 100 lbs/1000 ft<sup>2</sup>. New litter would then be added directly on top of the acid-activated bentonite. The TR also states (Lines 107-113), "The petitioner also describes reapplication methods in cases where ammonia levels exceed 25 ppm. The reapplication is intended to occur while birds are present at an application rate of 100 lbs/1,000 ft<sup>2</sup>, as indicated by the petitioner. Use instructions for Poultry Guard® do not address the need for reapplication, but do state that the product will be effective to reduce ammonia for several weeks. Broilers are grown out to 6 or more weeks, while other poultry such as laying hens and turkeys have longer grow out periods. If litter treatment loses effectiveness while birds are still in the poultry house, it is likely that reapplication or other ammonia mitigation measures may need to occur."

**Discussion:**

The intended use of the petitioned substance is to reduce ammonia levels in poultry houses, which effectively improves the air quality and thus the living conditions of poultry. With reduced ammonia concentration in poultry houses, birds are at lower risk of respiratory damage, infectious disease, and other negative effects of ammonia, including mortality (Shah, Westerman, and Parsons 2006). One study associated the use of acid-activated bentonite as a poultry litter treatment with reduced instances of breast blisters, foot-pat dermatitis, and air-sac lesions in poultry (McWard and Taylor 2000). Use of acid-activated bentonite litter treatments is also associated with reductions in salmonella levels in litter (Watkins, Southerland and Hunt 2002) and darkling beetles (McWard and Taylor 2000).

According to the TR, since acid-activated bentonite is a highly acidic substance and handlers of the substance are required to prevent direct contact, it is reasonable to expect that direct contact of the substance with poultry, either on their feet or through incidental ingestion, would also pose health risks. The potential for direct contact depends on the structure of the poultry house. In some houses, the birds are placed on raised slatted flooring on top of the litter, in which case the birds would not have direct contact with the litter or litter treatments. Houses without raised flooring would allow birds to peck and scratch through the litter, posing a higher risk of direct contact with the litter treatment. Data is not available in the literature to quantify the amount of litter containing acid-activated bentonite that may be ingested by birds. It is unlikely that significant amounts would be ingested unless there was a shortage of suitable feed. (Lines 383-391.)

Because the petitioned substance is applied to poultry litter, the subsequent use of the spent poultry litter must be considered in assessing the total impact of the petitioned substance on the agro-ecosystem. Spent poultry litter is typically intended for application to agricultural land for the purpose of improving soil fertility and organic matter content. Environmental concerns that arise from the land application of poultry manure include nitrogen leaching, phosphorus contamination of surface waters, and heavy metal buildup in soils (Bolan, et al. 2010). Ammonium sulfate is produced as a result of the reaction between gaseous ammonia in the poultry house and the sulfate ions of the sulfuric acid-activated bentonite. Ammonium sulfate is a common water-soluble inorganic fertilizer used in conventional crop production. Ammonium sulfate has little to no surface volatilization loss when applied to most soils and is effective as a starter nitrogen source. Compared to other forms of soil nitrogen, the ammonium ion is less subject to leaching from clay since its positive charge keeps it held by the clay's negatively charged sites (Vitosh, Johnson and Mengel 1995). However, increased loss of nitrogen through leaching has been associated with greater application rates of ammonium sulfate fertilizer (Olson 1979). Another study reported that while nitrogen derived from ammonium sulfate is more readily taken up by plants than nitrogen from leguminous nitrogen-fixing plants, it is also lost from the soil more readily in the first year after application (Harris, et al. 1993).

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the Board received one public comment that stated that there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not approve synthetic poultry litter amendments when there are already effective OMRI listed products being used in the marketplace.

## Category 1: Classification

1. **Substance is used for:** Livestock
2. **For LIVESTOCK use:**
  - a. Is the substance Agricultural or non-agricultural? This substance is non-agricultural
  - b. If the substance is non-agricultural, is the substance: non-synthetic or synthetic. This substance is synthetic

The finished product of the present petition (acid-activated bentonite, (CAS# 98561-46-7) is prepared by treating naturally occurring bentonite clay with sulfuric acid. The product is manufactured by spraying 46 weight percent concentrated sulfuric acid (CAS # 7664-93-9) onto a pre-weighed bed of bentonite clay granules (CAS# 1302-78-9) as they are tumbled in a Munsen mixer. After a short period of mixing, the acid-activated granules are transferred to a bagging line where 50 lb. aliquots are loaded into high melt-temperature plastic bags and heat sealed. The petitioner notes that small amounts of crystalline quartz (CAS# 14808-60-7) occur naturally in the bentonite clay used to make the finished product.

3. **For LIVESTOCK:** This product would be listed at 205.603 Livestock Production-Synthetic. The substance contains sulfur compounds (sulfuric acid). The substance is not an inert ingredient.

## Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

The literature does not indicate that the petitioned substance would have chemical interactions with other substances used in organic livestock production, other than the mode of action of the petitioned substance with poultry litter.

2. **What is 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? [§6518(m)(2)]**

According to the TR, the by-products of acid-activated bentonite used as a poultry litter treatment are ammonium sulfate ((NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>) and spent clay. Ammonium sulfate is produced as a result of the reaction between gaseous ammonia in the poultry house and the sulfate ions of the sulfuric acid-activated bentonite.

Ammonium sulfate is a common water-soluble inorganic fertilizer used in conventional crop production. Ammonium sulfate has little to no surface volatilization loss when applied to most soils and is effective as a starter nitrogen source. Compared to other forms of soil nitrogen, the ammonium ion is less subject to leaching from clay since its positive charge keeps it held by the clay's negatively charged sites (Vitosh, Johnson and Mengel 1995). However, increased loss of nitrogen through leaching has been associated with greater application rates of ammonium

sulfate fertilizer (Olson 1979). Another study reported that while nitrogen derived from ammonium sulfate is more readily taken up by plants than nitrogen from leguminous nitrogen-fixing plants, it is also lost from the soil more readily in the first year after application (Harris, et al. 1993). (TR Lines 299-312)

**3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

TR Lines 339-360

*Manufacturing* – Bentonite, the starting material, is sourced by quarry mining. Mining usually has negative environmental impacts that can include release of heavy metals to soil and water, and generation of the air pollutants sulfur and nitrogen dioxide, residual waste tailings, slag and acid drainage. The manufacturing of the acid treatment sulfuric acid generates sulfuric acid emissions into the air which, if not otherwise neutralized, result in dilute acid solutions that may contribute to acid rain. The activation of bentonite with sulfuric acid as described in the petition does not appear to add additional negative environmental impacts beyond the manufacturing of its ingredients.

*Use and Handling* – The U.S. Department of Transportation regulates the shipping of acid-activated bentonite as a “corrosive material” (Hazard Class 8) due to the sulfuric acid content. This class of materials is defined at 49 CFR 173.136 as a liquid or solid that causes full thickness destruction of human skin at the site of contact within a specified period of time. Care must be taken to ensure that incompatible corrosive materials are not mixed. The Material Safety Data Sheet for the petitioned acid-activated bentonite indicates that it does not emit any volatile organic compounds. Applying water directly to the material must be avoided; aqueous runoff is acidic and corrosive.

*Misuse* – Since the substance is a granular solid material, spills are relatively manageable to contain and clean up. The Material Safety Data Sheet for the petitioned acid-activated bentonite indicates that spills greater than 2,000 lbs must be reported to the National Resources Center.

*Disposal* – Use instructions for Poultry Guard® state that the product can be neutralized with household ammonia or baking soda.

**4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

Handlers of acid-activated bentonite must take care to protect themselves from direct contact with the substance. Direct exposure to the substance may cause skin irritation or burns. The petitioned product contains crystalline silica which is naturally occurring in the bentonite starting material, a small fraction (0.00064% by weight) of which is in the respirable range. Inhalation of excessive concentrations of the substance may lead to lung injury. Applicators should wear protective clothing, impervious gloves, goggles, and a dust mask.

Use of the substance as petitioned is not likely to have negative effects on human health because the substance decreases ammonia concentration in the atmosphere of poultry houses, which has a positive impact on both the health of the birds and the health of the handlers.

**5. Discuss any effects the substance may have 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. [§6518(m)(5)]**

According to the TR (Lines 376-403): The intended use of the petitioned substance is to reduce ammonia volatilization in poultry houses, which effectively improves the air quality and thus the living conditions of poultry. With reduced ammonia concentration in poultry houses, birds are at lower risk of respiratory damage, infectious disease, and other negative effects of ammonia, including mortality (Shah, Westerman and Parsons 2006). One study associated the use of acid-activated bentonite as a poultry litter treatment with reduced instances of breast blisters, foot-pat dermatitis, and air-sac lesions in poultry (McWard and Taylor 2000).

Since acid-activated bentonite is a highly acidic substance and handlers of the substance are required to prevent direct contact, it is reasonable to expect that direct contact of the substance with poultry, either on their feet or through incidental ingestion, would also pose health risks. The potential for direct contact depends on the structure of the poultry house. In some houses, the birds are placed on raised slatted flooring overtop of the litter, in which case the birds would not have direct contact with the litter or litter treatments. Houses without raised flooring would allow birds to peck and scratch through the litter, posing a higher risk of direct contact with the litter treatment. Data is not available in the literature to quantify the amount of litter containing acid-activated bentonite that may be ingested by birds. It is unlikely that significant amounts would be ingested unless there was a shortage of suitable feed.

The acidifying function of litter treatments can inhibit growth and survival of pathogenic and nonpathogenic bacteria in litter (Choi, Kim and Kwon 2008). Use of acid-activated bentonite litter treatments is also associated with reductions in salmonella levels in litter (Watkins, Southerland and Hunt 2002) and darkling beetles (McWard and Taylor 2000).

Because the petitioned substance is applied to poultry litter, the subsequent use of the spent poultry litter must be considered in assessing the total impact of the petitioned substance on the agro-ecosystem. There are many environmental considerations if the poultry litter is applied to agricultural land. Some considerations are addressed in Evaluation Question #5. See Technical Reports for aluminum sulfate (OMRI 2015a) and sodium bisulfate (OMRI 2015b) for additional information regarding the reuse of treated poultry litter for fertility purposes.

**6. Are there any adverse impacts on biodiversity? (§205.200)**

Because the petitioned substance is applied to poultry litter, the subsequent use of the spent poultry litter must be considered in assessing the total impact of the petitioned substance on the agro-ecosystem. Spent poultry litter is typically intended for application to agricultural land for the purpose of improving soil fertility and organic matter content. Environmental concerns that arise from the land application of poultry manure include nitrogen leaching, phosphorus contamination of surface waters, and heavy metal buildup in soils (Bolan, et al. 2010).

Ammonium sulfate is produced as a result of the reaction between gaseous ammonia in the poultry house and the sulfate ions of the sulfuric acid-activated bentonite. Ammonium sulfate is a common water-soluble inorganic fertilizer used in conventional crop production. Ammonium sulfate has little to no surface volatilization loss when applied to most soils and is effective as a starter nitrogen source. Compared to other forms of soil nitrogen, the ammonium ion is less subject to leaching from clay since its positive charge keeps it held by the clay's negatively charged sites (Vitosh, Johnson and Mengel 1995). However, ammonium sulfate has a neutral charge and so would not be held to clay in the same way. Increased loss of nitrogen through leaching has been associated with greater application rates of ammonium sulfate fertilizer (Olson 1979). Another study reported that while nitrogen derived from ammonium sulfate is more readily taken up by plants than nitrogen from leguminous nitrogen-fixing plants, it is also lost from the soil more readily in the first year after application (Harris, et al. 1993).

### Category 3: Alternatives/Compatibility

#### 1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

Alternatives to litter amendments include management practices such as proper air exchange in barns, removing caked areas and keeping litter areas dry.

TR LINES 435-449

Clay-based adsorbents can be used to bind NH<sub>3</sub> to the surface of the clay, and they also decrease NH<sub>3</sub> volatilization by absorbing moisture (McCrary and Hobbs 2001). Nonsynthetic forms of these substances include naturally occurring zeolite, diatomaceous earth, and montmorillonite (non-activated bentonite). Peat (*Sphagnum facum*) has physical and chemical properties that result in effective ammonia management. Peat can adsorb 2.5 times its weight in NH<sub>3</sub> and absorb up to 20 times its weight in water (McCrary and Hobbs 2001). Clay and peat are both nonhazardous materials. At the time of this report, there are several products that are OMRI Listed® for this use, such as Barn Fresh Natural Ammonia Control manufactured by Absorbent Products Ltd, which is listed in the “diatomaceous earth” category (OMRI 2015). Another product, Litter Life manufactured by Southland Organics, is a liquid poultry litter treatment that is approved under the U.S. EPA Design for the Environment program (Southland Organics 2015).

Microbial and enzymatic treatments can be used to inhibit microbial growth and urease production through competitive exclusion and enzyme inhibition (Ritz, Fairchild and Lacy 2014). These types of products are generally not practical or economical for growers due to the rapid breakdown of the product, and they are more expensive than other alternatives (McCrary and Hobbs 2001).

During the Spring 2016 in-person public comment session at the National Organic Standards Board meeting in Washington, DC, the board received one public comment that stated there are OMRI listed poultry litter amendments currently in use. The Board was provided information from a manufacturer of a poultry litter amendment product, which is currently OMRI listed, that expressed concerns they had with the TR. The commenter felt that the board should not

approve synthetic poultry litter amendments when there are already OMRI certified listed being used in the marketplace.

**2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

Yes, but it is unclear if this substance is needed in organic agriculture as alternatives exist. The Subcommittee would like to pose the following questions:

1. Are there alternatives available to reduce ammonia in poultry barns?
2. Do the alternatives work in the area of reducing or eliminating Salmonella that could be present in barns?

**Classification Motion:**

Move to classify acid activated bentonite, as petitioned, as synthetic

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Listing Motion:**

Move to add acid activated bentonite as petitioned at §205.603

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0