National Organic Standards Board Meeting
Sheraton Denver, Denver, CO
April 19-21, 2017

PLEASE NOTE:

Discussion documents, recommendations, reports and/or other documents prepared by the National Organic Standards Board, including its subcommittees and task forces, represent the views of the National Organic Standards Board and do not necessarily represent the views and policies of the Department of Agriculture. Please see the NOP website for official NOP policy, regulations, guidance and instructions.

Sunset 2019
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 2017

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at www.regulations.gov by March 30, 2017 as explained in the meeting notice published in the Federal Register.

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances Under Review:

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

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

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

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

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

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

Written public comments will be accepted through March 30, 2017 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2019
Meeting 1 - Request for Public Comment
Handling Substances §§205.605(a), 205.605(b), 205.606
April 2017

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

Reference: 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)).''

§205.605(a) Nonsynthetics allowed:
Attapulgite
Bentonite
Diatomaceous earth
Nitrogen
Sodium carbonate

§205.605(b) Synthetics allowed:
Acidified sodium chlorite
Carbon dioxide
Chlorine Materials: calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Magnesium chloride
Potassium acid tartrate
Sodium phosphates

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Casings
Konjac flour
Pectin (non-amidated forms only)

Attapulgite

Reference: 205.605(a) – as a processing aid in the handling of plant and animal oils.
Technical Report: 2010 TR
Petition(s): 2009 Attapulgite
Past NOSB Actions: 04/2011 NOSB recommendation; 10/2015 sunset review
Recent Regulatory Background: Added to National List effective 08/03/2012 [77 FR 45903]
Sunset Date: 08/03/17 (NOP renewal pending)

Background:
The original petition (2009) is a 158 page document with literature review. The petition also included information regarding the use of attapulgite in animal feed. In 2011 the NOSB recommended addition of attapulgite to §205.605 with the annotation "allowed as a processing aid in the handling of plant and animal oils".

Attapulgite is characterized as a natural clay most often composed of a complex of magnesium (Mg) aluminum (Al) silicates that creates an open-channel structure with a large surface area and cation-exchange capacity that is important to its function to absorb, adsorb and filter substances (TR lines 19-21, 28-30,44-46, 75-83). In bleaching of oils/fats, the clay adsorbs color and other impurities to create the finished oils (TR lines 87-89). Common names for the substance include Fullers Earth, Palygorskite and Hormite (2009 Petition pg. 2).

Attapulgite (Doc. No. 1943) is listed under Everything 64 Added to Food in the United States (EAFUS) and referred to in 21 CFR Part 582 -- Substances Generally 65 Recognized as Safe (GRAS), §582.99 Adjuvants for pesticide chemicals (TR lines 63-65). The material is also listed by EPA as an inert ingredient in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) pesticide products applied 69 to food use site (e.g., food crops, animals used for food) and nonfood use site (e.g., ornamental plants, 70 highway right-of-ways, rodent control). In addition, attapulgite can be used, under 40 CFR §180.910 Inert 71 Ingredients, during pre- and post-harvest. It is exempted from the requirement of a tolerance. (TR lines 67-71)

Modern extraction is by open-pit mining where clay is removed and sent for processing of drying, milling, sieving, and possible acid activation (sulfuric, hydrochloric) to increase inherent attapulgite properties (TR 143-146, 148-151, 224-227). There is an adverse environmental impact due to mining and dust byproduct; environmental and mining regulations are in place to return disturbed earth and control dust output, minimizing overall net environmental impact (TR 233-244). Worker safety from dust concern is addressed through worker protective equipment and monitored through OSHA (TR 239-244). Material meets OFPA criteria.

This material was reviewed by the Board for Sunset during 2015: 3 Yes to remove, 11 No votes to maintain listing.

Additional information requested by NOSB
None requested.

Bentonite

Reference: 205.605(a)
Technical Report: 1995 TAP Kaolin Clay and Bentonite
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290),
Sunset Date: 06/27/17 (NOP renewal pending)

Background:
Bentonite/Kaolin is a natural clay composed of alumina, silica and water derived from volcanic ash or tuff (1995 TAP pg. 1, 2). Clays have functional properties of large surface area with adsorptive properties that make them useful for filtering and purification functions with no function in finished food products (1995 TAP pg. 1, 2).

Bentonite is a mined substance obtained through open pit mining. Environmental impacts are monitored and subject to environmental regulations by other agencies to minimize long term impacts.

During Sunset Review in 2015 the Subcommittee sought public comment to specifically address the ongoing need for bentonite/kaolin and received clear indication from a range of stakeholders that it continues to be necessary. There was no public comment in opposition. Material meets OFPA criteria.

Additional information requested by NOSB
None requested.

Diatomaceous earth

Reference: 205.605(a) - food filtering aid only

Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 10/21/17 (NOP renewal pending)

Background:
The NOSB reviewed diatomaceous earth (DE) in November 2005, April 2010, most recently in October 2015, and recommended relisting each time.

Diatomaceous earth is comprised of accumulated shells of hydrous silica secreted by diatoms and is used as a filter aid in production of syrups, juices, beer, beverages and other products (1995 TAP pg. 4). Diatomaceous earth does not exist within the final organic product, and is classified as a processing aid and not an ingredient.

Diatomaceous earth is a mined substance and processors must adhere to environmental regulations for removal and production purposes. Dust produced during processing can be a human health concern for workers and would be subject to OSHA requirements (1995 TAP pg. 5). Waste material can, in some states, be considered a hazardous waste requiring special disposal requirements (1995 TAP pg. 5).

The 1995 Technical Advisory Panel was made up of 3-people. . One reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify "food grade" quality of DE. DE is also used in swimming pool filters, which is not a food grade form. Diatomaceous earth satisfies the OFPA criteria

Public comment indicates a widespread use of diatomaceous earth as a filter aid.

Additional information requested by NOSB

None requested.

Nitrogen

Reference: 205.605(a) - oil-free grades.

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 10/21/17 (NOP renewal pending)

Background:

Use: Nitrogen is used to displace oxygen and thereby reduce oxidation of product during processing, storage and packaging. It can be used in the flash freezing of foods. It also functions as a propellant when used under pressure, and doesn't have ozone-depleting properties.

Manufacture: Nitrogen is a colorless, odorless gas. Cryogenic distillation, where air is compressed, cooled, and then filtered, is the most economic and highest purity method for separating nitrogen from air.

International: The use of Nitrogen in permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Nitrogen satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

Additional information requested by NOSB:

None requested.

Sodium carbonate

Reference: 205.605(a)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 10/21/17 (NOP renewal pending)

Background :

Use: Used as a raising (leavening) agent. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a stabilizer, as well as a neutralizer for butter, cream, fluid milk, and ice cream. Sodium carbonate is the material used to give pretzels and lye rolls their brown crust without burning. Sodium carbonate is also used in the processing of olives prior to canning, in the making of ramen noodles, and in cocoa products.

Manufacture: Sodium carbonate is produced in North America from natural deposits of trona ore (sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then concentrated by evaporation to crystallization. This is considered to be the most sustainable form of producing sodium carbonate. Also, in California, sodium carbonate can be produced from a similar method using natural brine (Searles Lake).

International: The use of Sodium carbonate is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Sodium chlorite satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

Additional information requested by NOSB:

None requested.

Acidified sodium chlorite

Reference: 205.605(b) - Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Technical Report: 2008 TAP, 2013 TR for Livestock

Petition(s): 2006 Sodium Chlorite, Acidified

Past NOSB Actions: 2009 NOSB recommendation; 10/2015 sunset review

Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089)

Sunset Date: 03/15/17 (NOP renewal pending)

Background:

Specific Uses of the Substance:

Acidified Sodium Chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation for using on direct food contact and indirect food contact:

- Direct Food Contact (Secondary Direct Food Additive) – Poultry carcass, organs and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted or formed meat products; and
- Indirect Direct Food Contact – Hard surface food

Manufacture: In the petition it states that ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. Sodium chlorite (25%) and citric acid (50%) solutions are stored separately in bulk on site. Both solutions are pumped by proportional pumps and a water dilution module to make the final use dilution product, which typically contains 0.1% sodium chlorite and 0.6% citric acid and 99.3% water. Sodium chlorite is made by the reduction of chlorine dioxide, which is, in turn, from the reduction of sodium chlorate in the presence of sulfuric and hydrogen peroxide or sulfuric acid and sodium chloride. The resulting solution may be dried to a solid and the sodium chlorite content may be adjusted to about 80% by the addition of sodium chloride, sodium sulfate, or sodium carbonate. Sodium chlorite is marketed as a solid or an aqueous solution (such as 25% by weight). The acid used to acidify sodium chlorite is natural citric acid, which is stated in the petition. However, there is no information in the petition regarding how the natural citric acid was manufactured.

Discussion: Previous public comments asked for a comprehensive review of all sanitizers but the Subcommittee feels that a review of that scope is beyond the sunset review process.

Additional information requested by NOSB

1. Is the substance essential for organic food production and handling?

2. Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of acidified sodium chlorite to provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

3. Provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

Carbon dioxide

Reference: 205.605(b)

Technical Report: 1995 TAP; 2006 TAP

Petition(s): 2005 Carbon Dioxide

Past NOSB Actions: 10/1995 NOSB minutes and vote; 2007 NOSB Committee recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 06/27/2017 (NOP renewal pending)

Background:

Use: Carbon dioxide is used in modified atmospheric packaging, modified atmospheric storage, the freezing of foods, beverage carbonation, as an extracting agent, processing aid, and for pest control in grain and produce storage.

Manufacture: It is available in limited supplies from underground wells and as a byproduct of various manufacturing processes. All of the processes require purification of the carbon dioxide before being used in the food processing and handling.

International: The use of carbon dioxide is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Carbon dioxide satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

Additional information requested by NOSB:

None requested.

Chlorine materials

Reference: 205.605(b) Chlorine materials - disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Technical Report: 2006 TR - Handling

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 06/27/2017 (NOP renewal pending)

Background:

Specific Uses of the Substance:

Sodium and Calcium Hypochlorite

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals. These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems.

Chlorine Dioxide

Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies. It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses.

Approved Legal Uses of the Substance:

Regarding organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. In addition, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L or 4ppm).

Discussion: Previous public comments asked for a comprehensive review of all sanitizers but the Subcommittee feels that a review of that scope is beyond the sunset review process.

Additional information requested by NOSB

The NOSB in its initial request for public comment asks:

1. Is the substance essential for organic food production and handling?
2. Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of chlorine materials to provide detailed comments describing the situations in which they are the most appropriate or effective antimicrobial for a given application.

Magnesium chloride

Reference: 205.605(b) – derived from sea water.

Technical Report: 1995 TAP; 2016 TR

Petition(s):N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 06/27/2017 (NOP renewal pending)

Background:

Use: Magnesium chloride is used in organic food processing as a processing aid, and as a coagulant/ firming agent in tofu production. It can also be used to dress cotton fibers, or as a color retention agent and as a source of essential mineral magnesium in infant formula.

The EPA regulates magnesium chloride as a pesticide on List D, pesticides of less concern (EPA 1998). Magnesium chloride has also been used to treat bovine hypomagnesemia (low blood magnesium levels.

Magnesium chloride is currently allowed under the National Organic Program regulations at 7 CFR 205.605(b) as a nonagricultural synthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." The current annotation reads, "derived from sea water".

During the 2015 Sunset Review, public comment from tofu producers, trade associations and certifiers indicates that this material "makes a specific type of tofu texture that cannot be duplicated with other coagulants. Elimination from the National List would be extremely detrimental to all tofu manufacturers in the United States".

In its initial review in 2015 the Handling Subcommittee asked whether this material should be annotated "for use only in tofu production". Public comment indicated that at least one NGO recommends an annotation "as a coagulant in making tofu". Public comment suggests that while use of magnesium chloride for making tofu is consistent with organic practices, the use of this material for color enhancement may not be consistent with organic.

Following the 2015 Sunset Review this material was recommended for continued listing but issues related to classification were raised and a Technical Report (TR) was requested. The TR, dated November 30, 2016 was utilized by the subcommittee in this initial Sunset 2019 Review.

Manufacture: Natural commercial sources of magnesium chloride can be classified as (a) sea water; (b) terminal lake brines; (c) subsurface brine deposits; and (d) mineral ore deposits. Magnesium chloride produced from each of these natural sources is the product of a brine comprising soluble ions of various mineral elements, primarily sodium, potassium, magnesium, calcium, chloride and sulfate (TR 2016, 186-189).

(a) Sea Water

Sea water is processed in solar ponds to produce concentrated brines from which specific minerals crystallize and are recovered. These specific minerals, called "evaporites," crystallize in a sequence based on the concentrations of anions and cations in the brine and their innate solubility in water (TR 192-194).

(b) Terminal lake brines

A terminal lake is a lake where water is flowing in but no water flows out, so that the dissolved salts concentrate and form brine as the water evaporates. The Great Salt Lake in Utah is a familiar example.

Great Salt Lake brine is the primary source of magnesium chloride in North America. The Great Salt Lake contains sodium-magnesium-chloride-sulfate brine with low alkalinity (Domagalski, Orem, and Eugester 1989). Like solarization of seawater, the first evaporite of Great Salt Lake brine to form is halite (sodium chloride), followed by schoenite (magnesium-potassium sulfate), kainite (potassium chloride-magnesium sulfate double salt), and carnallite (potassium-magnesium chloride), resulting in a magnesium chloride brine (Neitzel 1971). Evaporating the water in this magnesium chloride brine creates crude solid magnesium chloride (TR 2016, 221-234).

(c) *Subsurface brine deposits*

Brine deposits in Midland, Michigan, have been a source of magnesium chloride since the 1890s. The Dow company originally obtained its bromine, chlorine, sodium, calcium and magnesium from the brine of ancient seas under Midland (TR 2016, 264-266).

(d) Mined mineral deposits

The two major mined mineral sources of magnesium chloride are bischofite and carnallite, both of which were formed during prehistoric solar evaporation of sea water (Butts 2004). Solution mining of these ore bodies creates a brine that is processed on the surface. Water is pumped into the ore body to dissolve these soluble minerals, forming a brine which is pumped to the surface. Most of the patented processes for purification and concentration of these brines rely on water and evaporation, without any additional chemicals However, because magnesium chloride is soluble in alcohol while potassium chloride is not, several patented processes for separating pure magnesium chloride from carnallite employ a low molecular weight alcohol, such as methanol, to recover pure magnesium chloride (TR 2016, 291-297).

Synthesis of magnesium chloride by the reaction of a magnesium compound such as the oxide, hydroxide, or carbonate with hydrochloric acid is a chemical process, which involves chemical reaction of an acid and an alkali to form a salt. (TR 2016, 340-342).

GRAS: Magnesium chloride hexahydrate is affirmed by the FDA as Generally Recognized As Safe (GRAS) as a food ingredient (21 CFR 184.1426). It is allowed by the FDA as a flavoring agent, adjuvant, nutrient supplement, and may be used in infant formula (TR 2016, 94-96).

Ancillary substances: Magnesium chloride hexahydrate is commercially available as colorless, odorless flakes, crystals, granules or lumps. Both JECFA and FCC require that the material assays at 99% to 105% $MgCl_2 \cdot 6H_2O$. Commercial sources contain no additional or ancillary ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents or other materials) (TR 2016, 110-113).

International: International Organic food processing standards allow use of magnesium chloride – see TR 2016 for scope of specifications (TR 2016, 156-181). EU standards include use of term nigari. Nigari consists of the natural components of sea water including magnesium chloride, magnesium sulfate and other elements of sea water that remain after sodium chloride crystallizes from solar brine (TR 2016, 120-122).

Classification: During initial Review in 2015 the subcommittee requested public comment on whether or not this material should be re-classified as non-synthetic because it is simply derived from sea water by brine drying, with no ancillary substances. Public comment supports that this material should be re-classified as non-synthetic and moved from a listing at 205.605 (b) to 205.605 (a). However, information provided in the TR 2016 indicates that this material can be produced both synthetically and non-synthetically, and the annotation "derived from seawater" can apply to both synthetic and non-synthetic.

Magnesium chloride produced by reacting a magnesium compound or mineral with hydrochloric acid is considered synthetic. This is because the substance undergoes a chemical change so that it is chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-354)

Natural sources of magnesium chloride can be extracted by various means which may affect the classification of the final substance as synthetic or non-synthetic. Evaporation and crystallization are physical processes which do not result in chemical change. Magnesium chloride extracted from brine by the two-step process involving calcium hydroxide and carbon dioxide is not chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-361)

Additional information requested by NOSB

1. Are any producers/handlers using synthetic magnesium chloride? If yes, would they be able to switch to a non-synthetic version?
2. What impact on producers/handlers would result, if any, if magnesium chloride was removed from 205.605 (b) and added to 205.605(a)?
3. Besides a coagulant in making tofu, are there any other uses of magnesium chloride in organic processing/handling?

Potassium acid tartrate

Reference: 205.605(b)
Technical Report: 1995 TAP; 2017 TR
Petition(s): N/A
Past NOSB Actions 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 06/27/2017 (NOP renewal pending)

Background:
Potassium acid tartrate is a by-product of wine making. It is commonly known as Cream of Tartar. It is used in baked goods, a component of baking powder, and can be used to stabilize egg whites or other food uses. No public comment opposing continued listing of this material was received during the 2015 Sunset Review.

Potassium acid tartrate is currently allowed under the National Organic Program (NOP) regulations at 7CFR 205.605(b) as a "**nonagricultural, synthetic substance** for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." The FDA authorizes use of potassium acid tartrate in a variety of applications as a direct food substance, including as a leavening agent, a pH control agent, and an antimicrobial agent.

History: During its 2015 Sunset review, the NOSB noted a number of inconsistencies in the historical documents about this material, confusion with specific names of similar sounding materials, and confusion in classification of this material. However, until the NOSB received an updated TR, it recommended continued listing of potassium acid tartrate. . A new TR, dated January 11, 2017, was received and is utilized for this Sunset 2019 review. A detailed discussion of the historical documents relevant to potassium acid tartrate is provided in the 2017 TR.

Manufacture: During the winemaking process, sediments must be removed to produce a clear wine. "Lees" is the name of the sediment consisting of dead yeast cells, grape pulp, seed, and other grape matter that accumulates during fermentation. "Argol" and "tartar" are synonyms used to describe the crust that builds up in wine vats and casks. Argol is defined as crude potassium hydrogen tartrate, deposited as a crust on the sides of wine vats. Tartar is defined as a substance consisting essentially of cream of tartar that is derived from the juice of grapes and deposited in wine casks together with yeast and other suspended matter as a pale or dark reddish crust or sediment. Tartar consists of about 80% potassium acid tartrate. Potassium acid tartrate is only slightly soluble in cold water but highly soluble in hot water (6.1g/100 mL at 100°C). Extracting wine lees with hot water dissolves the potassium acid tartrate. When the filtered extraction solution is cooled, potassium acid tartrate precipitates as very pure crystals (>99.5% pure). No other reagents or solvents are involved in the extraction. (TR 2017, 58-69).

GRAS: Potassium acid tartrate is Generally Recognized as Safe (GRAS) (TR 2017, 350).

Ancillary substances: There are no ancillary substances associated with potassium acid tartrate.

International: International guidance and regulations include the use of potassium acid tartrate (INS 336i) in organic processing, generally consistent with the limited uses described by FDA at 21 CFR 184.1077(c). The European-focused regulations and guidance – CODEX, IFOAM and the EU – additionally include potassium tartrate (dipotassium tartrate) (INS 336ii) as an allowed potassium tartrate. (TR 2017, 184-187).

Classification: Potassium acid tartrate is present in grape juice and wine; it is extracted from natural sources: press cake, lees, and sediment recovered from winemaking. It is extracted with potable water and undergoes no chemical change during extraction or crystallization. Based on the decision tree in Draft Guidance NOP-5033-1, this manufacturing process could be considered nonsynthetic, although it is currently classified as a synthetic substance at §205.605(b) (TR 2017, 339-343).

The FDA defines "potassium acid tartrate" at 21 CFR 184.1077(a): "Potassium acid tartrate ($C_4H_5KO_6$, CASReg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture" (TR 2017, 368-371).

No method of manufacture other than as a by-product of wine manufacture is encompassed by this regulation. The FDA definition of potassium acid tartrate would appear to require an agricultural source. Grapes and wine are agricultural products. The by-products that naturally settle out of grape juice and fermenting wine are used to make this food ingredient, with minimal processing (hot water extraction). However, the NOP regulation classifies potassium acid tartrate as nonagricultural at 7 CFR 205.605.

Interestingly, potassium acid tartrate is a precursor to tartaric acid, which is another substance on the National List. Tartaric acid, with the annotation "made from grape wine," is listed at §205.605(a) as an allowed *non-synthetic*, nonagricultural (nonorganic) substance. This classification came from a 1995 NOSB vote. Thus, tartaric acid from grape wine is classified as non-synthetic, while the precursor, potassium acid tartrate from grape wine, is classified as synthetic.

This material appears to meet the OFPA criteria but it may be inaccurately classified as non-agricultural and synthetic as opposed to agricultural and non-synthetic.

Additional information requested by NOSB

Should this material be re-classified as agricultural or non-synthetic and therefore be listed at §205.606 or §205.605(a)?

Sodium phosphates

Reference: 205.605(b) - for use only in dairy foods.

Technical Report: 2001 TAP; 2016 Phosphates
Petition(s): 1995 N/A, 2001 Sodium Phosphate
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review

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

Sunset Date: 06/27/2017 (NOP renewal pending)

Background:
The material was added to the National List in 1996 with the "dairy use only" annotation. The material is derived from phosphoric acid.

Uses: Acidity control agent, antimicrobial, boiler water additives, sequestrants, texturizer, nutrient, and dietary supplement. Prevents separation of water and fat in cheese; emulsifier in non-fat cheese and milk; creates organoleptic characteristics not otherwise present.

Use in soy processing was not added to the permitted uses for sodium phosphates because the reviewers found that the petitioner did not adequately justify its essentiality.

The petition, dated March 21, 2001, was a request from the manufacturer for use of sodium phosphate in "Food and Beverage Products formulated with Soymilk and Dry Soymilk Similar to or equivalent to Dairy Products." A Technical Panel Report was requested.

The technical advisory panel (TAP) report, dated September 21, 2001, indicates a lack of consensus of the use of these orthophosphates (mon- di- and tri sodium phosphate). One reviewer suggested prohibition based on review of all OFPA criteria; one reviewer suggested use only as limited by 21 CFR requirements. Another reviewer suggested that it be listed with stringent conditions on all uses of sodium orthophosphates, which would allow all FDA permitted uses, but only with a case by case determination of need, essentiality, nutritional impact and alternatives.

The TAP Review (2001) notes that "toxicity of sodium phosphates is generally related to sequestration of calcium and the subsequent reduction of ionized calcium. It is an irritant, and ingestion may injure the mouth throat and gastrointestinal tract, resulting in nausea, vomiting, cramps and diarrhea" (p 5). Other human health/medical impacts were noted by TAP reviewers related to use of phosphates as bowel purgatives and cleansers. They also noted low calcium reported in susceptible individuals (p 6).

The relationship between sodium phosphate and calcium sequestration raises issues of concern given that this material is for use only in dairy products. When calcium combines with phosphate the body's ability to absorb calcium is reduced. Phosphates also combine with iron and magnesium and perhaps niacin.

There appear to be a number of alternatives that could be used such as lecithin, agar, alginic acid, pectins and gums.

International: Sodium phosphates are permitted on the Canadian organic standards' list for dairy products only, but are not listed in the following organic standards: EU, CODEX, IFOAM or JAS.

Public comment: Industry supports the listing of this material, especially as an emulsifier in cheese production where its use is considered essential. It is also considered essential in making high protein smoothies, stabilizing the texture of the product. Another comment indicates its use as a chelating/buffering agent in ultra-pasteurized heavy cream, reducing production time.

Public comment indicated a dramatically increased demand for phosphates in production of processed foods but that consumers are not necessarily aware of this increase in phosphorus intake because phosphorus may not appear on the nutritional panel. Without knowledge of phosphorus amounts in each organic product where phosphates are added, the consumer cannot make an informed choice. Other commenters recommended removal based on lack of essentiality and incompatibility with organic agriculture.

Public comment also raises new information relating to possible negative human health impacts associated with the cumulative effect of phosphates used as food additives. One organization stated "recent studies have shown that inorganic forms of phosphate, such as calcium and sodium phosphate, cause hormone mediated harm to the cardiovascular system." Other commenters provided examples of peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal

renal function, from cumulative phosphorus, and specifically from cumulative impact of sodium phosphate. A daily limit of 70 mg/kg/day was recommended in one study.

Such public commenters recommended either removal from the National List or at least an annotation to eliminate uses prohibited by 205.600 (b)(4) to ensure the OFPA criteria is met. Clinical studies appear to indicate that while the phosphorus content of each processed product may be low, and not in itself detrimental to human health, the cumulative effect of consuming many products with added phosphates as ingredients, may be considerable.

In Conclusion: There are 5 phosphates on the National List at 205.605(b). No single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population. Given the new information and research since last Sunset Review, the Handling Subcommittee requested a new Technical Report (TR) which it received in 2016. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long term cumulative impacts are not fully understood.

Additional Information requested.
Given that this material is not allowed in organic foods produced in Europe, what alternatives are used?

Casings

Reference: 205.606(a) casings, from processed intestines

Technical Report: N/A
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset review
Recent Regulatory Background: Added to NL effective 06/21/07 (72 FR 35137); Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Uses: The intestines of beef, lamb and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

Manufacture: Intestines are washed in pure water with no chemicals, and salted in NaCl salt and water. No other ingredients or processing aids are used. Animal intestines used may be from organic or non-organic animals. Slaughterhouses do not separate certified organic and non-organic offal.

Certified organic intestines from certified animals are not available commercially.

History: On 4/21/2007 the NOSB found that "...no processor with the equipment or technology to process slaughter by-products into casings, from processed intestines, has organic certification and /or

is unwilling to use their equipment for a batch so small as size as would be needed to fulfill current organic requirements."

In 2007 there were no public comments specifically opposing the listing of casings from processed intestines.

In 2015 the NOSB requested additional information during first posting of this material:

1. Are there companies manufacturing casings made from certified organic livestock?
2. Are casings from intestines of organic animals commercially available in the US or international?
3. What chemicals, other than salt, are used to process animal intestines into casings?

Public Comment during review in 2015:

Although more organic animals are being slaughtered than in 2007, no public comment provided any new information as to manufacture process or possible availability of certified organic intestines.

Industry strongly supports continued listing and no commenter asked for removal.

Additional information requested by NOSB

No additional information requested

Konjac flour

Reference: 205.606(n) Konjac flour (CAS # 37220-17-0).
Technical Report: None
Petition(s): 2001 Petition
Past NOSB Actions: 05/2002 NOSB minutes (determined to be agricultural); 10/2010 NOSB sunset recommendation; 10/2015 sunset review
Recent Regulatory Background: 2007 Interim Rule (72 FR 35137); Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background :

Konjac flour is derived from tubers of the elephant yam, *Amorphophallus konjac*, and is primarily grown in tropical and subtropical regions of Asia. It is also called glucomannan. It is a soluble dietary fiber that's been used in traditional foods in Asia such as shirataki noodles and konjac curd (konnyaku). Shirataki noodles are marketed as a zero calorie, zero carbohydrate alternative to pasta and rice.

Konjac is also used as a binder, gelling agent, thickener and stabilizer. Konjac flour is unique in its ability to absorb up to 50 times its weight in water. It is widely used in weight loss supplements because it promotes a sense of fullness and pushes more calories through the colon instead of letting them be absorbed. It is one of the few fibers that are tolerated by diabetics and helps lower serum cholesterol and blood glucose.

Because of konjac's ability to quickly absorb water, there is some concern regarding the potential for capsule supplements or shirataki noodles to block the esophagus. However it appears this is largely avoided by consuming capsules with plenty of water and sufficient chewing of the noodles.

An internet search found several commercially available organic konjac products, including alternatives to rice and several forms of pasta (spaghetti, fettucine, etc.) made from organic konjac flour.

History: Konjac flour was reviewed at the Fall 2015 NOSB meeting. There was no new information regarding the OFPA criteria, and no sources of organic konjac flour were identified in public comment. One trade association indicated that it was still important, particularly for use with meat products like sausages and in fruit gels. Other starches and gums do not produce the unique combination of functions that konjac flour has.

Additional information requested by NOSB:

There appears to be increased availability of organic konjac sources, particularly for gluten-free alternatives to pasta & rice products. With sources seemingly more available, the Subcommittee is interested in the following questions:

1. In addition to alternative pasta & rice products, are the sources of this organic konjac sufficient to provide manufacturers with the form and function required for organic products such as sausages, fruit gels and supplement powder?
2. Do you make an organic product using konjac flour?

Pectin

Reference: 205.606(s) Pectin (non-amidated forms only).
Technical Report: 1995 TAP; 2009 TR; 2010 supplemental TR; 2015 TR (limited scope)
Petition(s): 2005 Petition – low methoxy pectins
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset review
Recent Regulatory Background: Sunset Review effective 06/27/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Use: Pectin is extracted from citrus and pome fruits but so far there is no organic source of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. The excess sugar has the potential for more negative human health effects than pectin.

Manufacturing: The most common production of non-amidated pectin is the treatment of pectin containing byproducts (pome fruit cores, citrus peels) with acidified water. Insoluble materials are filtered and removed and the pectin is precipitated out with alcohol.

International: A review of international standards showed pectin was compliant with the Canadian organic standards (both high and low methoxy allowed), the IFOAM organic standards (unmodified

forms only), the EU standards (Pectin allowed in all products but meat based products), Japanese organic standards (Pectin allowed in all products but meat based products) and Codex (Pectin allowed in all products but meat based products, in dairy products pectin must be unmodified).

Ancillary Substances: Ancillary substances used in pectin include sugar and dextrose for standardizing products, and trisodium citrate (or other salt buffers described in the 2015 TR).

Discussion: In 2015, pectin was widely supported in public comment from its users. No negative comments were received with substantive information on why pectin would not meet the OFPA criteria.

Questions:

1. Have organic sources of pectin become available since the last review in 2015?

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
L-Methionine

January 17, 2017

Summary of Petition

Nature's One has petitioned for L-Methionine to be added to §605.205(b) as a synthetic, non-agricultural substance, allowed in or on nutritionally complete enteral pediatric formulas labeled "organic" or "made with organic (specific ingredients)" with the annotation, "for use in nutritionally complete pediatric enteral formulas based on soy protein".

Summary of Review:
L-Methionine is an essential amino acid, which cannot be synthesized by the human body. The material exists as a clear or white powder.

L-Methionine exists in a category around which there has been much controversy, specifically, the addition of synthetic nutrient vitamins and minerals and accessory nutrients on the National List.

In 1995, the National Organic Standards Board (NOSB) made the following recommendation in "The Use of Nutrient Supplementation in Organic Foods" (USDA, 2011) *Upon implementation of the National Organic Program, the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.* (2012 TR, lines 162-167)

Since that recommendation, the National Organic Program (NOP) published a proposed rule that clarifies a previous reference to FDA's 21 CFR 104.20 for nutrient vitamins and minerals, which indicates that L-Methionine would not be allowed under that provision. Hence the separate petition for its inclusion on the National List.

Nature's One has petitioned for the addition of L-Methionine to the National List at §205.605(b) with a very narrow annotation. The material was petitioned so that organic soy-based enteral products may meet the nutritional requirements for protein. While the FDA does not have specific requirements for enteral products, a sister agency, The Centers for Medicaid and Medicare, has defined nutritionally complete pediatric enteral formulas through the Healthcare Common Procedure Coding System (HCPCS). B4159 is the HCPCS for nutritionally complete pediatric enteral formulas based on soy protein.

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:

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:

3. For **LIVESTOCK**:
   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)]
   None identified. L-Methionine is a synthetic material petitioned for use in the formulation of enteral soy-based pediatric formulas and would have no impact on 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)].
   Physiologically, methionine is required for nitrogen balance, cell metabolism, protein formation, and growth (Brosnan and Brosnan, 2006). (2012 TR lines 61-62).
   The material breaks down into nitrogen oxides, carbon monoxide, sulfur oxides and carbon dioxide. (2012 TR lines 53-54).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)].
   None identified. There are several processes used to manufacture L-Methionine. The most commonly used is an enzymatic process.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].
   Methionine is an essential amino acid that cannot be synthesized by the body; thus, it is used primarily as a dietary supplement in humans and a feed additive in livestock. Physiologically, methionine is required for nitrogen balance, cell metabolism, protein formation, and growth (2012 TR, lines 60-62, Brosnan and Brosnan, 2006).

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)]
   N/A. L-Methionine is a synthetic, manufactured and used in final product formulations.

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

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)].
   As petitioned, there is no suitable alternative for L-Methionine in soy-based pediatric enteral formulas. L-Methionine is added to soy based formulas in order to meet protein requirements for pediatric formulas.

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)).
   As petitioned, protein levels in organic soy-based formulas are insufficient without the addition of L-Methionine.

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)).
   Most L-methionine is produced from synthetic DL-methionine, and DL-methionine can be produced in following ways: In general, L-methionine is produced from DL-methionine via optical resolution or by enzymatic selection. Because much of the DL-methionine supply is synthesized using chemical methods, the L-methionine produced from it is also synthetic. While non-synthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005). (2012 TR lines 279-284)
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).
   The nutritional quality of the food is deficient in soy-based enteral formulas without the addition of L-Methionine.

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)). L-Methionine is for nutritional amendment only and does not improve flavors, colors, or nutritive value lost during processing.

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, L-Methionine is listed as GRAS. (2012 TR line 97).

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6)) The addition of L-Methionine is essential for soy-based enteral formulas due to the need to supplement protein levels.

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)

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

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

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?

5. Does the industry information 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;

    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;

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

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

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)

Classification Motion:

Motion to classify L-Methionine as non-agricultural, synthetic.
Motion by: Tracy Favre
Seconded by: Harold Austin
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add L-Methionine to §205.605(b), as petitioned: allowed in or on nutritionally complete enteral pediatric formulas labeled "organic" or "made with organic (specific ingredients)" with the annotation, "for use in nutritionally complete pediatric enteral formulas based on soy protein".

Motion by: Tracy Favre
Seconded by: Jean Richardson
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOP January 17, 2017

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Short DNA Tracers

January 31, 2017

Summary of Petition, Petition Addendum

Short DNA tracers are being petitioned by manufacturer Safe Tracers for addition to §205.605(b). The petitioner states that inclusion of short DNA tracers in organics would be an improved method for traceability and that current record keeping practices could be simplified and/or supplemented by using short DNA tracers. An advantage pointed out by the petition is that since the short DNA tracers are added to the food, and not to the packaging, it cannot be separated from the food, accidentally or intentionally. Additionally, short DNA tracers do not affect appearance, flavor, aroma, nutritional values or storage requirements of labeled foods and ingredients.

The short DNA tracers could be added by processors to wax or other coatings used in fresh fruits and vegetables. They may also be added to dried products in powder form, encapsulated in various materials that are certified organic or included on §205.605 or §205.606, such as maltodextrin, agar agar, etc. They can also be added directly in liquid form to liquid products such as wine, olive oil, or honey. To obtain maximum sensitivity producers are likely to include short DNA tracers in foods at levels around 1 milligram per ton, which is 1 parts per billion (ppb). The addition of a distinct short DNA tracer would be easily distinguishable through testing at different points in the supply chain, basically tracing the movement and authenticity of the food or ingredient containing the short DNA tracer. Testing currently takes less than an hour and costs less than $100.

The following is a summary of the manufacturing process of short DNA tracers as explained in the petition. First, full length genomic DNA is purified from a natural source, to serve as the template. Then this template is used to biochemically copy a short targeted region of 50-150 pb in length. This process does not involve genetic modification, and no genes are produced or transferred.

Step one in the manufacturing process is isolation of genomic template DNA from a natural source. Tissue is trimmed, washed and then homogenized through mechanical grinding or via freezing and/or drying. This allows for the release of DNA without breaking into pieces that are too small to be detected later as tracers. Then the homogenate is dissolved in water with the addition of 1-10% lecithin, which breaks up the proteins and lipids. Undissolved solid material is then separated via centrifugation. The clarified liquid is taken from the top and .1-10% sodium chloride is added and stirred to dissolve the solution. Sodium in the salt serves to bind and neutralize the negative charges on the DNA, so the molecules may be forced to clump together in the next step. Next, cold alcohol is added, causing the DNA to be physically forced out of the solution, form a solid, which is separated via centrifugation. The solution, containing the sodium chloride and lecithin, is removed from the top and discarded; the crude DNA pellet is re-suspended in cold alcohol and washed.

Step two is the biochemical copying. After the genomic DNA has been isolated, it is used as a template for biochemical copying. The laboratory biochemical process that reproduces the natural DNA synthesis process requires a pair of single stranded DNA 20-30 bases in length, called primer oligonucleotides. These primer oligonucleotides are manufactured synthetically, as they are too short to reliably procure

from the original natural source (from which the short DNA sequence originates). The primer oligonucleotides represent about 25% of the final product.
The biochemical reaction Polymerase Chain Reaction (PCR) is used for preparation of short DNA tracers from templates. This method does not require insertion, deletion, or modification of any genetic material, and it takes place with no living organism.

Short DNA tracers may also be directly manufactured from genomic DNA using a process involving treatment with restriction endonuclease enzymes but this practice is currently prohibitively expensive.

Summary of Review:
The Handling Subcommittee recommends that the petitioned material, short DNA tracers, not be added to the National List as it fails the "Essentiality & Availability" criteria. Additionally, the use of short DNA tracers would not simplify or change current recordkeeping practices by producers.

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:

   Short DNA tracers are not a product of agriculture. The process to make short DNA tracers mimics the natural synthesis of DNA that occurs in the cells of living things.

   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 petition describes step two in the manufacturing process as follows (underlining added by Subcommittee):
   "After the genomic DNA has been isolated, it may be used as a template for the second step, which is biochemical copying. The laboratory biochemical process reproduces the natural DNA synthesis process, with a few differences. The main difference is that the lab method requires a pair of single stranded DNA 20-30 bases in length, called primer oligonucleotides. These DNA molecules are designed to bind to either end of the target 50-150 bp region on the template. They serve to delineate the short region of the genomic DNA that is targeted for copying."

   While DNA replication does occur in nature and the technique used is intended to mimic what happens in nature, the use of synthetically derived oligonucleotide primers make this substance synthetic. The synthetic primer oligonucleotides represent about 25% of the final product.

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

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)]

   The manufacture of the substance is carried out in controlled environments. Any environmental contamination resulting from production and purification of DNA would be subject to regulations governing waste discharges from the laboratories. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

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

   The manufacture of the substance is carried out in controlled environments. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

   The product is considered non-hazardous and does not require a Material Safety Data Sheet.

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

   Biochemically produced DNA is GRAS. The petition states that “NIH considers short DNA tracers safe, and this material is not regulated”, and that “…although it is not considered an essential nutrient, DNA is used legally as a dietary supplement, for which FDA registration is not required”.

   DNA is a nutrient that is normally abundant in human diets. The amount of short DNA added for tracing purposes is less than one trillionth the amount found in a typical meal. Normal digestive processes completely destroy short DNA tracers, breaking them down into individual nucleotides.

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)]

Short DNA tracers are not intended for use on soil, crops, or livestock. Even if small amounts were occasionally released into the environment, almost all life forms readily use foreign DNA as food source.

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

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 practice to using Short DNA Tracers would be to continue the record keeping processes currently utilized by certified organic operations.

   The petition also points out an alternative tracer called Grainfetti, ¼" pieces of paper with printed alphanumeric codes that are mixed into grain. This tracer is not currently approved for organic use.

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)]

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 use of synthetic primer oligonucleotide is necessary because the naturally occurring enzymes that are used in the DNA production (DNA polymerases), can only attach new DNA nucleotides to an existing strand of nucleotides. The primer oligonucleotide serves to prime and lay a foundation for the DNA production. The primer oligonucleotides are manufactured synthetically because they are too short to reliably procure from the original natural source from which the short DNA sequence originates.

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))

The manufacture of the substance is carried out in controlled environments. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

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)

   Biochemically produced DNA is GRAS. The petition states that "NIH considers short DNA tracers safe, and this material is not regulated", and that "…although it is not considered an essential nutrient, DNA is used legally as a dietary supplement, for which DFA registration is not required".

   DNA is nutrient that is normally abundant in human diets. The amount of short DNA added for tracing purposes is less than one trillionth the amount the amount found in a typical meal. Normal digestive processes completely destroy short DNA tracers, breaking them down into individual nucleotides.

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 primary use of the substance is as a tracer, not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing.

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))

   A GRAS notification for short DNA tracers was submitted to the FDA, and a No Questions Letter was received on August 25, 2014.

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

   The Handling Subcommittee does not believe that the use of short DNA tracers is essential for the handling of organically produced products. The production and sale of organic products has been established and continues to grow without the use of short DNA tracers or similar alternatives.

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)

   The handling subcommittee does not believe that the use of short DNA tracers is essential for the handling of organically produced products. The production and sale of organic products has been established and continues to grow without the use of short DNA tracers or similar alternatives.

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 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 Short DNA Tracers as nonagricultural, synthetic
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add Short DNA Tracers, as petitioned, at 205.605(b)
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 21, 2017

National Organic Standards Board
Handling Subcommittee Proposal
Annotation Change for the Listing of Tocopherols to §205.605(b)

January 17, 2017

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 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 eliminated the annotation "Derived from vegetable oil when rosemary extracts are not a suitable alternative." Public comment in the earlier Sunset review of tocopherols indicated that rarely is rosemary extract used as an alternative. Further, because there is not a specific instruction that rosemary extract must be organic, the subcommittee felt the annotation should be eliminated. In order to have consistency between the listings at §205.605(a) and §205.605(b), and to eliminate confusion among producers and certifiers, the subcommittee is proposing to eliminate the annotation at §205.605(b). For the Fall 2016 NOSB meeting in St. Louis, the Handling subcommittee brought forth a proposal with the following motion and annotation:

Motion to eliminate the annotation for tocopherols listed at §205.605(b) of the National List : "Derived from vegetable oil when rosemary extracts are not a suitable alternative."

During the Fall 2016 NOSB public comment period, comments in support of the additional listing and the concept of the revised annotations were predominant. However, several commenters expressed the opinion that the additional listing at §205.605(a) to allow for non-synthetic tocopherols was not sufficient incentive for processors to switch from synthetic versions to non-synthetic versions. Commenters urged the NOSB to more specifically require through annotation: 1) when listed at §205.605(b), the use of non-synthetic or organic versions when commercially available; and 2) when listed at §205.605(a), the use of organic versions when commercially available. One commenter

suggested an expiration date on the listing at §205.605(b) to further increase the sense of urgency to increase commercial availability of organic tocopherols.

Additional comments were received that suggested the need to consider allowance of tocopherols from other natural sources, such as nut and seed oils. As the original annotation to specify vegetable oils was intended to specifically prohibit tocopherols derived from non-natural sources, i.e., petroleum products, rather than specifically narrow the origin to vegetable oils, the Handling subcommittee elected to return this proposal to subcommittee for further refinement.

The Handling subcommittee agrees with the comments that suggested a more specific annotation and therefore has amended the annotation as was presented at the Fall 2017 NOSB meeting.

The proposal for the new listing at §205.605(a) will be deferred to the Fall 2017 meeting so that comments to this proposal can be assessed before finalizing. Ultimately, the decision tree, NOP 5033-1, as published on December 2, 2016, will be used to determine the non-synthetic/synthetic status of tocopherols.

Vote in Subcommittee
Motion to change the annotation for tocopherols listed at §205.605(b) of the National List: "Derived from vegetable oil when rosemary extracts are not a suitable alternative" to the following annotation – "Derived from plant oils. Non-synthetic or organic tocopherols are to be used when commercially available."

Motion by: Tracy Favre
Seconded by: Jean Richardson
Yes: 8 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB on January 17, 2017.

National Organic Standards Board
Handling Subcommittee Proposal
Marine Algae listings on the National List

January 17, 2017

I INTRODUCTION

During its recent five year sunset review of almost 200 materials the NOSB and public comment noted that the listings of the nine (9) marine materials on the National List includes overlap in species, and lack of scientific clarity. A discussion document was posted and substantive public comment received in Fall 2016. Based on public comment from a broad cross section of stakeholders this proposal recommends that the marine algae materials be annotated with Latin binomials where possible, or by Class, and that the NOP review the word "kelp" as used in organic production and clarify if marine materials on the List should be classified as agricultural or non-agricultural.

II BACKGROUND

There are nine separate listings for marine materials on the National List, which are the subject of this document. An identical proposal is also brought forward by the Crops Subcommittee:

1. **Aquatic plant extracts** (Technical report 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) is in the *Fucaceae*, a brown seaweed, Class *Phaeophyceae.*

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), *Durvilea* (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 Eucheuma 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 carrageen-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. gramminifolium, S. henslowianum, S. mcclurei, S. siliquosum, S. vachelliannum* fromVietnam; *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 β-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).

7. **Kelp** (TR 2016) 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.*

   NOP 5027 states that kelps are brown algae and are among the most common seaweeds consumed as food. Stationary kelps/seaweeds rooted via a holdfast are wild harvested from the intertidal (eulittoral zone) and deeper (sublittoral zone) waters throughout the world's oceans.

   However the term "kelp" as used in fertilizer means ANY macroalgae seaweed, brown (*Phaeophyceae*), red (*Rhodophyceae)* or green (*Chlorophyceae)* (Assoc. of American Plant Food Control Officials (AAPFCO)).

   To further confuse the definition of kelp the American Association of Feed Control Officials (AAFCO – as distinct from AAPFCO) approves dried kelp from the families *Laminariaceae* and *Fucaceae* for use as ingredients in livestock feed (see also NOP 5027).

   NOTE: Kelp used in organic livestock production must be certified, but for use in processing/handling for humans non-organic kelp is allowed.

   The FDA lists 4 species under the definition of Kelp, Macrocystia pyrifera, Laminaria digitata, Laminaria saccharina and Laminaria cloustoni (21 CFR 172.365).

   OMRI definition of Kelp:

(1) Crop production- The dried marine algae of the botanical divisions of *Rhodophyta* (red algae) *Phaeophyta* (brown algae and *Chlorophyta* (green algae) (AAPFCO)
(2) Livestock production – Seaweed of the families *Laminariaceae* and *Fucaceae* (American Association of Feed Control Officials (AAFCO).
(3) Processing and Handling – The dehydrated, ground product prepared from the brown algae species *Macrocystis pyrifera*, *Laminaria saccharina* , and *Laminaria coustoni* (21 CFR 172.365)

Kelp classification: The NOP received comments asserting that kelp is not agricultural and should be permitted only as a nonsynthetic, nonagricultural ingredient in organic livestock feed as per § 205.237(a). This position implies that kelp should not have to be certified organic to be used in organic livestock feed. However, kelp is currently listed as an agricultural product under § 205.606 of the National List of Allowed and Prohibited Substances (National List). Because kelp is listed at § 205.606, the NOP considers kelp an agricultural product and, therefore, kelp must be certified organic to be included in livestock feed. (See comments received in response to publication of draft guidance, NOP 5022 – Wild Crop Harvesting. 70 FR 62693 [October 13, 2010].)

Pacific Kombu, and *Undaria innatifida,* listed separately on the National List*,* are also Kelp species.

8. **Seaweed- Pacific Kombu** is a kelp, often *Laminaria japonica or Saccharina 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, FDA, NOP GUIDANCE, NOP POLICY MEMO, OMRI

§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.

205.237 (a) § 205.237 Livestock feed.
(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and handled by operations certified to the NOP, except as provided in § 205.236(a)(2)(i), except, that, synthetic substances allowed under § 205.603 and nonsynthetic substances not prohibited under § 205.604 may be used as feed additives and feed supplements, Provided, That, all agricultural ingredients included in the ingredients list, for such additives and supplements, shall have been produced and handled organically

21 CFR 172. 365 – FDA, Title 21, Food for Human Consumption – Kelp

Kelp may be safely added to a food as a source of the essential mineral iodine, …..The food additive kelp is the dehydrated, ground product prepared from *Macrocystis pyrifera, Laminaria digitata, Laminaria saccharina* and *Laminaria cloustoni*.

21 CFR 172.620 – FDA- Carrageenan – (a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families *Gigartinaceae* and *Solieriaceae* of the class *Rodophyceae* (red seaweed): *Chondrus crispus*, *Chondrus ocellatus*, *Eucheuma cottonii, Euchema spinosum, Gigartina acicularis, Gigatina pistillata, Gigartina radula, Gigartina stellate*.

21 CFR184.1115 – FDA – Agar-Agar (a) A dried, hydrophyllic, colloidal polysaccharide extracted from one of a number of related species of red algae (class *Rhodophyceae*).

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

NOP 5027, March 4, 2013, The Use of Kelp in Organic Livestock Feed. This guidance establishes that kelp are brown algae and may be certified organic as a wild crop under 7 CFR § 205.207 and must be certified organic if used as an ingredient in livestock feed per § 205.237.

NOP 5020, effective 1/15/16, Guidance: Natural Resources and Biodiversity Conservation. Purpose; To clarify organic regulations at 7 CFR 205.200, which states "to maintain or improve the natural resources of the operation….".

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.

OMRI definition of kelp:
(1) Crop production- The dried marine algae of the botanical divisions of *Rhodophyta* (red algae) *Phaeophyta* (brown algae and *Chlorophyta* (green algae) (AAPFCO)
(2) Livestock production – Seaweed of the families *Laminariaceae* and *Fucaceae* (AAFCO)
(3) Processing and Handling – The dehydrated, ground product prepared from the brown algae species *Macrocystis pyrifera, Laminaria saccharina , and Laminaria coustoni* (21 CFR 172.365)

IV DISCUSSION:
The NOSB submitted brief information on each of the nine materials and posed seven questions for the limited scope TR in 2016. Questions were posed to the public in the subsequent NOSB discussion document (November 2016), and thousands of pages of public comment and peer reviewed scientific research articles were received, providing the NOSB with a substantive body of documented research from a number of perspectives.

Public comment included concerns for the following:

- Lack of clarity as to which species are allowed on the National list and confusion over names used.
- Desire to encourage organic cultivation and wild harvesting of marine materials.
- 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 and cultivated algal species.

Public comment from all sectors strongly supported a proposal to clarify and annotate the marine algae listing through use of Latin binomials as far as possible, and recommended NOP Guidance.

V PROPOSAL:

1. Motion to annotate the marine algae listings as follows, shown in underline:

§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; ...). Derived from brown seaweeds, class Phaeophyceae

Agar-agar. Derived from red seaweeds, class Rhodophyceae

Carrageenan. Derived from red seaweeds, class Rhodophyceae.

(b) *Synthetics allowed:*

Alginates. Derived from brown seaweeds, class Phaeophyceae.

§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). Derived from green algae, class Chlorophyceae.

(l) Kelp – for use only as a thickener and dietary supplement. Derived from Macrocystis pyrifera, Laminaria digitata, Laminaria saccharina and Laminaria cloustoni.

(t) Seaweed, Pacific Kombu, derived from Laminaria japonica, class Phaeophyceae

(x) Wakame Seaweed (*Undaria pinnatifida*).

Vote in Handling Subcommittee:

Motion by: Jean Richardson
Seconded by: Harold Austin
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

2. Motion to recommend that the NOP develop Guidance to clarify the term "kelp" as used in organic production and wild harvesting.

Motion by: Jean Richardson
Seconded by: Harold Austin
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 17, 2017

National Organic Standards Board
Handling Subcommittee Proposal
Ancillary Substances Permitted in Cellulose

January 3, 2017

This proposal addresses the additional ancillary substances for use with cellulose, which is currently listed on the National List at §205.605(b) Cellulose- for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

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 their processing, some may remain in the final product in tiny amounts.

While the ancillary substances for use in cellulose in the current chart were approved during the recent sunset review and vote by the NOSB at the St. Louis meeting, there were several additional ancillaries (listed in chart below) that were identified during the second public comment period that were not on that list. These additional ancillary substances were identified after the final proposal had been posted[1] and thus there is a need to bring those forward now.

The Handling Subcommittee believes that this should capture all of the functional classes in use for cellulose, along with those ancillary substances currently in use with cellulose under said functional classes. Any additional ancillaries that fall within one of the functional classes listed below do not need to be reviewed further in order to be used. Any new functional class of ancillaries however, would need to be petitioned in order to be allowed for use with cellulose.

1. Identity of Additional Ancillary Substances Permitted for use in cellulose.

Functional class	Substance name	CAS or INS number- if known	Synonyms
Shirring Aid	Food Grade Mineral Oil		
Shirring Aid	Food Grade "White" Mineral Oil	CAS # 8042-47-5	
Humectant	Glycerin	CAS # 56-81-5	Glycerine
Coating	Polyvinylidene, vinyl chloride	CAS # 9002-85-1	
Coating	Kymene		
Coating, pH control agent	Sodium Hydroxide	CAS # 1310-73-2	
Peeling aid	Carboxymethyl cellulose, with	CAS # 9000-11-7	

[1] Substantive changes are not allowed once the final document has been posted

	Polysorbate 80 as an emulsifier to aid the CMC	CAS # 9005-65-6	
Synthetic binder	Resin		

2. Identify any ancillary substances, or categories of substances prohibited for use in Cellulose:
Mineral oils, untreated or mildly treated, appear on the IARC list - However, "food grade" mineral oils and white mineral oils are not included under this listing. The food grade types of mineral oils go through a refinement process that classifies them as a "highly refined" mineral oil with the potential carcinogens having been removed via these processes. Thus, mineral oils that are untreated or mildly treated, should not be allowed as an ancillary substance for use with cellulose or any other substance used in organic handling. Only highly refined mineral oils (food grade or white) should be allowed. (Information provided in the Report on Carcinogens for Mineral Oil: Untreated or Mildly Treated; Fourteenth Edition. National Toxicology Program, Department of Health and Human Services).

3. Describe need for material, review of material, discussion, and subcommittee vote.
Ancillary substances for cellulose consist of coating agents (used primarily in casings), anti-caking/anti-sticking agents, binders, carriers, and as releasing agents. Because of the 3 different types of listed uses for cellulose on the National List, the presence of these ancillaries may vary slightly depending on how each type of cellulose is intended to be used. Ancillary substances, including those on this additional list, were discussed at the fall 2016 NOSB Meeting in St. Louis. It was at that time the decision was made that an additional proposal would need to come forward so that those additionally identified ancillaries could be added to the ancillary chart for cellulose.

Evaluation Criteria:

1. **Impact on Humans and Environment**: Is there any evidence the substance(s) may be harmful to human health or the environment?

   The Handling Subcommittee ascertains that the small amounts of ancillary substances used in cellulose have not shown to be of concern to human health or the environment. Additionally, the Subcommittee is confident that cellulose manufacturers are following all regulations about waste disposal and are properly adhering to those regulations to ensure worker safety due to any possible unnecessary exposure.

2. **Essential & Availability**: Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

   During the most recent Sunset Review of cellulose, organic handlers provided the NOSB with comments about essentiality. According to the latest technical evaluation report (TR), while there are sources of cellulose that may not contain ancillary substances, these materials are

needed for consistency and performance in cellulose used for several applications. While some handlers have found alternatives to cellulose, those that still use cellulose provided the NOSB with a broad variety of reasons why it is still essential to their handling process.

3. **Compatibility & Consistency**: Is the substance's use consistent and compatible with organic handling practices?

   Yes, the Subcommittee found no reason why the use of these ancillaries in cellulose should not be allowed for the currently allowed uses of cellulose as listed, with annotations, on the National List.

Subcommittee Action & Vote:

Motion to accept this document in support of, or to restrict the use of, the following ancillary substances or categories of substances in cellulose, as shown in the above chart and/or text of this document
Motion by: Harold V. Austin IV
Seconded by: Ashley Swaffer
Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOP January 3, 2017

National Organic Standards Board
Handling Subcommittee
Bisphenol A (BPA) in Packaging Discussion Document

February 21, 2017

I. INTRODUCTION

The National Organic Standards Board (NOSB) initiated a work agenda item for evaluating packaging materials in 2013. At this time, the Handling Subcommittee (HS) has decided to proceed with a discussion document to collect input from organic stakeholders on this issue while an independent technical report is in process.

Bisphenol A (BPA) is a chemical widely used in manufacturing polycarbonate plastics and epoxy resins used in many industries, including the lining of cans for food. Releases of BPA to the environment exceed 1 million pounds per year (EPA, 2010). It is a known endocrine disruptor, and several studies and biomonitoring programs demonstrate that BPA leaches out of the linings of cans used for food and that human populations are widely exposed (EPA, 2010). For example, BPA was frequently detected in participants in U.S. CDC and California biomonitoring programs (CDC; State of California 2017a) and studies worldwide (Vandenberg LN et al., 2010). Several studies indicate that food contact materials are a primary source of BPA exposure in humans (Carwile et al., 2011; Rudel et al. 2011). For example, in 2011, researchers at the Harvard School of Public Health determined that volunteers who ate a single serving of canned soup a day for five days had ten times the amount of BPA in their bodies as when they ate fresh soup daily (Carwile et al., 2011). Several studies suggest BPA may be harmful to human health at low exposure levels (Sowlat et al., 2016, Rochester JR, 2013, Ejaredar M, 2016) and it is listed as a chemical known to be a reproductive toxicant under the California Safe Drinking Water and Toxic Enforcement Act (State of California 2015).

BPA is currently allowed for use in cans and other packaging containing organic food. In the interest of organic integrity for processed foods, the NOSB is reviewing concerns about BPA in the same way that other synthetic materials that come into contact with organic food are evaluated.

While some organic processors have found alternatives to BPA in their products, the NOSB does not have information on how much BPA is still used in organics and whether alternative packaging materials are widely used. The NOSB would also like to know more about what alternatives to BPA are being used and if any of the alternative materials might raise human health concerns. The Handling Subcommittee and most organic consumers agree that organic food should be produced in a manner that minimizes exposure to toxic materials in any form. Therefore, this discussion document will alert stakeholders to this issue and begin information gathering to determine whether changes are needed in the regulations to ensure harmful substances do not come into contact with organic food.

II. BACKGROUND

In December 2013 a request was submitted by the NOSB Handling Subcommittee to the National Organic Program to add the issue of BPA in packaging to the NOSB work agenda. In November 2014 the NOP issued a Memorandum to the NOSB, titled "*Packaging substances used in organic food handling"*, in which the NOP acknowledged the request and that there were recent studies that raised concern about BPA and similar packaging substances. They suggest:

> "That NOSB start with a discussion paper that provides a review of current literature, evaluation of current uses in the organic market, availability and suitability of alternatives, and impact of removal of these packaging substances on the organic trade."

The memorandum was accompanied by a letter from Senator Dianne Feinstein that supports a ban on BPA.

Additionally, several public comments addressing plastics and BPA were submitted in 2015 and 2016. These comments raised human health and environmental concerns about the use of plastic packaging for organic foods, and many specifically focused on BPA.

A request for a Technical Report (TR) was submitted in August 2015. The following specific issues were posed to the writers of the TR:

- "There is much criticism by both sides of the BPA safety debate over the validity of various research methods, from what breed of rats are used to human cell studies in vitro vs. animal studies. There are also collusion, conflict of interest, and bias contentions in some research efforts. Please examine these objectively using the citations below and others, and give an evaluation of which research is the most valid.
- Evaluate the conclusion from the paper by Yang cited above that they can identify existing compounds, additives, or processing agents that have no detectable estrogenic activity and have similar costs. What are these alternatives?
- Review recent research on some of the BPA alternatives in use, such as Tritan (containing triphenyl phosphate or TPP), Bisphenol S (BPS) and Bisphenol F (BPF) and any others. Some citations are below.
  What is the status of BPA in other countries? How widespread are bans on BPA and are any of the alternatives banned as well? What evidence was used in making those determinations?"

The NOP contracted for the TR in January 2016 with the Agricultural Analytics Division of the USDA AMS. The TR was provided to the NOSB on October 19, 2016. In December of 2016 the HS determined that the report was technically insufficient according to the criteria in the NOSB PPM. In response, NOP issued another statement of work to externally contract this work and OMRI received the award for BPA. The OMRI report is currently in development.

III. RELEVANT AREAS OF THE RULE

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

IV. DISCUSSION

In this discussion the NOSB Handling Subcommittee is seeking information from the industry on several points, including whether BPA should be prohibited and how widespread BPA is used in organic foods.

The HS would also like to collect information on the factors that affect the choice of alternatives and what those alternatives are. This information will be considered along with the final TR when it is publically available.

A. Should BPA be prohibited?

A concise summary of the situation regarding BPA is described in the Environmental Protection Agency BPA Action Plan (EPA, 2010).

> "Because BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic, there are questions about its potential impact particularly on children's health and the environment. Studies employing standardized toxicity tests used globally for regulatory decision-making indicate that the levels of BPA in humans and the environment are below levels of potential concern for adverse effects. However, results of some recent studies using novel low-dose approaches and examining different endpoints describe subtle effects in laboratory animals at very low concentrations. Some of these low-dose studies are potentially of concern for the environment because the concentration levels identified with effects are similar to some current environmental levels to which sensitive aquatic organisms may be exposed.
>
> Regulatory authorities around the world reviewing these low-dose studies have generally concluded that they are insufficient for use in risk assessment because of a variety of flaws in some of the study designs, scientific uncertainty concerning the relevance to health of the reported effects, and the inability of other researchers to reproduce the effects in standardized studies. However, since the low-dose studies do raise questions and concerns, some authorities have taken action to protect sensitive populations, particularly infants and young children."

The latest review from the Food and Drug Administration, published in June 2014 (FDA, 2014), reviewed all the literature since the previous review in 2008:

> "The conclusion of this report is that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses."

FDA also note that there is significant uncertainty associated with extrapolating safety data obtained from rodents and non-mammalian chordates to primates (including humans) because there is a decreased capacity of non-primates to metabolize BPA and there have been large variability in study results.

On the other hand, scientific articles are being published regularly that show that low doses of BPA may be more harmful than higher doses, and that these troubling results are resulting from well conducted research (Johns et al. 2016, Kinch et al. 2015, Science Daily).

For example, human epidemiological studies have shown associations between BPA and a number of adverse outcomes on child behavior, metabolic disorders, and fertility, among other outcomes. Additionally, in 2015 BPA was listed as a chemical known to the state of California to cause reproductive toxicity (Rochester 2013, Johns et al. 2016, Sowlat et al. 2016, Ejaredar et al. 2016, State of California 2015).

There are also concerns about two of the main alternatives to BPA: BPS and BPF. For example, BPS and BPF share similar chemical structures with BPA and may have estrogenic activity and act by similar mechanisms (Hashimoto et al. 2001, Rochester and Bolden 2015, Chen 2002, Kinch et al. 2015).

Individual epidemiologic studies are observational and therefore cannot show causation. However, human studies are most relevant to inform our understanding of human health risks, and a growing

literature suggests that BPA may adversely impact human health, potentially at environmentally relevant levels. Finally, as described above, there is evidence of widespread human exposure with food packaging materials as a primary exposure source.

In summary, as evidence of negative effects on health builds and organic consumers raise concerns about their food choices, evaluation of BPA and similar chemicals by the NOSB is warranted.

B. How much BPA is in use in organic food?

Many, but not all, organic brands have removed BPA from food contact materials (http://www.ewg.org/research/bpa-canned-food). Also, very few companies label their cans as not having BPA so it is hard for consumers to make informed decisions from food labels. A report from the Environmental Working Group provides some information on BPA substitutes used in canned food (EWG, 2015). However, there does not appear to be any independent testing to verify that cans are BPA free. The state of California is developing a database of canned products containing BPA (State of California 2017b), but this data set has not been evaluated in relation to organic products. In summary, more information is needed before the NOSB can make a decision.

C. What alternative materials and practices are being used by organic processors and what factors are prohibiting more products from using alternatives?

- There are can coatings that do not contain epoxy resins, such as those with polyester.
- Baked organic coatings have been used in cans, including oleoresinous, epoxy-amine, and acrylic enamel coatings. Oleoresinous coatings are made from vegetable oil and resin (Deshpande 1995).
- Glass jars are a good alternative although there may still be BPA used in the sealing ring under the lid.
- More BPA migrates from the can lining into the food at higher temperatures and over longer time sitting on the shelf. So processing at lower temperatures and not storing canned goods for long periods will lessen exposure. BPA leaching can also be minimized by increasing the curing time for coatings that contain it. It is not possible for consumers to find out if the curing of the cans for any individual brand was done correctly (Rossi et al. 1970, Lambert et al. 1998).
- Polyethylene and polypropylene packaging can be used instead of BPA cans. These are likely to have less estrogenic activity (Yang et al. 2011). Bioplastics from starch materials, cellulose materials, polylactic acid (Polyester, PLA), polyhydroxy acid (polyester, PHA) that are not only BPA free, but have melting points above 200^{o}C, good moisture barrier characteristics and good compostability and biodegradability properties are now in development (Siracusa et al., 2008) The bioplastics may be combined with nanoscale fillers such as layered silicate nanoclays, e.g. montmorillonite and kaolinite which may also have a role in effective and environmentally friendly food packaging (Rhim et al, 2013). Bioplastics may be problematic for organic food producers because they are often sourced from genetically modified corn. Currently there are no restrictions on these products.

V. REQUEST FOR PUBLIC COMMENT

The NOSB is requesting public comment from both companies who no longer use BPA in packaging, and from those who still think it is necessary. From the former group we would like to hear what is being used instead, and how well it is working. From the latter we would like to know what, if anything, has been tried and rejected, and why. Also, we would like to know reasons why it is still important for specific product categories to allow BPA in packaging. Specific questions include:

A. Should BPA be prohibited?
B. How widespread is the use of BPA in organic canned foods utilizing metal cans?

C. How widespread is the use of BPA in lids or other materials in contact with canned organic food in glass jars?
D. Is BPA present in any other packaging or processing materials that are in contact with organic food?
E. The California Office of Environmental Health Hazard Assessment has compiled a database of canned foods with BPA in metal can liners or jar lids: https://www.p65warnings.ca.gov/bpalist Is this database complete and have any members of the organic community examined this data to determine the prevalence of organic brands using BPA?
F. Are there specific product categories where BPA should be allowed if some uses, such as BPA in linings for canned foods, are prohibited?
G. What alternatives materials and practices have been chosen by organic processors and how well are they working?
H. Have any alternative materials been tried and rejected? If so, why?
I. What factors are prohibiting more products from using alternatives?
J. What are the human health and/or environmental concerns of BPA alternatives, such as BPS and BPF?

The NOSB welcomes comments on the use of BPA in food packaging. Please see https://www.ams.usda.gov/event/nosb-spring-2017-meeting-denver-co for information on how to submit written or oral comments for the Spring 2017 meeting.

Vote in Handling Subcommittee
Motion to accept the BPA discussion document
Motion by: Scott Rice
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

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Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 17, 2017

Sunset 2019
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2017

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at www.regulations.gov by March 30, 2017 as explained in the meeting notice published in the Federal Register.

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

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

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

For Comments That Support Substances Under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

(1) not harmful to human health or the environment;
(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and

(3) consistent with organic livestock production.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with livestock production.

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through March 30, 2017 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2019
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2017

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Chlorhexidine
Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Glucose
Oxytocin
Tolazoline
Copper sulfate
Lidocaine
Procaine

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Technical Report: 01/2010 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background from Subcommittee:
Specific Uses of the Substance: Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre- and post- teat dip to aid in controlling bacteria that causes mastitis. There are numerous synthetic disinfectants currently on the National List of Approved Synthetics for Organic Livestock production including iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide. Not all are useful both in a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation.
Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in

northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months.

Approved Legal Uses of the Substance: Used in agriculture for disinfection during livestock surgery, on teats pre and post milking and on milking equipment. Also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Discussion: In April 2015, the NOSB recommended adding one more teat dip: Acidified Sodium Chlorite- allowed for use on organic livestock as a pre and post teat dip treatment.

Additional information requested by NOSB

1. Does chlorhexidine provide an essential function that other natural materials or synthetics proposed or currently on the national list do not provide?
2. Is chlorhexidine used widely in organic livestock production?

Chlorine Materials

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

Technical Report: 2006 TR
Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background:
Specific Uses of the Substance: Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities.

Approved Legal Uses of the Substance:
Regarding organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. Similarly, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 mg/L).

Discussion: Previous public comments had asked for a comprehensive review of all sanitizers however, the Subcommittee feels that a review of that scope is beyond the sunset review process.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP

Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background:
Glucose has been on the National List since 1995, and has received minimal public comment, both pro and con at each sunset review. It is used most frequently in organic dairy operations, to manage ketosis or other situations where an infusion of glucose is needed to restore the blood sugar balance in an ill animal. On non-organic dairy operations, propylene glycol, glycerin or corticosteroids might also be used. Careful management of feed rations before and immediately after birthing is typically used to avoid the occurrence of ketosis. There may be some excipient ingredients in glucose used in livestock production.

Additional information requested by NOSB
1. Is this material essential in organic production and why?
2. Are there nonsynthetic materials or methods that can be used to treat the illnesses associated with glucose use?

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(17) Oxytocin—use in post parturition therapeutic applications

Technical Report: 1995 TAP; 2005 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 06/27/17 (NOP renewal pending)

Background:

Oxytocin is a hormone, naturally produced in the pituitary glands of humans, cattle and other mammals. In nonorganic production, it can be used regularly to help dairy cows relax and "let down their milk". There are some concerns with over use of oxytocin in nonorganic production systems, as well as the abuse of this hormone in the human population. In the NOP regulations, it is only allowed post birthing, in a therapeutic way to ease various dam issues that are associated with the birthing of the calf, including displaced abomasum and retained placenta. It has been on the National List of approved synthetics since 1995, with minimal public comment on this material, pro or con. Some organic milk marketers require their organic milk suppliers to not use this material. There was very little public comment on this material over the years, and it appears to be used rarely in organic production. However, it could be considered essential for animal health and welfare in emergency situations.

Additional information requested by NOSB

1. Is oxytocin an essential material for organic production and why?
2. Are there nonsynthetic alternatives, or other methods that can be used to accomplish the same results as oxytocin?

Tolazoline

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(22) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

Tolazoline is used in conjunction with xylazine, which is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine.

During the 2015 comment period for the 2017 sunset, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list.

Additional information requested by NOSB

1. Is tolazoline still considered useful and/or necessary by the organic community for the purpose allowed?
2. Are there any alternative practices or substances available that might be preferable?

Copper Sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (1) Copper sulfate.

Technical Report: 1995 TAP; 2015 TR

Petition(s); N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

Copper Sulfate in livestock management is used specifically as a walk-through footbath to help control and prevent hoof- related diseases in dairy cattle and sheep. Some of the specific problems affect skin adjacent to the claw horn of dairy cattle and sheep, i.e., digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions. Depending on the severity of the infection the impact on managed cattle and or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems and in the dairy industry a reduction of milk production ranging from 20 to 50 percent (Brown, et al., 2000, Losinger, 2006). A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes.

According to the Technical Review commissioned by the Livestock Subcommittee, there are no natural (nonsynthetic) products available that can be used as a management strategy to treat hoof- related diseases and lameness in dairy cattle and sheep operations. However, there are various management tools available that could help reduce the cost of treatment and prevent hoof-related diseases. These include the use of additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices (Maas 2009).

Zinc sulfate may be considered a viable alternative, and the NOSB voted at the Spring 2015 meeting to add this substance to the National List for foot and hoof treatment (rulemaking in process by NOP).

Additional information requested by NOSB

1. The livestock subcommittee requests public comment on the use of Copper Sulfate and its essentiality in organic processing.

2. Are there any alternative practices or substances available that might be preferable?

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Lidocaine is a local anesthetic which has a rapid onset of action and is short term in duration. It numbs only the area to be worked on. For example, Lidocaine is used to humanely de-bud horns on calves, and for minor surgery on mature animals.

During the 2015 sunset review of lidocaine and procaine the Livestock Subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) implies that perhaps the 90 days is a doubling of the FDA or FARAD (Food Animal Drug Residue Avoidance) withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources**.**

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

The NOSB in its initial request for public comment in April 2015, for Sunset 2107 Review had asked:

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

In 2015 public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Lidocaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A discussion document on changing the withholding period was presented at the October 2015 meeting, and a proposal to amend section 205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

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

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

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supports a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production**.** The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list lidocaine and for the annotation for shorter withholding period.

Additional information requested by NOSB

No additional information requested.

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on and can be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

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

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

The NOSB in its initial request for public comment in 2015 for Sunset 2017 Review, asked:

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

In 2015 and 2016 Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Procaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A Discussion Document on changing the Withholding period was presented at the October 2015 meeting, and a Proposal to amend Section 205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC. As follows:

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

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

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supported a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production**.** The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list procaine with the annotation for shorter withholding period. Public comment indicates procaine is not readily available in the United States and does not appear to be widely used. Procaine may not be essential and may not need to continue to be listed.

Additional information requested by NOSB

1. Is procaine used in organic livestock production?
2. Is procaine available in the US in its pure form or only in combination with antibiotics?

National Organic Standards Board
Livestock Subcommittee Discussion Document
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production

December 20, 2016

I INTRODUCTION

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

This discussion document is intended to seek public comment from a broad cross section of stakeholders to determine if any changes should be made to Section 205.238, Livestock Healthcare Practice Standard as it pertains to parasite prevention plans and use of approved synthetic parasiticides, and if clarification of the term "emergency" is needed

II BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides; Ivermectin, Moxidectin and Fenbenzadole, as part of its Sunset Review. In April 2016 the NOSB unanimously approved annotations amending the use of Fenbenzadole and Moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of Ivermectin from the National List. These recommendations are presently pending rulemaking.

During the two years during which these changes were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information some sectors of stakeholder suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused. Some stakeholders approved removal of Ivermectin and annotations to the other two parasiticides but urged clarification of what constitutes an "emergency".

III RELEVANT AREAS OF THE RULE

The language below reflects the recommendations unanimously approved by the NOSB and presently in rulemaking.

§205.238 Livestock health care practice standard.

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

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed

under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.

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

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. 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 provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

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

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

IV DISCUSSION

The following quotes are examples from public commenters concerning the term "emergency" as used in practice prior to use of approved synthetic parasiticides:

Certifier: "*We believe that further transparency on the meaning of the term "emergency use" is imperative. …..it has been difficult to explain "emergency" to (recent) transitioning producers (who are) proposing a more routine use of these materials as a preventative when there is an historical problem with parasites. The annotation changes, which allow a much shorter withdrawal time between use and sale of organic products from these treated animals, will most certainly result in greater use of these synthetics."* Another accredited organic certification agency also *"believes that the term "emergency use" must be clearly defined through regulation as soon as possible."*

A dairy producer association stated: *"Certifiers need to ensure that producers engage in a number of preventive measures, such as rotational grazing, providing healthy herd rations, and keeping susceptible animals on clean pastures, to manage parasites in their livestock herds…. Certifiers should enforce the use of parasiticides for emergency use only and ensure that the organic system plan is changed to prevent further use in future years. NODPA asks the NOSB livestock subcommittee to develop an "emergency use" definition as it relates to a livestock operation in the final regulation. It is essential for operators and certifiers to have clarification of this "emergency" term….. Certifiers interpret the current regulations differently with some producers using a more routine use of these materials as a preventative when there is an historical problem with parasites. Different cultures and communities have different standards for emergency use and as the NOP organic standards are used internationally,*

definitions within regulation are increasingly important. Providing a hierarchy of activities, similar to what is used in crop production when approaching pest management, is one way to provide direction, and we believe with input from the organic community, the development of this definition need not be an onerous task….. ***the term "emergency use" must be clearly defined through regulation as soon as possible to balance the lowering of the withdrawal time, provide clear standards for use internationally and retain the integrity of the organic seal."***

Another producer association commented: "The *NOSB has an opportunity to strengthen the standards and improve compliance, while also retaining the parasiticides needed in an emergency…… Creating a definition for 'emergency.'"*

Industry comment: "W*e encourage NOSB to consider additional guidelines they can provide to operators and ACAs to properly identify and document emergency situations, so that the changes to annotations and use of parasiticides proposed by the Livestock Subcommittee do not result in routine use of these substances."*

The IOIA: "*our greater concern is the unequal application of emergency treatment. As inspectors, we see considerable difference in how emergency is determined. We are opposed to any changes that make it too easy for parasiticide use to become routine in an organic system. Perhaps there's a need to define emergency use better or to describe the need to follow a decision making hierarchy as currently exists in the regulation for 3 both crop and handling standards."*

V REQUEST FOR PUBLIC COMMENT

1. Does the term "emergency" need to be defined?

2. If so, how should the term "emergency" be defined?

3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer's parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?

4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

VI MOTION TO APPROVE THIS DISCUSSION DOCUMENT.

Motion by: Jean Richardson
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB December 20, 2016

National Organic Standards Board
Certification and Accreditation Subcommittee (CACS)
Proposal
Personnel Performance Evaluations of Inspectors

December 13, 2016

I INTRODUCTION

Over the 26 years since the Organic Food Production Act (OFPA) was passed and the National Organic Program (NOP) was subsequently established to implement the Statute, many Rules, Guidance, Instruction, and other Policies and Procedures have been implemented. The organic industry has gown, and with that growth has come challenges for ensuring consistency and integrity in this process-based program which now serves producers worldwide. There are numerous levels of inspection and oversight with checks and balances. The producer submits an Organic System Plan (OSP) and must be inspected annually by the certifier; the inspector must be evaluated annually by the certifier; the certifier must submit documentation on all aspects of its operations to be accredited and is inspected/audited by NOP auditors every 5 years, with an interim audit at about 2-year intervals; the NOP auditors are evaluated every 3 years; the NOP is required to have a Peer Review evaluation annually. The fast growing nature of organic production has created some challenges.

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 requires that every inspector be evaluated not only based on inspection reports and written evaluation instruments every year, but also on **in the field** annual evaluations. Many certifiers have expressed considerable concern for the logistics and expense of meeting this instruction and the potential negative impact it will have on organic production in the marketplace over time.

A Discussion Document on this topic was posted in Fall 2016, public comment was received, and the topic was discussed at the NOSB meeting in St Louis in November 2016. Public comment was substantive in nature and clearly identified challenges if full compliance with NOP 2027 is to be fully enforced. Most serious is the concern that full compliance for in-field evaluations of every organic inspector worldwide “at least annually” would have serious negative economic implications for organic agriculture in the US and overseas, and it doesn’t best serve the intended goal of continuous improvement for all involved.

This Proposal is a recommendation that the NOP revise NOP 2027 as soon as possible to clarify and establish a standard that certifiers can meet in a sustainable and economic manner.

II BACKGROUND

History

On December 2, 2011, following receipt of public comment, 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* stating that there should be in-field evaluations "at least annually."

In 2014, the NOP issued non- compliances to certifiers who failed to evaluate every inspector in the field 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 a lengthy and detailed 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 be limited to one calendar year. ACA also requested certifiers be permitted to share 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 worldwide 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 reported that they worked with 10 certifiers to provide in-field evaluations of 106 inspectors. There are about 80 NOP accredited certifiers worldwide, with 48 based in the USA.

In Fall 2016, the CACS posted a Discussion Document with specific questions to seek public comment:

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 requirement, 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.?

Substantive Pubic comment was received and is discussed below.

III RELEVANT AREAS OF THE RULE, NOP INSTRUCTION, NOSB RECOMMENDATION
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: …

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; ……

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned;
(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.

7 CFR 504 Evidence of Expertise and Ability.
A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§205.100 and 205.101, §§205.201 through 205.203, §§205.300 through 205.303, §§205.400 through 205.406, and §§205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in §205.501:

(a) *Personnel.*
(1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification;

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit: (1) A list of all production and handling operations currently certified by the applicant; …….

(2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested;

NOP Memorandum to NOSB, June 23, 2011, requesting a Proposal from NOSB on Inspector Qualification Requirements.

NOSB Recommendation, December 2, 2011, Inspector Qualification Requirements.

NOP Instruction 2027, August 2, 2013, and Revised March 31, 2016, Instruction: Personnel Performance Evaluation.

NOP Instruction 2501, December 8, 2015, Evaluating Auditor Performance

IV DISCUSSION

In the absence of specific regulatory requirements for the qualifications of organic inspectors, ACAs have instituted a wide range of requirements and criteria in their hiring process, training, and performance monitoring. While the CACS is aware of the requirements of a few ACAs in particular, the actual extent and range of these specific requirements among the 80 worldwide USDA-accredited ACAs is not fully known, and the total number of organic inspectors is also not known.

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 in the US and overseas.

Stakeholders all agree that all inspectors must be professionally evaluated every year. Professional evaluation of inspectors takes place via the review of inspection reports and evaluations provided by certified operations. Stakeholders agree that in-field evaluations should take place, but many certifiers disagree about the requirement of an in-field evaluation of every inspector every year, worldwide. This disagreement is based on logistics, cost, and sustainability. Further, the push to fulfil the every inspector every year requirement may lead to evaluations chosen to simply check off completion versus selecting a location which would best demonstrate an inspector's ability.

The NOP expressed considerable concern about the quality of work of some inspectors that the NOP auditors 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 worldwide 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.

The following is a sampling of public comment received from certifiers, the IOIA, and inspectors.

- 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.
- NOP 2027 says in–field evaluations "should" be conducted, but NOP has issued non-compliances where 100% of all inspectors have not received in-field evaluations. NOP appears to interpret "should" as "shall".

The following are more detailed excerpts from the public comments of one medium-sized certifier as illustrative of the concerns, with proposals for revisions for NOP 2027 which the CACS sees as sensible alternatives to the current every inspector, every year requirement.

> We certify approximately 2000 operations in more than 20 States; we employ 15 staff Certification Specialists who perform inspections, and we contract with approximately 50 independent inspectors annually.
>
> In 2014, we were issued a noncompliance during our NOP audit for conducting onsite evaluations of less than 100% of our contract inspectors, per Standards section 205.501(a)(6). We addressed this. In 2015 and 2016 we conducted an onsite evaluation of 100% of the 65 inspectors currently working for us. We've given many, many hours of consideration to NOP 2027, and we are well-qualified to provide comments and feedback on this issue.
>
> In summary, we do not support NOP 2027 as written, specifically section 3.2.b which requires an annual onsite evaluation of all inspectors. We support a continuous improvement system that

includes onsite evaluations as a tool for training and upholding performance criteria of inspectors. However, the requirement that each inspector be peer evaluated annually significantly increases the cost of inspections for certified operators, limits our ability to support the growth of the organic industry as well as the much needed growth of the inspector pool, and is unnecessarily prescriptive and is more stringent even than the evaluation requirement NOP has of its own auditors per NOP 2501 5.2.b.

Overall, we estimate the onsite evaluation process for independent inspectors costs us roughly $25,000-30,000 annually. However, that can fluctuate upwards significantly based on travel requirements and evaluator availability. We estimate that salary costs to manage and coordinate evaluations and to evaluate staff inspectors roughly translates to an additional $10,000.

Since 2014, the cost of our onsite evaluations has quadrupled, but we have not (yet) raised our certification fees. We've been trying to do more with less, i.e. using a fewer number of inspectors for an ever-growing number of operations, in order to keep the number of evaluations we must perform manageable. We're well aware that this doesn't serve the organic community in the long run, as it limits the number of new inspectors we take on, and it puts a cap on the overall number of inspections that can be done. This has the impact of depressing growth. In fact, in August 2016, we began turning away new client requests for crop certification, due in part to our lack of our capacity to perform an onsite evaluation of new inspectors.

Requiring an annual onsite evaluation for each inspector has almost completely erased our ability to be strategic and thoughtful with these evaluations. In our commitment to remain 100% compliant and complete the annual evaluation cycle, we find it difficult to match the onsite visit with what would actually be, in our opinion, the best evaluation for the inspector. For example, we identify in #3 (risk criteria) below, that an inspector new to a scope would require an onsite evaluation. With the current non-risk-based requirement of evaluating 100% of inspectors annually, we cannot guarantee that we would be evaluating at a site which includes the new scope. We feel the requirement to complete all annual onsite evaluations downgrades the goal of assisting with strategic professional development of the inspector. This is contrary to the spirit of promoting continuous improvement and providing better value to all stakeholders in the organic industry.

We are also left with the question about what happens when, despite our best efforts, we can't perform an onsite evaluation of an inspector. For example, if a contractor performs several inspections for us but quits prior to his/her scheduled onsite evaluation, are we noncompliant with the 100% requirement in NOP 2027?

We would like onsite evaluations to focus on and support inspector development as a tool to maintain a pool of qualified inspectors which grows at a pace commensurate with the growth of the organic industry, especially in underserved areas.

Our proposal for a better-focused onsite evaluation process is to develop a risk-based approach. On an annual basis we would evaluate:

- Novice inspectors
- Inspectors in their first year of inspecting for us

- Inspectors new to a scope
- An inspector who, from Operator or our reviewer feedback, shows the need for additional guidance based upon our review criteria.

For inspectors who are experienced and have demonstrated competency based upon their past onsite evaluations, reviewer feedback, and annual performance evaluations, we propose a three-year evaluation cycle, similar to the frequency with which evaluations are required for auditors working for the NOP.

Costs and Benefits of NOP 2027, based on public comment overall:

Benefits of NOP 2027:

- ACAs report that they no longer hire poor performing inspectors.
- Allows ACAs to identify where further training is needed.
- Opened a broader dialogue between certification staff and inspectors.
- Increases consistency between some certifiers.
- Increases oversight and accountability for inspectors.

Costs/Challenges of NOP 2027:

- Indicates gaps in consistency inasmuch as only 7 out of 80 ACAs provided comment.
- 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.
- Disincentives to hire contract inspectors who conduct only a handful of inspections each year.
- Disincentive for ACAs to accept new clients locally or in distant locations.
- Very expensive. Costs per inspection range from $400 to $2000 per inspection. Huge annual budget change for every certifier.
- Not sustainable.
- Not cost-effective: e.g. certifier with 70 inspectors who performs 4,800 inspections every year @ between 1 and 200 inspections per inspector.
- Logistically burdensome.
- Cannot conduct international inspector in-field evaluations.
- Could not complete all 100% in 2015 or 2016
- IOIA found it very challenging to service 100 evaluations in one season.
- Sharing files through unsecure e-mails places client confidentiality at high risk.
- Sharing evaluations/witness audits between certifiers is inconsistent.
- Confusion over terms “personnel evaluation”, which is a normal aspect of the contract between certifier and independent contract inspector, versus “Witness Audit” which could be conducted without the overtones of a personnel evaluation by a peer.
- Places peer inspectors in a difficult professional relationship with fellow inspectors who may be competing for the same inspections or close friends over many years, with resultant inconsistency in evaluation.
- Increases time, cost, and stress for clients and inspectors and ACA staff.
- If ACAs adopt risk-based in-field witness audits over a period of three years, how will consistency be maintained between certifiers?

It is worthwhile re-visiting the NOSB Recommendation of December 2, 2011 on Inspector Qualifications, which was based on a range of public comment at that time:

> B. As continuing organic inspector criteria:
> 1. Continuing Education
> a. Annual training by Accredited Certifiers Association (ACA) to update on specific procedures of the ACA as well as National Organic Program (NOP) standards updates and guidelines.
> b. Minimum 8 hours annual continuing education related to the type of inspection work performed. Each hour of curriculum time (e.g. class time, coursework, field study, testing), equals one hour of continuing education hours. Trainings conducted by ACAs and closed to the general inspection community do not apply toward continuing education hours given their tendency to focus on certifier procedures rather than broad knowledge such as agronomic and food industry practices and general auditing skills.
> c. In-depth training on the topic of recordkeeping and/or accounting must be included as part of continuing education, and IOIA is encouraged to develop a training to fulfill this need.
> d. Continuing education credits include webinars, seminars, workshops, and colleges and university extension programs related to the type of inspection work performed or new scope of inspection interest.
>
> C. ACA accreditation criteria to ensure adequate monitoring and oversight of inspector qualifications:
> 1. Annual attendance of NOP trainings.
> 2. Documented inspector qualification monitoring program that readily provides verification that all inspectors employed or contracted in the service of the ACAs are qualified according to these criteria.
> 3. Provide programmatic and consistent annual training to inspectors regarding processes, policies, and procedures specific to the ACA. Training materials used must be available for review during accreditation audits and be included in annual ACA updates to the NOP.
> 4. Provide all inspectors with performance assessment and oversight accordingly:
> 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.
> b. Evaluation of every inspection provided to the inspector.
> c. Annual performance evaluation provided to the inspector.
> d. All serious or persistent performance issues that arise during any of the above assessments must be documented by the ACA and must include documented corrective action and improvement measures as deemed necessary by the ACA.

In Summary:
Organic Inspectors are not licensed per se, and the flexibility of the present training and evaluation of inspectors has been helpful during these formative years of organic certification. But many of the concerns raised by the NOSB in 2011 continue to suggest that certifiers must work towards greater consistency in inspector training and evaluation. All inspectors must receive a personnel evaluation annually, but the inclusion of an in-field witness audit as part of this annual evaluation need only be conducted every 3 years, or more frequently where concerns have been raised about the individual inspector's work. Witness audits should be conducted preferably by certifier staff, but alternatively Senior Peer Inspectors may be used provided that they have been properly trained in witness audits and are not placed in the position of conducting a personnel evaluation of a peer who is not in their employ.

Presently not all ACA's attend annual NOP trainings, and yet they are critical to the overall success of the organic program. If ACA's are unable to attend, they must be required to review all the written material and meeting reports, all of which must be readily available on the web. The NOP trainings must include clear direction as to inspector qualification, continuing education, scope of annual evaluations, and periodic in-field witness audits.

Language in NOP 2027 appears to conflate annual **personnel evaluations** with witness audits. While a witness audit may be one part of the annual personnel evaluation, it is a **witness audit** which may be conducted by a peer if logistics dictate that a certifier staff person cannot attend.

If the IOIA continues to provide the service of in-field peer witness audits, there should be a mechanism in place to inspect and evaluate the IOIA.

ACAs should work to clearly determine the total number of available organic inspectors so that logistics, costs, and market impact of conducting in-field witness audits, without unnecessary and costly replication, can be better understood.

V PROPOSAL

The NOSB Recommends that:

1. All ACAs attend annual NOP trainings, and those trainings must include clear direction as to inspector qualifications, continuing education, annual evaluations, and periodic in-field witness audits. If the ACA is unable to attend, it is the ACA'S responsibility to review all training materials.

2. All ACAs must include in their annual contracts with inspectors the number of hours of required continuing education, annual evaluation criteria, periodic in-field witness audits, and provide a written annual evaluation sent to the inspector with suggestions for improvement.

3. All ACAs must maintain in their files detailed procedures for how annual personnel evaluations of staff and contract inspectors are conducted and include a justification for the frequency of in-field inspections for each inspector.

4. All inspectors must receive a personnel evaluation annually, but an in-field witness audit need only be conducted every three years, or more frequently where concerns have been raised about the individual inspector's work or for a novice inspector.

5. Witness audits should be conducted, preferably by certifier staff, but alternatively, by senior peer inspectors, provided that they have been properly trained in witness audits and are not placed in the position of "evaluating" a peer who is not in their employ.

VI VOTE:

Motion to approve that NOP 2027 be revised to incorporate the recommendations 1-5 listed above.
Motion by: Jean Richardson
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB December 13, 2016

National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee (CACS)
Discussion Document
Eliminating the Incentive to Convert Native Ecosystems to Organic Production

January 10, 2016

I INTRODUCTION

The Organic Foods Production Act (OFPA) of 1990 (as amended) and Regulations promulgated by the NOP to implement the statute, NOP policy documents, and NOSB recommendations and principles clearly establish that soil health, biodiversity and conservation of the ecosystem are critical components of organic agriculture. Over the last two years the NOSB has received public comment describing loss of high value conservation and fragile ecosystem acreage when farmers transition to organic production. The NOSB has been asked to review this issue and propose some incentives and disincentives to reduce conversion of high value conservation ecosystems.

When a producer submits an application for organic certification of their farm or wild crop harvesting they must provide detailed information on the previous three years of land use on the acreage to be certified as part of their Organic System Plan (OSP). Many farms convert lands from conventional agricultural use to organic agriculture. Where lands are converted from a wild, "non-productive" state the transition period may be eliminated. This can result in destruction of high value conservation lands and fragile ecosystems. Fallow land that had agricultural production in the past, such as land that is in the Conservation Reserve Program, would not be considered a high conservation value ecosystem, since it has been significantly changed from its native state.

This discussion document is intended to provide some background as a framework for seeking public comment from a wide cross section of stakeholders. The goal is to ascertain the scope of this unintended consequence of the three year transition, and to determine if the NOSB should recommend to the NOP a Rule change, Guidance or other mechanisms to address this issue.

II BACKGROUND

There are about one billion acres of land in the US under agricultural production. Most of this acreage (over 99%) is in conventional agriculture. Agriculture, by its very nature, reduces biodiversity and fragments ecosystems.

Organic agriculture presently uses about 5.4 million acres in the U.S. The conservation of natural resources and biodiversity is a primary tenet of organic production. The NOP regulations define organic production as follows: "A production system that is managed in accordance with the Act and regulations to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."

The NOP provided Guidance on Biodiversity in 2016 (NOP 5020) encouraging the protection and maintenance of a high level of biodiversity on a farm because it brings benefits not only to the entire ecosystem in that geographic area, but also to the farmer. For instance, native vegetation interspersed throughout a certified organic operation provides food, cover, and corridors for beneficial organisms such as pollinators, slows water down for erosion control and groundwater recharge, and filters pollution. Using practices that attract or introduce beneficial insects, provide habitat for birds and

mammals, and provide conditions that increase soil biotic diversity serve to supply vital ecological services to organic production systems. Advantages to certified organic operations that implement these types of production practices include: 1) decreased dependence on outside fertility inputs; 2) reduced pest management costs; 3) more reliable sources of clean water; and 4) better pollination (NOP 5020).

The National Organic Standards Board (NOSB), a federal advisory committee that advises the USDA on organic issues, has made multiple recommendations related to natural resources conservation and biodiversity. The May 2009 NOSB recommendation asked the NOP to establish: 1) consistent discussion and review of biodiversity protection and enhancement in all certified operations' organic system plans; 2) increased education and information for certified operations, inspectors, and certifiers; 3) uniformity of inspection and certification procedures with regard to how certified operations implement the biodiversity standards; 4) incorporation of biodiversity standards into the procedures for accreditation and certifier audits; and 5) use of materials evaluation criteria that foster consideration of biodiversity conservation when adding or deleting materials from the National List of Allowed and Prohibited Substances (NOP 5020).

Public comment submitted to the NOSB for its April 2016 meeting provided some observations on the unintended consequences of the three year transition requirement and its impact on previously unaltered or relatively unaltered ecosystems. Following are some examples of these comments:

> *In the US, 1.6 million acres of grasslands older than 20 years were torn up, primarily for crop production between 2008 and 2012 (Lark, Salmon and Gibbs, 2015). The remaining prairie is often referred to as "marginal" land because it is not well-suited for crop production. Nevertheless, it is very productive for ranchers and for flood mitigation and erosion control.*
>
> *NOP requires that, in order to transition to organic certification, lands must be free from pesticides for three years. Unfortunately, despite often being highly erodible, valuable prairie, historic oak woodlands or other diverse ecosystems, land that has not been plowed or previously planted is an easy target for those looking to quickly overcome NOP's three-year waiting period.*
>
> *NOP's three-year waiting period for transitioning to organic production serves a critical purpose and it should be retained. However, I urge NOSB to recognize that the conversion of native ecosystems that have no cropping history to organic production is an unintended consequence of the requirement, and to develop regulatory language to discourage such conversion.*
>
> *The required three-year transition before new organic farmers can realize the financial benefits of organic production is a major disincentive to the transition of chemical- intensive agriculture to organic agriculture and an incentive to turn natural ecological communities into organic farms. Therefore, we ask the CACS to focus heavily on incentivizing the transition to organic production while removing incentives to convert native land to organic farms.*

In summer 2016, The Wild Farm Alliance, working through the International Organic Inspectors Association (IOIA), and certifiers asked inspectors to share the degree to which they have seen new parcels and/or farms convert from natural habitat, (not old/fallow field or conventional) by asking following questions:

> *Is this common? Growing? Do you regularly see it? Have you ever seen it?*
> *Where is it common or not? Are there good stories in this regard? Of all the new farms/acreage*

you've seen in X period, what percent of ground was a natural ecosystem to organic conversion? Please ensure that you are describing generalities and are not naming any specific farms. In your response if you could describe natural ecosystems as unplowed grasslands, savannahs, woodlands/forests, and riparian areas/wetlands it would be appreciated.

Here is a sample of inspector observations which were provided as part of public comment in response to these questions:

There are a couple of areas that I have seen regular development...This summer I witnessed the tilling of native short grass prairie in the western Colorado Plains...to grow corn, milo and wheat. In most cases the farmers are conventional farmers who are trying their hand at organic agriculture since they don't have a conversion period...I would estimate the land witnessed in the last year would be 1000 acres in the Midwest.

These native prairies in Colorado also support animals like endangered black-tailed prairie dogs, and burrowing owls that have a "Species of Conservation Concern" designation. If the organic community (and agriculture as a whole) doesn't act to protect these ecosystems, more species will be listed as "Threatened" or "Endangered," increasing government expense and reducing private management of these habitats.

We see this all the time on the high desert-new hay pivots going in…from the native sagebrush rangelands between Bend and Vail and down to the Christmas valley, Fort Rock, Lake View, K Falls, etc.

I have seen quite a bit of this. First the Eastern Oregon region, (Burns OR) has a huge amount of sagebrush being converted to farmland. I think this has drastically reduced the migration patterns of certain animals (elk and deer) plus birds…

An organic inspector in Mexico commented on the conversion of native desert to cropland, and coastal sub-tropical scrub. *"This is particularly prevalent in Baja California and on the coastal plains of Sinaloa (around Mazatlan and Culiacan) as well as the states of Michoacan and Guerrero. Chiefly the crops being planted are warm season vegetable crops like tomatoes, cucumbers and peppers.*

Other public comment included inspector observations from California, China and New Mexico.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

The Organic Food Production Act (OFPA) of 1990, as amended, 7 USC, Chapter 94:

7 USC 6504 (2) …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;

7 USC 6513(f) Management of wild crops; (2) include a 3 year history of the management of the area showing that no prohibited substances have been applied; (3) include a plan for the harvesting and gathering of wild crops assuring that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop;

7 USC 6518 National Organic Standards Board,
6518 (b) Board composition, (4) three shall be individuals with expertise in areas of environmental protection and resource conservation; (6) one shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry;

The OFPA Preamble to the Final Rule establishing the NOP states: "[t]he use of 'conserve' [in the definition of organic production] establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation." (76 FR 80563)

7 CFR 205.2 Definitions:
Natural Resources of the operation: Physical, hydrological and biological features of a production operation, including soil, water, wetlands woodlands and wildlife.

Organic Production: production system that is managed to respond to site-specific conditions by integrating cultural, biological and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

7 CFR 205.200 Producer …must maintain or improve the natural resources of the operation, including soil and water quality.

7 CFR 205.202 Land requirements.
Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic" must:
(b) Have had no prohibited substances, as listed in 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop;

NOP 5020, effective 1/15/16, Guidance, Natural Resources and Biodiversity Conservation.

16 USC 1531 et seq, Endangered Species Act.

NOSB Recommendation May, 2009, Implementation of Biodiversity Conservation in Organic Agriculture Systems. - "Conversion of native habitat to crop production has consequences to biodiversity that must be considered and the producer should discuss such planned conversion with his or her certifier before action is taken."

NOSB Policy and Procedures Manual, Principles of Organic Agriculture Organic agriculture, adopted 2001, 1.1, Organic agriculture…is an ecological production management system that *promotes and enhances biodiversity,* biological cycles, and soil biological activity.

IV DISCUSSION
For over sixty years biogeographers and conservation biologists have documented and described with enormous concern the conversion of native ecosystems to agricultural production and have documented the status of biodiversity worldwide (see for example, Stein et al, 2000)[1] (see also National

[1] Stein, B.A, J.S. Adams and L.S. Kutner, The Status of Biodiversity in the United States. Oxford University Press, New York, 2000.

Wildlife Federation website, 2017, www.nwf.org/WildlifeThreats-toWildlife/Habitat-Loss.aspx). There are immediate benefits in terms of agricultural production when new soils are first cropped, but over time the short term benefits from loss of biodiversity can lead to economic losses (see for example "Lost Landscapes and Failed Economies" (Powers, 1996)[2]). Habitat loss includes actual destruction by tree or ground cover removal and clearance, to habitat fragmentation and habitat degradation through ecosystem disruption.

The United Nations Environment Programme (UNEP) considers conversion of tropical natural areas to crops one of the main reasons for the continuing loss of biodiversity (UNEP, 2013[3]). The literature is replete with a large body of scientific research documenting for example loss of bird species as bird habitat is replaced with agricultural cropping (for example Stein et al , cited above and Firbank et al., 2008)[4]. It is clearly documented that crop pollination from native bees is at risk from loss of species diversity in croplands (Kremen et al, 2002[5]). Similarly we know that habitat eradication and cropland intensification reduces natural pest control in annual crop fields (Letourneau, 2015[6]). Many authors, such as Smuckler et al (2010[7]) have described the changes in biodiversity and multiple ecosystem functions in organic farmscapes.

The challenge is that human populations keep increasing and so does demand for food, and there are different perspective on soil and ecosystems. To the biogeographer and conservation biologist these are fragile ecosystems, complex gene pools of vitally important biodiversity critical to long term sustainability of human beings (see Haddad et al., 2015[8] for example). To others these are "unproductive" lands from which mankind can benefit through conversion to food, fibre or fuel. Both perspectives have validity and, as Garrett Hardin pointed out in 1968[9], no stakeholder intended the negative ecological and environmental consequences which have taken place over time in some geographical areas.

There are thousands of organic farmers who are dedicated to soil conservation and high levels of biodiversity on their farms, but pressure is intense to convert more native and fragile ecosystems to agriculture for food, fibre and fuel (see for example Lark, 2015[10]). Research suggests that organic agriculture can have beneficial impacts on biodiversity - see for example Fuller et al., 2005[11], and also

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[2] Power, Thomas Michael, Lost Landscapes and Failed Economies, Island Press, Washington DC, 2009.
[3] United Nations Environment Programme (UNEP) *Crop Expansion and Conservation Priorities in Tropical Countries*, 2013.
[4] Firbank et al., *Assessing the impacts of agricultural intensification on Biodiversity: A British Perspective*. Philosophical Transactions of the Royal Society, Biological Sciences, Feb. 2008.
[5] Kremen, C., N.M.Williams, and R.W. Thorp, *Crop pollination from Native Bees at Risk from Agricultural Intensification.* Proceedings of the National Academy of Sciences 99, No. 26 (December 24, 2002).
[6] Letourneau et al., *Habitat Eradication and Cropland Intensification May Reduce Parasitoid Diversity and Natural Pest Control Services in Annual Crop Fields*, Elementa: Science of the Anthropocene 3, No 1, 2015.
[7] Smukler et al., *Biodiversity and Multiple Ecosystem Functions in an Organic Farmscape*, Agriculture, Ecosystems and Environment, 139, No 1, 2010.
[8] Haddad, N.M., et al., *Habitat fragmentation and its lasting impact on earth's ecosystems.* Science Advances, 1 (2), 2015.
[9] Hardin, Garrett, *The Tragedy of the Commons*, Science, New Series, Vol. 162, pp 1243-1248, Dec .13, 1968.
[10] Lark, et al., *Cropland expansion outpaces agricultural and biofuel policies in the United States.* Environmental Research Letters 10, No 4, 2015.
[11] Fuller, R.J. et al., *Benefits of organic farming to biodiversity vary amongst taxa.* Biology Letters, 1(4), pp 431-434, 2005.

Bengtsson et al., 2005[12].

NOP Guidance and International Standards

The NOP provided Guidance in 2016 (NOP 5020) on Natural Diversity and Biodiversity, but the Guidance does not attempt to address conversion of native ecosystems. Indeed, one could argue that jurisdiction by the NOP does not attach to the organic producer until the producer has submitted his/her Organic System Plan pursuant to 7 CFR 205.202, and by then the conversion of lands has already taken place. And while the Guidance in NOP 5020 does clarify and provide considerable information on biodiversity protection and opportunities for assistance from Natural Resource Conservation Service (NRCS) etc., it does not seek to prevent further conversion of native ecosystems.

In contrast a review of international organic standards indicates that many other countries do provide clear language protecting native ecosystems. For example:

Australian Certified Organic - The clearing of primary forest and destruction of primary ecosystems on certified lands is not permitted. The clearing of primary forest and destruction of primary ecosystems on land intended for organic production prior to application for certification is also not permitted. (Sec. 4.6.9)

Argentina's Argencert – Section 1.2 and 2.0. No deforestation of primeval forests

Bolivia's Bolicert- Article 14, (f) Para garantizar la biodiversidad, está prohibido el laboreo en sotobosque y/o espacios de bosque alrededor de arroyos y/o riachuelos; en un área de protección según los casos específicos entre 10 y 50 m de franja de seguridad.
Article 14 (n) La tumba y roza de bosque primario y/o suelos vírgenes, están prohibidos. Solo se podrá autorizar la habilitación de parcelas en bosque primario o suelos vírgenes cuando el plan de conversión garantice la conservación de áreas de bosque virgen para no afectar los ciclos naturales del ecosistema. See also Article 16.

International Federation of Organic Movements (IFOAM) - No conversion of high conservation value areas. Farming areas installed on land that has been obtained by clearing of High Conservation Value Areas in the preceding 5 years shall not be considered compliant with this standard. This applies to global scheme.

New Zealand's AsureQuality Limited - The clearing of primary forest and ecosystems or High Conservation Areas is prohibited (Sec. 4.5.1)

The NOP has Memoranda of Agreement and Equivalencies with several of the above listed countries.

Recent public comment also states that there are several non-organic international ecolabel standards which address this issue, such as:

. Better Cotton Initiative - No conversion of natural habitat
. Bonsucro - No conversion of high conservation value areas
. Demeter USA - No clearing of virgin forest for agricultural usage. Must conserve areas of high ecological value.
. Fairtrade International - No conversion of high conservation value areas

[12] Bengtsson, J., et al., *The effects of organic agriculture on biodiversity and abundance; a meta-analysis.* Journal of Applied Ecology, 42 (2), pp 261-269, 2005.

. Forest Stewardship Council - No conversion of high conservation value areas
. Global Roundtable on Sustainable Beef - No conversion of high conservation value areas
. Linking Environment and Farming - No conversion of biologically diverse areas
. Rainforest Alliance - No conversion of natural areas

The certifiers listed above appear to verify their standards using a variety of methods, including satellite images, Google Earth, and old photographs of ecosystems. Aerial images help to show intact forests and grasslands versus row crops. Ground-truthing is required, and some accept affidavits from disinterested parties that have been submitted by the producer. USDA Farm Service Agency records and NRCS records can be used as documentation.

Certifiers listed above appear to use a range of definitions such as:

"High Conservation Value Areas" (HCVA),: Lands or aquatic environments that are habitat for vulnerable, threatened or endangered plant, mammal, bird, amphibian, reptile or other species as identified by the IUCN Red List, including the federal and state lists and those compiled by NatureServe;

A large landscape-level ecosystem which is significant at global, regional or national levels, and that contains viable populations of most of the naturally occurring species in natural patterns of distribution and abundance; rare ecosystems as protected by local law or defined by the IUCN Red List of Ecosystems. In the U.S., refer to NatureServe's Terrestrial Ecological Systems of the United States;

Areas that provide critical ecosystem services (e.g. watershed protection or erosion control, and areas providing barriers to destructive fires).

To date the NOSB has not received detailed public comment on exactly how verification takes place. This Discussion document is intended to provide a general background in order to seek further, more detailed public comment.

The Organic System Plan:

Certified organic operations and applicants for certification must develop and submit an organic system plan (OSP) to a certifier (7 CFR § 205.201). In the OSP, the operation must describe or list activities (plans, practices and enhancements) that explain how it will comprehensively conserve biodiversity by maintaining or improving all natural resources, including soil, water, wetlands, woodlands, and wildlife, as required by §205.200 of the regulations and per the §205.2 definition of natural resources of the operation. In many cases, the certifier will provide the operation with an OSP template with a designated section for the operation to describe its activities and its biodiversity monitoring approach (e.g., visual assessment of soil erosion, species counts for biodiversity, or testing for water quality).

The operation may refer to a current conservation plan and/or contract developed in conjunction with NRCS or other conservation agency or non-governmental organization as part of their OSP, to meet the requirements of 7 CFR. §205.200.

Organic crop and livestock producers who are located in the United States and its territories and who are planning to transition land to organic production may be eligible for technical and financial assistance through NRCS to develop and implement plans for addressing natural resource concerns. One option is to work with an NRCS certified outside vendor or Technical Service Provider (TSP), to complete a Conservation Activity Plan (CAP) 138. Organic producers who are approved for and complete a CAP

138 may submit to their certifiers the CAP 138 Resource Inventory section together with the necessary Resource Inventory Supplement(s). When submitted together, these documents contain all the required components of a complete OSP.

In the last year the NOP has worked closely with NRCS in order to ensure that soil and natural resource conservation measures are more easily understood and readily accessible to organic producers, and thus the ground work has been established to clearly protect high value and fragile ecosystems.

In summary:

Research literature indicates that conversion of native ecosystems to agriculture has negative impacts on biodiversity and, in the longer term, on economies. To what extent is such conversion of fragile ecosystems taking place in connection with transition to organic agriculture? Could this issue be addressed by adding additional clauses to 7 CFR 205.202 Land Requirements…for organic production, such as:

(d) Have not converted native ecosystems or high value conservation lands to agricultural production in the last 5 years.

(e) Will actively monitor and where possible improve plant and animal biodiversity on the farm, and will not convert native ecosystems or high value conservation lands to agricultural use in future.

V REQUEST FOR PUBLIC COMMENT

1. Please provide specific data on the occurrences of organic agricultural conversion of high value lands or fragile ecosystems.
2. What definition of high value conservation land or fragile ecosystem should be used?
3. How can high value land and fragile ecosystems best be protected under in USDA organic certification. Should the NOP issue Guidance on conversion of high value land, or fragile ecosystems? Should a Rule change, such as an addition to 7 CFR 205.202 be recommended in order to address conversion of high value lands or fragile ecosystems?
4. What incentives, and/or disincentives could be implemented within current USDA organic regulations to prevent the conversion of high value land and fragile ecosystems?
5. Should there be an extended waiting period for land seeking organic certification that has recently been converted from high value land or fragile ecosystems? If so, what duration should the waiting period be and why?

Vote in Subcommittee
Motion to approve this discussion document for posting for the spring 2017 NOSB meeting
Motion by: Jean Richardson
Seconded by: Harriet Behar
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB January 10, 2017

Sunset 2019
Meeting 1 - Request for Public Comment
Crops Substances
April 2017

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at www.regulations.gov by March 30, 2017 as explained in the meeting notice published in the Federal Register.

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances Under Review:

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

(1) not harmful to human health or the environment;
(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
(3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with crop production.

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through March 30, 2017 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2019
Meeting 1 - Request for Public Comment
Crops Substances
April 2017

Note: With the exception of biodegradable biobased mulch film, the materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

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

Chlorine materials: calcium hypochlorite,
chlorine dioxide, sodium hypochlorite
Herbicides, soap-based
Biodegradable biobased mulch film
Boric acid
Sticky traps/barriers
Coppers, fixed
Copper sulfate
Humic acids
Micronutrients: soluble boron products
Micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt
Vitamins B1, C, E

205.602 Nonsynthetic substances prohibited for use in organic crop production
Lead salts
Tobacco dust (nicotine sulfate)

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Chlorine materials - Calcium Hypochlorite

Reference: 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/27/12 (77 FR 33290)

Sunset Date: 6/27/17 (NOP renewal pending)

Background from Subcommittee:

Calcium hypochlorite is an EPA registered pesticide (OPP No. 014701) that is used in controlling bacteria, fungi, and slime-forming algae (2011 TR lines 86-87). In water and soil, calcium hypochlorite separates into calcium, hypochlorite ions (OCl-), and hypochlorous acid (HOCl) molecules. The hypochlorous acid molecules diffuse through cell walls of microorganisms, changing the oxidation-reduction potential of the cell and inactivating triosephosphate dehydrogenase, an enzyme essential of the digestion of glucose, destroying the microorganism's ability to function (2011 TR lines 122-133).

Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed (TR lines 194-195).

Calcium hypochlorite is highly caustic and is a concern for occupational exposure. Acute exposure to high concentrations can cause eye and skin injury. Ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus and stomach (2011 TR lines 411-418).

During the 2017 sunset review, comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. There was also concern expressed that chlorine sanitizers can be harmful to human health and the environment, and alternatives should be used when possible.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

Chlorine materials - Chlorine Dioxide

Reference: 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials - For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(ii) Chlorine dioxide

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/27/12 (77 FR 33290)

Sunset Date: 6/27/17 (NOP renewal pending)

Background from Subcommittee:

EPA has registered the liquid form of chlorine dioxide for use as a disinfectant and sanitizer. The Agency also has registered chlorine dioxide gas as a sterilant. Chlorine dioxide is added to drinking water as a disinfectant in some municipal water-treatment systems in the United States. EPA has set a maximum contaminant level (MCL) of 0.8 mg/L for chlorine dioxide in drinking water and 1 mg/L for chlorite (chlorine dioxide's oxidation product) (2011 TR lines 104-110).

Chlorine dioxide kills microorganisms directly by disrupting transport of nutrients across the cell wall. Chlorine dioxide is an effective disinfectant at a pH of between 5 and (2011 TR lines 149-157).

To form chlorine dioxide, sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid is reacted with methanol (CH_3OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate (2011 TR lines 206-210).

Chlorine dioxide is a severe respiratory and eye irritant. The reaction products of chlorine dioxide (chlorite and chlorate) can cause oxidative damage to red blood cells and mild neurobehavioral effects (2011 TR lines 433-436).

During the 2017 sunset review, comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. There was also concern expressed that chlorine sanitizers can be harmful to human health and the environment, and alternatives should be used when possible.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

Chlorine materials - Sodium Hypochlorite

Reference: 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iii) Sodium hypochlorite

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/27/12 (77 FR 33290)

Sunset Date: 6/27/17 (NOP renewal pending)

Background from Subcommittee:

Sodium hypochlorite is an EPA registered pesticide (OPP No. 014703) that is used in controlling bacteria, fungi, and slime-forming algae (2011 TR lines 86-87). In water and soil, sodium hypochlorite separates into sodium, hypochlorite ions (OCl-), and hypochlorous acid (HOCl) molecules. The hypochlorous acid molecules diffuse through cell walls of microorganisms, changing the oxidation-reduction potential of the cell and inactivating triosephosphate dehydrogenase, an enzyme essential of the digestion of glucose, destroying the microorganism's ability to function. (2011 TR lines 122-133).

Sodium hypochlorite is highly caustic and is a concern for occupational exposure. Acute exposure to high concentrations can cause eye and skin injury. Ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus and stomach (2011 TR lines 411-418).

Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na2CO3) (TR lines 199-202).

During the 2017 sunset review, comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. There was also concern expressed that chlorine sanitizers can be harmful to human health and the environment, and alternatives should be used when possible.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

Herbicides, soap-based/ (Soaps, herbicidal)

Reference: 205.601(b) As herbicides, weed barriers, as applicable (1) herbicides soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Technical Report: 1996 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: Actions: 1996 recommendation; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 6/27/17 (NOP renewal pending)

Background:

Soap based herbicides generally are comprised of a fatty acid component with carbon, hydrogen and oxygen atoms with potassium or ammonium counterions. Potassium salts of fatty acids include individual soap salts such as potassium laurate, potassium myristate, potassium oleate and potassium ricinoleate). Potassium salts of fatty acids are produced through a process known as saponification, whereby aqueous potassium hydroxide (KOH) is added to fatty acids commonly found in animal fats and plant oils (NPIC, 2001; Nora, 2010). Alternatively, ammonium salts of fatty acids, such as ammonium nonanoate, are produced through the room temperature reaction of aqueous ammonia (NH3) or ammonium hydroxide (NH4OH) with fatty acids (Reiling, 1962; Dunn, 2010).Commercially available soap salt products are used as acaricides, algicides, herbicides, insecticides and animal repellents, controlling a variety of insects, mosses, algae, lichens, liverworts and other weeds.

Technical Review Evaluation Report, Soap-Based Herbicides, February 27, 2015:
Potential Human Health Impact Concerns: The US Food and Drug Administration (FDA) classifies "salts of fatty acids" as Generally Recognized As Safe (GRAS) when used in food and in the manufacture of food components (7 CFR 172.863). Ammonium salts of fatty acids are not included in the FDA's description of GRAS fatty acid salts. Despite the lack of systemic toxicity associated with soap salts, both potassium and ammonium salts of fatty acids can lead to various forms of irritation.

Potassium soaps are classified as corrosive to the skin, side effects include skin redness, cracking and fissuring of skin. Even though potassium soaps are only moderately irritating to the skin, they are corrosive to the eyes and may cause permanent eye damage in extreme exposure scenarios (US EPA, 2012).

Reproductive, weight loss, and failure to maintain pregnancies were observed in laboratory animals administered soap salts at high doses. However, the incidences of fetal loss, malformations, visceral or skeletal anomalies and skeletal variants were within the historical control range for young mice in the 500 mg/kg-day dose group. The International Agency for Research on Cancer (IARC) has not listed potassium or ammonium soaps as carcinogens (IARC, 2014).

Potential Aquatic Organisms Impact Concerns: The Technical Review (TR) states that the acute and chronic toxicity of soap salts is markedly different for land- and water-dwelling organisms. Terrestrial animals—including mammals, birds, and insects—are largely unaffected by exposure to even high doses of potassium and ammonium salts of fatty acids; however, aquatic animals are moderately (fish) to highly (crustaceans) sensitive to these substances (Thurston County, 2009a; Thurston County, 2009b). Studies submitted to US EPA for registration of potassium and ammonium salts of fatty acids indicate that potassium salts are generally more toxic to aquatic organisms than their ammonium counterparts.

The TR also states that they may harm many soil-dwelling organisms including insects, earthworms, and nematodes that are supportive of organic production.

International Standards, Soap-Based Herbicides: Organic standards for COR, EU, Codex Alimentarius Commission 209, JMAFF, and IFOAM Fatty allow fatty acid potassium salts for differing uses in organic production. COR specifically does not allow ammonium soaps to be in direct contact with soil or edible portion of crops production.

10/2015 NOSB Final Review Crops Substances Sunset Recommendation**:** The majority of public comments requested that soap-based herbicides be renewed on the National List, and the NOSB found soap-based herbicides compliant with OFPA criteria, and did not recommend removal from the National List.

Additional information requested by NOSB

1. Please provide more information on the potential health and environmental issues of herbicidal soaps.
2. Do herbicidal soaps have a special niche in weed management that cannot be met by alternatives such as natural materials and methods?

Biodegradable biobased mulch film

Reference: 205.601(b) As herbicides, weed barriers, as applicable (2) Mulches (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

Technical Report: 2012 TR; 2015 Report; NOP Policy Memorandum 15-1; Supplemental Technical Evaluation Report 2016

Petition(s): 2012

Past NOSB Actions: Actions: 10/2012 NOSB Recommendation

Recent Regulatory Background: Final Rule published 09/30/14 (79 FR 58655)

Sunset Date: 10/30/19

Background from Subcommittee:
Biodegradable biobased mulch films were approved for placement on the National List of approved synthetics without detailing how much non-biobased content would be allowed. The vast majority of mulch films in this category contain 20% or less biobased materials, with the remainder consisting of polymers, colorings, and other synthetic materials. There are some products that might meet the biobased aspect of this material's definition on 205.2, but are either not biodegradable or are not used widely in production due to brittleness or other production issues. In January 2015, the National Organic Program issued Policy Memorandum 15-1, requiring that biodegradable biobased mulch film must not contain any synthetic polymer feedstocks. The NOSB requested a limited scope technical review (TR) in 2016. This TR focused upon biobased biodegradable mulches that contain polymers, and the soil and crop health effects they may have as they biodegrade. The supplemental TR was inconclusive, since research on these materials is currently limited.

Additional information requested by NOSB

1. Can you provide additional information to answer the questions in the 2016 Supplemental Technical Evaluation Report (TR) on biodegradable biobased mulch films?
2. Can you provide information on the existence or development of biobased biodegradable mulch films that would meet the requirements of NOP policy memorandum 15-1?

Boric acid

Reference: 205.601(e) As insecticides (including acaricides or mite control). (3) Boric acid—structural pest control, no direct contact with organic food or crops.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)

Background:
Boric acid, derived from the mineral borax, is a weak acid that has long been considered a "least-toxic" pesticide because it is non-volatile when placed in bait or gel formulations and therefore eliminates risk of direct exposure. However, when used as a dust for structural pest control, exposure can occur, causing hazards for exposed populations.

Boric acid is a reproductive toxicant, a suspected endocrine disruptor, and toxic to plants and animals if misused. Boric acid has a low toxicity to mammals and humans (1995 TAP). Borax mining causes environmental damage. Boric acid raises challenging issues of health and environmental/mining impacts, and there are alternative materials and practices that may be less harmful. Of the alternative choices of pest control products, boric acid is considered to be among the least toxic, as noted in the sources used for this review.

A number of members of the public did comment regarding the listing of boric acid, and the majority supported re-listing.

History: The following question was put forth by the NOSB to the public in 2015: "Are there situations in which boric acid is the only, or safest, means of controlling the pest?", and some response was received. It was stated that boric acid is good to have as a means for control, and as a back-up for insect problems. Other comment indicated that natural alternatives do exist, and that management changes, rather than a material application, is best if problems do occur.

While boric acid is not fully compliant with many sub-components of the OFPA criteria the alternatives often have equally challenging issues with OFPA compatibility.

Additional information requested by NOSB

None

Sticky traps/barriers

Reference: §205.601(e) As insecticides (including acaricides or mite control). (9) Sticky traps/barriers.

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 6/27/17 (NOP renewal pending)

Background:

This listing covers a wide range of traps and coatings made with a number of different materials, including coated paper, coated plastic, and brushed on sticky chemicals applied directly to plants. They are typically used for pest control and monitoring in limited quantities and in confined areas, such as tree trunks. As noted in the 1995 TAP Review, these products are of low toxicity, and while persistent, they are unlikely to contaminate the surrounding environment. Coated plastic sticky traps produce a small amount of plastic waste. The sticky coating may contain petroleum distillates, and the traps may contain volatile attractants; however, as they do not come in direct contact with crops, there is minimal concern for human health effects. Some are non-specific and can trap non-targeted beneficial insects, spiders, mites, reptiles, and amphibians, although they do not attract non-targeted insects or animals.

One 1995 TAP reviewer suggested the traps are compatible with organic production only in processing plants. Another suggested they should be used only for monitoring, mass trapping, or barriers. Over twenty years later, more traps are now available, including targeted lures to attract only pest insects, and there is significant experience with their use in organic farming without negative consequences or problems.

During the 2017 sunset review, public feedback was solicited on the following questions: 1) should the wide range of products covered by this listing be categorized by use and materials, and 2) are some uses of sticky traps incompatible with organic production? There was support for the continued listing of sticky traps/barriers at §205.601 as a permitted synthetic given both product availability and effective insect control.

Additional information requested by NOSB

No additional information is being requested at this time.

Coppers, fixed

Reference: 205.601(i) As plant disease control. (2) Coppers, fixed —copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided,* That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

Technical Report: 1995 TAP; 2011 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation;

04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)

Background:
Coppers, fixed, and copper sulfate were reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers continue to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the national list. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). This review applies to both the listing for Coppers, fixed and the listing for Copper Sulfate on the National List 205.601.

The last Technical Report (TR) was completed in 2011 at which time the EPA had recently completed a re-assessment of copper products. The potential adverse impacts are well known and were discussed in the TR. The main concern with copper materials is their potential to accumulate to toxic levels in the environment. The TR notes the many factors that can affect copper accumulation (2011 TR lines 465 to 549). To address this concern, the copper listings on the National List have the annotation "That, copper-based materials must be used in a manner that minimizes accumulation in the soil..."

To put copper use patterns into perspective, we consulted the *Materials Fact Sheet Copper Products from the Organic Resource Guide, 2nd edition (2013):*
http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf

"In New York, maximum soil concentration rates for copper have been recommended based on soil type; rates range from 40 ppm in sandy soils, to 60 ppm in silt loam, to 100 ppm in clay soils. These rates have been suggested in order to protect against phytotoxicity and negative impacts on soil life (Harrison et al. 1999). Typically, each spray with a copper-based fungicide results in an application of 1 to 4 lb. of copper per acre, raising the topsoil concentration from 0.5 to 2 ppm; often several copper sprays are made per season. Under a heavy copper spray program, toxic topsoil levels could be reached in a matter of decades."

The effects on human health from agricultural copper were addressed in the TR as follows:

"In "III Summary of Coppers Risk Assessments" of RED-Cu (2009), human health risk, after aggregate or combined exposure to copper compounds, was adequately assessed. The basic considerations are that copper is naturally-occurring, ubiquitous in environment, copper itself is a nutrient, copper deficiency is more of a problem than copper over-exposure, the active assimilation of copper through routes of food, drink, air, non-occupational sources, and other exposure is efficiently modulated, excessively available copper is not assimilated but instead is actively excreted, and no systematic and carcinogenic effects are observed/confirmed. The overall conclusion is that copper, when used as pesticide following the label, would not cause toxic effects." (2011 TR lines 933 - 940)

The effects of copper on the agro-ecosystem (including on biodiversity) were also discussed in the TR:

The 2011 TR (lines 647 - 761) is quite extensive and evaluates many studies on soil microorganisms, earthworms, and crops. The conclusions in all instances is that it depends on the soil composition, soil pH, concentration of copper, species being studied, and crop species being grown.

And:
Copper can have a significant diminishing effect on biodiversity in an aquatic environment such as wetlands. However it is not prone to leaching or runoff in all but the sandiest of soils and is not likely to end up in the sensitive environments if used according to label restrictions. In contrast, copper can be used to control invasive aquatic plants that out-compete native plants in some ecosystems and this would have a positive effect on biodiversity. (2011 TR lines 870 - 874)

The TR closes with a quote from the "Reregistration Eligibility Decision (RED) for Coppers – Revised May 2009":

"U.S. EPA recognized the advantages of using copper pesticides (RED-Cu, 2009): "Through extensive outreach to the public as well as additional comments and refined information provided by the user community, the Agency has determined that there are many benefits that support the significance and continued agricultural uses of copper pesticides. A significant benefit is that copper exposure from all sources, including use as a pesticide in agricultural settings, does not pose any human health concerns. Although there is still potential for ecological effects to non-target organisms, there are many benefits to retain agricultural uses of copper pesticides" (from the 2011 TR lines 988-996, p.20)

The high variability in copper use patterns and organic farming situations led the NOSB to conclude in October, 2015, that the annotation in place for this substance is appropriate since certifiers can assess copper accumulation in the context of a specific farming operation. However, to make sure that this is true, public comment was requested from growers on the importance of this material, and the ways of monitoring accumulation. Input from certifiers was sought on whether testing was being required for monitoring and whether there have been non-compliances issued for enforcement of this annotation.

Comments from certifiers indicated that they require either a testing protocol or an overall copper monitoring plan for growers who include copper on their OSPs. None of the certifiers who wrote comments had issued a non-compliance for accumulation of copper, but several had done so for not having a monitoring plan in place.

Additional information requested by NOSB

In the October 2015 sunset review, several groups noted that while the intention of the current annotation is appropriate, it is not enforced evenly and some growers are abusing copper sprays to the point where the harvested crop turns color from high copper use. One possible annotation that could be considered is the language that some of the western certifiers had in their standards before OFPA and the USDA organic regulations were published. This annotation (which was in addition to the current one about accumulation) stated: "No visible residue is allowed on harvested crops." Should such an annotation be included?

Copper sulfate

Reference: 205.601(i) As plant disease control. (3) Copper sulfate —Substance must be used in a manner that minimizes accumulation of copper in the soil.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)

Background:
See above for Coppers, fixed.

Additional information requested by NOSB
None

Humic acids

Reference: 205.601(j) As plant or soil amendments. 3) Humic acids - naturally occurring deposits, water and alkali extracts only.
Technical Report: 1996 TAP; 2006 TR: 2012 TR for oxidized lignite/humic acid derivatives

Petition(s): N/A
Past NOSB Actions: 09/1996 meeting minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)

Background:
Humic acids, usually manufactured from oxidized lignite, are used as a component of traditional fertilizers, they do not provide additional nutrients to plants, but rather affect soil fertility by making micronutrients more readily available to plants. "Humates are applied as a soil conditioner to increase cation exchange capacity, enhance mineral availability, improve soil structure, stimulate soil microorganisms, and provide broad spectrum trace elements." Commercially available humic acids are derived from leonardite, lignite, or coal. Extracts from nonsynthetic humates by hydrolysis using synthetic or nonsynthetic alkaline materials are permitted including the use of potassium hydroxide and ammonium hydroxide. Humic acid derivatives are on the National List with the following annotation: naturally occurring deposits, water and alkali extracts only." [7 CFR 205.601(j)(3)].

In 2015 the Crops Subcommittee did not pose any questions to the public regarding this listing. The overwhelming majority of comments were in favor of keeping humic acids on the

National List. No new information was received from the public about humic acids in relation to the OFPA criteria. One commenter opposed the relisting because, as they stated: humic acids do not meet the criteria under OFPA due to the environmental hazards related to the extraction process, are not essential, and are not compatible with organic production. Alkali extracted humic acid derivatives are synthetic, derived mostly from coal sources, which raise some concerns about environmental and human health.

Humic acids from decaying organic matter have been empirically shown to have the same benefits as those from fossil sources, such as lignite. These include nutrient storage and release; cation exchange capacity; sorption of organic compounds; anion sorption; metal mobility; soil pH buffering and amelioration; and growth regulating substances. A long-term soil building program appears to provide the same benefits as those from oxidized lignite.

However, as reiterated through extensive public comment, humic acids are viewed as critical and necessary element of nutrient management in organic farming; removal from the National List would significantly, negatively impact many growers.

The issue of synthetically extracted humic acids not being allowed in Japan was discussed in subcommittee, as was the difference between synthetic alkali extractants and non-synthetic materials used for extraction. It is hoped that the Classification of Materials Final Guidance will clear up the latter issue.

Based on the Subcommittee review and public comment, the NOSB in 2015 found humic acids compliant with OFPA criteria, and did not recommend removal from the National List.

Additional information requested by NOSB
Should there be an annotation requiring that humic acids come from sources with the lowest environmental and human harm?

Micronutrients: Soluble boron products

Reference: 205.601 (j)(6) - As plant or soil amendments. Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing. (i) Soluble boron products.
Technical Report: 2010 TR Micronutrients
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 annotation change recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)

Background from Subcommittee:
Micronutrients, including soluble boron, are essential for plant health and are typically applied in very small quantities. While producers can choose to rely on the natural presence of micronutrients in their soil, many find deficiencies of some or all of these micronutrients on the National List. The lack of these micronutrients can be a limiting factor in water and macro-nutrient uptake, and can result in limiting growth and vitality of crops.

At the October 29, 2015 NOSB meeting, the Board voted to change the Micronutrients annotation from

205.601 (j) -As a plant or soil amendment.

(6) Micronutrients -not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil Deficiency must be documented by testing.

to:

205.601 (j) -As a plant or soil amendment.

(6) Micronutrients -not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Deficiency must be documented.

As of January 17, 2017, this annotation change has not been printed in the Federal Register.

Additional information requested by NOSB :
Is soluble boron considered essential for certified organic production?
Is there a nonsynthetic alternative for synthetic soluble boron?

Micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt

Reference: 205.601 (j)(6) - As plant or soil amendments. Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing. (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
Technical Report: 2010 TR Micronutrients
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 annotation change recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
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Background:
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At the October 29, 2015 NOSB meeting, the Board voted to change the Micronutrients annotation from:

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(6) Micronutrients -not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil Deficiency must be documented by testing.

to:

205.601 (j) -As a plant or soil amendment.

(6) Micronutrients -not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Deficiency must be documented.

As of January 17, 2017, this annotation change has not been printed in the Federal Register.

Additional information requested by NOSB :

1. Are synthetic sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt essential for certified organic production?
2. Are there nonsynthetic alternatives to synthetic sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt?

Vitamins B_1, C, E

Reference: 205.601 (j)(8) - As plant or soil amendments. Vitamins B_1, C, and E

Technical Report(s): 1995 TAP, 2015 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR33290)

Sunset Date: 6/27/17 (NOP renewal pending)

Background:

Vitamins, including synthetically derived vitamins B1 (Thiamine), C (Ascorbic Acid) and E (Tocopherols) are generally considered non-toxic essential nutrients for terrestrial and aquatic organisms. Nonsynthetic sources of all vitamins and synthetic sources of vitamins B1, C, and E may be used in certified organic crop production. Vitamin B1 is an ingredient in many commercial root stimulator products helping to establish nursery-grown planting stock once transplanted. As noted in the 2015 Technical Report (TR), the available literature does not support the premise that foliar and soil applications of vitamin B1 are responsible for root stimulation in transplanted crops. Vitamins C and E are used to promote both growth and yields and to protect plants from oxidative stress due to salinity. However, practical information regarding their use was unavailable, therefore the TR relied on peer-reviewed scientific literature.

An OMRI search for each of the three vitamins resulted in zero entries. However, an OMRI generic materials database search indicated that nonsynthetic plant hormones such as gibberellic acid, indole acetic acid (IAA), and cytokinins may be applied to organic crops as plant growth regulators. Additionally, there are several naturally derived, OMRI-listed substances marketed to stimulate root growth.

During the 2017 sunset review, there was some public comment in support of relisting these materials for the purpose intended. Commenters indicated that Vitamins B1, C, and E are rarely used individually but are included as ingredients in some of the products reviewed for crop fertility. To supplement the 1995 TAP report, the Crops Subcommittee requested a technical review (TR).

The TR indicated that the root growth claims associated with vitamin B1 are largely unsubstantiated. Alternative practices include encouraging the growth and productivity of beneficial soil microorganisms to help produce vitamin B1, reduce fertilizer use, refrain from applying fertilizer at the time of planting, and proper irrigation of the root ball and surrounding soil. There was no use information for vitamins C and E on agriculture extension websites.

Additional information requested by NOSB

1. Given that the 2015 TR stated that Vitamin B1 is not generally effective at reducing transplant shock or stimulating new root growth outside of a laboratory setting, should Vitamin B1 be removed from 205.601(j)(8), or are there other benefits attributed to Vitamin B1 that necessitates its continued listing as a plant or soil amendment?
2. As the tree fruit industry looks aggressively at alternative rootstock or tissue cultures to deal with fire blight concerns, is there a need for Vitamin B1 to assist in transplanting shock or replant disease issues?

Lead salts

Reference: 205.602 The following nonsynthetic substances may not be used in organic crop production: (d) Lead salts.

Technical Report: none

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation

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

Sunset Date: 6/27/17 (NOP renewal pending)

Background:
Lead poisoning can cause a number of adverse human health effects but is particularly detrimental to the neurological development of children. Lead accumulates in soils, so it is important to avoid soil applications of materials containing lead, whether the lead is in synthetic materials or naturally occurring (nonsynthetic) lead salts.

During the previous NOSB Review in 2015, the Board determined that lead salts do not meet the OFPA criteria and saw no reason to remove it from its prohibited status on the National List.

Additional information requested by NOSB

None.

Tobacco dust (nicotine sulfate)

Reference: 205.602 The following nonsynthetic substances may not be used in organic crop production: (i) Tobacco dust (nicotine sulfate)
Technical Report: none
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/17 (NOP renewal pending)
Background:
Tobacco Dust (nicotine sulfate) has been present on the National List since its first printing in 1995. This natural product has been used in the past as a pesticide and a fertility input. Due to the negative human health effects caused by this material, it has been relisted as a prohibited nonsynthetic on the National List at every sunset review with no objections from the public or from the NOSB. It is present on the Hazardous substance list and regulated by OSHA and the EPA as well as other agencies.

Additional information requested by NOSB

1. Is there any new information that would lessen the human and environmental concerns associated with the use of this material?

National Organic Standards Board
Crops Subcommittee Proposal
Strengthening the Organic Seed Guidance (NOP 5029)

February 15, 2017

Introduction

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

The organic community has repeatedly noted that progress towards full adoption of organically grown seed in organic systems is too slow. While organic seed availability continues to improve, there has been inconsistent progress in the proportion of organic seed in use by many growers. The state of the organic seed industry has changed since the first circulation of the 2011 NOP draft guidance, with further evolution since 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, the NOSB started soliciting public comment in 2016 on ways the organic seed guidance could and should be strengthened in order to achieve full compliance with the statements in the federal rule in §205.204 (a). This proposal addresses the main points brought up during both the public comment periods and the NOSB discussions of this and related topics.

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 (NOP 5029). 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 multiple benefits provided by organic seed were fully embraced on organic farms. Organic seed producers incorporate characteristics that are needed in organic farming systems and are not always present in nonorganic seed varieties. Organic seed breeders do not breed seeds with a “one size fits all” outlook, instead they include regional adaptions that provide more resilience for organic producers.

Since the mid-2000s, genetically engineered seeds have led 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 the NOSB feels it is important to revisit the topic of organic seed.

Relevant Areas of the Rule and Guidance

From the NOP Rule:

§205.2 Terms defined

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

§205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

.....

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§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.

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

b. 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.

c. 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. 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.

b. 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
This discussion will be framed around each major point brought up in public comment and NOSB deliberations, with a resulting proposal based on how and where "*The Guidance on Seeds*....." (NOP 5029 for reference purposes) should be improved. Also discussed in brief is the possibility of a rule change for some of these issues.

A. Crops at risk from GMO contamination might need to be acknowledged, emphasized and have additional requirements for sourcing seeds.
The NOSB has worked for almost four years on trying to ensure seed purity for at-risk crops but has not yet come to a recommendation that can be implemented within the NOP. Each time this subject is raised, growers, handlers, accredited certifying agents (ACAs) and the public all indicate that there needs to be more incentive for seed companies to develop organic seed, keep it protected from contamination, and require growers to use it consistently. The fact that the NOP 5029 does not even mention this subject is of concern to many stakeholders.

Commenters provided useful suggestions about strengthening the guidance itself, and we heard from certifiers that better guidance and training for ACAs on non-GMO status verification as well as what level of contamination would lead to a non-compliance for seed, is needed. This issue is important and the NOSB will continue the conversation in a future discussion document, planned for fall 2017, which will address seed purity from excluded methods.

For this discussion document, we are exploring possible places in NOP 5029 where seed purity from excluded methods could be included.

i. In the introduction to section 4.
    a. Policy—In addition to the procedures mentioned for procuring organic seeds and documenting them, procedures for preventing and avoiding contamination of at-risk crop seed could be mentioned. This could then lead into specific sub-sections in 4.1, 4.2, and 4.4 about how to do this. This is supported by the language in §205.201(a)(5) that states that an OSP must describe prevention from contamination. As of the writing of this discussion document (winter 2017) the at-risk crops would be: corn, soybeans, canola, alfalfa, beets, chard, cotton, rice, and summer squash. More at-risk crops can be added to the NOP guidance document if they become commercially available in the marketplace.

ii. 4.1.2 could include the additional clause about excluded methods, "Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available, *and the conventional replacement variety can be documented as being produced without the use of Excluded Methods. (italics added).*

iii. An alternative idea would be to add a section 4.1.6 which specifies that non-organic seed must be produced without excluded methods. While both of these ideas are good, amending 4.1.2 is cleaner and is preferred.

iv. Contamination level can be a valid reason not to use organic seed if an operation is testing seed. We would hope that organic seed tests lower in GMOs but without a threshold or testing program in place there is no assurance of that. Therefore 4.1.3 could have a part d, which states that contamination level is a valid reason to choose non-organic seed: *d. Contamination from GMO consideration: non-organic seed can be used if organic seed cannot be sourced because of GMO contamination.*

v. Section 4.2 on recordkeeping could be strengthened in several ways. 4.2.1 (b1) indicates that a minimum of three seed sources should be contacted and documented. Several commenters believed the search for at-risk crops should be raised to five sources, with a stronger emphasis on the last sentence that the sources used should be companies that offer organic seeds. The NOSB Crops Subcommittee agrees with this suggestion. See below for language.

> Certifying agents (ACAs) have the ability under the NOP rule § 205.201(a)(6) Organic production and handling system plan, to require: *"Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations."*

vi. With this in mind, section 4.4.1 could be amended to not only obtain organic varieties but to avoid contamination for seeds at-risk of GMO contamination. An appropriate addition to 4.4 of NOP 5029 could be to add 4.4.5 : Certifying agents review prevention measures taken to avoid contamination from seed of at risk of GMO contamination crops:

> *4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of at-risk crops*.
> The NOSB has already passed a comprehensive set of GMO prevention strategies that includes a section on seed, so it would be appropriate and logical to have ACAs verify those actions in the context of the seed guidance.

B. Organic seed usage as an Organic System Plan "goal"

The way that § 205.201 (Organic system plan (OSP)) is written in the regulations mandates the OSP meets the requirements of the section on organic production and must include descriptions of practices currently in use and records kept. It does not say anything about goals or future practices planned. That being said, part of compliance with the regulations includes § 205.204, seed and planting stock. If the practices currently used are not sufficient to result in using organically grown seed or determining that such seed is not available, the certifying agent may require additional information deemed necessary (§ 205.201(a)(6)).

It seems reasonable for ACAs and their inspectors to request seed lists of non-organic varieties used by producers along with reasons for using those varieties over organically available versions of that crop type. Since producers often use dozens if not hundreds of seed varieties, having complete documentation in the OSP on each of them is neither sound nor sensible. Having inspectors look at this information on-site is more appropriate. The OSP is an appropriate vehicle for producers to indicate the practices they use to source seed, the measures they take to avoid contamination, and the reasons why they need to use non-organic seed that is in compliance with the "equivalent variety" clause. The ACA must then evaluate if those efforts are sufficient and if they are not then the ACA can issue a path towards a correction. However this is different than an "OSP goal". Therefore the NOSB is not choosing to act on this particular point in this way.

C. Continuous improvement

Almost every commenter wanted to have the concept of continuous improvement incorporated into the NOP 5029. However, much of the discussion section above about OSP goals applies here. Nowhere in the NOP regulations is there a statement which mandates improvement: not in ingredient selection for processed foods, choices of materials on the national list, or livestock management. Yet this has philosophically been one of the core values of the organic movement.

The seed portion of the rule is a "practice standard" and the definition of this term in § 205.2 above is that it is a minimum level of performance. Yet the minimum level of performance should be to use organic seed. Therefore if a producer has not reached that level of performance the ACA may require additional conditions to establish that performance.

That leaves the NOSB with two possible avenues to make a recommendation: seeking a rule change to the seed practice standard § 205.204 to require a demonstrable improvement over time until 100% organic seed use is achieved, or to work at strengthening the guidance NOP 5029 in ways that are consistent with the existing rule. These are not mutually exclusive; while waiting for a proposed rule change, the guidance could be strengthened as well. The issue becomes whether the NOSB should propose a rule change or not.

The simplest approach to a rule change might to add a subsection to § 205.204(a)(1) so it reads (new language in *underlined italics*):

§ 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;

(i) Improvement in sourcing and use of organic seed and planting stock must be demonstrated every year until full compliance with (a) is achieved.

If this were adopted then the guidance could specify a measure for sufficient improvement, i.e. an increase in percentage of acreage per year planted with organic seed and planting stock, increased sourcing efforts, etc.

D. Documentation of quality, quantity and equivalent variety

Working within the existing definition of a practice standard still leaves room for increased efforts on the part of producers to source organic seed and increase consistency by ACAs as they evaluate compliance. ACAs in particular noted that they did not have enough enforcement tools to use in situations where there is not much improvement from year to year in the amount of organic seed used on a specific operation. We believe it is reasonable for ACAs to ask for improvement in compliance over time and to impose increased efforts to achieve compliance if progress is too slow.

Some possible changes include:

i. 4.1.3 is considered too vague. It was frequently pointed out by commenters that one reference to the OSP for describing the considerations leading to use of non-organic seed is not being diligently enforced by ACAs. Commenters requested clarification about form, quality and quantity, as well as more explicit guidance on what would not be allowed. It is not clear to the CS what could be added here except to the section on quantity. In this case it would be appropriate for the OSP to state what quantity of a variety is needed and the seed search to document what quantity was or was not available. For large operations with many seed varieties used, a few major ones could be represented in the OSP in this way, while others evaluated during inspections. It is not clear that this needs new language however, or is already covered in other sections, so no proposal is made for this section.

ii. 4.2.1 is the main section that could be strengthened according to most commenters. This is also the area where enforcement is very inconsistent. Some specifics include:

   a. 4.2.1(a) Justification for use of varieties needs to be specific to each variety on the list and which issue (form, quality, quantity, or equivalence) is the problem. This must be done in a consistent enough manner that an ACA can look for increasing the level of compliance over time. We suggest adding a sentence in this area:
   b. 4.2.1(a). 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*. Justification for use of varieties needs to be specific to each variety on the list and which issue (form, quality, quantity, or equivalence) is the reason*. Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.

iii. A better description is needed for the role of variety trials. ACAs felt that they could not mandate or even suggest them, yet they are one of the best ways to determine equivalence and quality of other organic varieties. Many growers perform variety trials, but documenting them has been a problem for both producers and ACAs. We suggest that this does not truly belong in the recordkeeping section because it is a production practice and therefore we are suggesting adding it as §4.1.2(c):
§4.1.2(c) On-farm variety trials of organic seed may be used by producers to evaluate equivalency and quality of varieties that are available as organic seed. Trials are encouraged and records should be kept of results to show inspectors but they are not mandatory.

iv. 4.2.1(b) generates much discussion because of the three sources requirement. While this is the cornerstone of what ACAs require of producers, it is very prescriptive about the number, but not prescriptive enough about the quality of information that is received. Some companies just issue the same form letter every year without indicating which specific varieties they are referring to, while some growers use seed brokers and they simply say they checked their sources but don't name them. The most common suggestion for changes, was to require five sources. Other ideas included limiting the number of years that three sources could be used as an excuse for not using organic seed, or to require more or different sources when improvement is not seen over time.

v. The CS agrees that checking more than three sources makes sense especially for at-risk crops. Most of these crops have had more development in the supply of organic seed that the vegetable industry. Trying to set a limit of three years on compliance is not feasible for inspectors or ACAs to monitor. We feel that a better approach is to aim for better compliance from both the producers and the seed companies and brokers who are the sources. Things like not checking the *same* three sources every year, specifying that brokers have to name the places they looked in their letters, and making seed sources prove that they carry organic seed are some examples. We have chosen not to be prescriptive about acreage or number of varieties planted because flexibility is needed for a great variety of cropping systems and markets, and because we do not want to inadvertently lead to a reduction of the genetic diversity in or crop choices. However we feel that ACAs can use benchmarks in improvement as a tool to verify compliance.

vi. A proposed rewrite of §4.2.1(b)(1) (changes in *underlined italics*):
1. Evidence of efforts made to source organic seed, including

a. documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. *Five sources must be contacted for seed of at-risk crops when this number of sources is available for a specific variety or cultivar.*

b. Sources should include companies that offer organic seeds and planting stock. *Such sources should provide evidence of their organic certification (if relevant),*

ability to source organic seed and planting stock, and specific varieties sourced every year.

c. Failure to demonstrate improvement in sourcing organic seed and planting stock over time may result in an increase in the required number of additional seed and planting stock sources, or the addition of steps taken to procure organic seed and planting stock.

vii. It is clear from public comment and from the report given during the Fall 2016 meeting on the State of Organic Seed report, that the organic seed requirements are not being enforced equally among all certifiers and upon all scales of operations. The conclusion is that the certifying agents, as described in section 4.4 of NOP 5029, are not doing a complete job, or are not following section 4.4 in a careful manner. Much of this issue could be resolved with training for ACAs rather than changes to section 4.4, but if it is possible to put specific language about what constitutes non-compliance the ACAs would really appreciate it.

viii. §4.4.4 contains the statement regarding the review of progress in obtaining organic seeds compared to previous years. This is interpreted as meaning that improvement is required. Inserting language parallel to what we are suggesting in §4.2.1(b)(1)(iii) is one way to strengthen it:

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

a. If sufficient progress is not demonstrated a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed.

b. Non-compliances should be issued for repeated lack of progress in sourcing and using commercially available organic seed over time.

E. Handlers supplying seed to contract growers

This issue was included in the 2008 NOSB recommendation on organic seed but not adopted by the NOP with the following comment:

"Handlers Purchasing Seed for Contracted Growers. Several commenters stated that 7 CFR §205.204 applies to handlers purchasing seed for contractual growing purposes, and that language should be included in the guidance emphasize this. However, this guidance is applicable to crop producers subject to requirements of §205.204, and handlers are not typically certified as crop producers subject to this requirement. All growers must meet the same standard and use organic seeds unless they can demonstrate that organic seeds are not commercially available. All producers must provide the necessary documentation regarding lack of commercial availability of organic seeds to justify use of non-organic seed or planting stock. Contracted growers should inform their buyers of the need to use organic seeds unless they are not commercially available."

It has been very clear that this has turned into a loophole where contract producers are not pressuring their buyers enough and buyers are not held accountable for promoting and requiring the use of organic seed when contracting with crop producers. The Crops Subcommittee believes that the guidance could explicitly contain a statement similar to the last sentence above, and this would support both growers and certifiers to put more pressure on buyers who may require a specific variety be grown to fulfill a contract for organic crops. Also when appropriate, it should state in the grower's OSP the handler is sourcing or requiring a specific seed. This would then trigger inspectors and ACAs to require documentation illustrating organic seed sourcing and trialing would have been done. Many buyers work with specific seed sources and those sources could be encouraged to develop organic seed offerings, or equivalent organic varieties.

Therefore we are proposing addition of §4.2.1 (b) (3) (in *underlined italics*):
4.2.1 The following records should be maintained by organic producers:

> *3. If seed sourcing is carried out or mandated by the buyer of a contracted crop, the producer must keep records of the buyer's documentation on attempting to source organic seed as part of the producer's own Organic System Plan. Such documentation must be comparable to that required of a producer who sources their own seed.*

F. Organic Seed Finder

In order for producers to find organic seed, there needs to be a more comprehensive and accessible clearing house for listing the availability of seed varieties serving crop, vegetable and livestock producers. While we have a website *www.organicseedfinder.org,* managed by the Association of Official Seed Certifying Agencies (AOSCA), there is a cost for companies to list their available organic varieties, which leads to less than optimal use of this resource. There are other options that could be considered, such as having certifiers provide organic seed availability of their certified clients, in such a way as to include this information in a separate field in the National Organic Program Organic Integrity Database. Operators could then search that field for a specific variety of organic seed, and all certified operations who carry that seed would then be found.

Another option is for the National Organic Program to provide some funds to an entity to manage an organic seed variety availability database, which could provide more in-depth information than the Organic Integrity Database. A more in-depth listing would cover varietal characteristics, to aid seed purchasers in determining if there are organic equivalent varieties to the nonorganic seeds they are currently purchasing and planting.

One public commenter discussed the direction specific countries in the European Union have taken in promoting more organic seed use on organic operations. These countries no longer allow the use of nonorganic seed in certain crops that have been determined to have sufficient quantity of organic seed supply. This is not the direction the NOSB Crops Subcommittee is suggesting, but it is interesting to see how other certifying bodies are addressing this issue. Our

preference would be to provide more consistent and accessible information on the availability of equivalent organic seed varieties.

G. Accredited Organic Certifier and Organic Inspector Training

NOP guidance 5029 states:

4.4.6 Certifiers are responsible for training their reviewers and inspectors on what protocols and documentation would constitute acceptable compliance in meeting commercial availability requirements when reviewing the organic seed mandate.

While it is beyond the scope of this discussion document to start development of possible trainings that would aid consistency in verifying commercial availability of organic seed at on-site inspections and certification review, this is still an important topic that must be addressed in some future activity or discussion document. Numerous public comments were received from both the certification community as well as other stakeholders, stating more training is needed for certification personnel who are reviewing use of organic seed. Each certifier and inspector has their own approach on how to verify compliance to the various requirements surrounding the use of organic seed. The entire organic community could benefit from a more consistent and comprehensive approach, so all understand what is expected and how best to meet the requirements.

The Accredited Certifiers Association, as well as the International Organic Inspectors Association (IOIA) both hold trainings tailored for their audiences, at a minimum of once per year, providing venues for the dissemination of information, once a curriculum has been developed.

The NOSB would be willing to work with these groups, within the Certification, Accreditation and Compliance Subcommittee structure to develop the requirements that should be met as part of a comprehensive training on organic seed use and determination of commercial availability. ACA and IOIA, as well as other stakeholders should provide us with feedback if they feel this approach is acceptable, or if there are other methods for achieving the goal of consistent implementation of the organic seed search and use requirement.

Proposals *(all proposed text is in underlined italics)*

1. To amend the National Organic Regulations §205.204 Organic seed and planting stock practice standard as follows:

(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 fan 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;

(i) Improvement in sourcing and use of organic seed and planting stock must be demonstrated every year until full compliance with (a) is achieved.

2. Changes to NOP 5029 Guidance

The Guidance for Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production should be amended as follows:

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). Producers must also provide clear documentation regarding the inputs and materials used during crop production (as required at § 205.201(a)(2)). *Producers must prevent and avoid contamination from excluded methods in seed of at-risk crops (corn, soybeans, canola, alfalfa, beets, chard, cotton, rice and summer squash).* Certifying agents must assess procedures and documentation of certified production and handling operations as they source seeds, annual seedlings, and planting stock on an annual basis. Each of these concepts is described in more detail below.

4.1 Sourcing of Seeds

4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available, *and the conventional replacement variety can be documented as being produced without the use of Excluded Methods.*

> *§4.1.2(c) On-farm variety trials of organic seed may be used by producers to evaluate equivalency and quality of varieties that are available as organic seed. Trials are encouraged and records should be kept of results to show inspectors, but they are not mandatory*.

4.1.3 The following considerations could be acceptable to justify use of non-organic seeds

> *d. Contamination from GMO consideration: non-organic seed can be used if organic seed cannot be sourced because of GMO contamination*

4.2 Recordkeeping for Organic Producers

4.2.1 The following records should be maintained by organic producers:

> a. 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*. Justification for use of varieties needs to be specific to each variety on the list, and include the reason for use (form, quality, quantity, or equivalence).* Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.

b. 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

i. documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. *Five sources must be contacted for seed of at-risk crops when this number of sources is available for a specific variety or cultivar.*

ii. Sources should include companies that offer organic seeds and planting stock. *Such sources should provide evidence of their organic certification (if relevant), ability to source organic seed and planting stock, and specific varieties sourced every year.*

iii. Failure to demonstrate improvement in sourcing organic seed and planting stock over time may result in additional seed sources being required or additional steps taken to procure organic seed and planting stock.

....

3. If seed sourcing is carried out or mandated by the buyer of a contracted crop, the producer must keep records of the buyer's documentation on attempting to source organic seed as part of the producer's own Organic System Plan. Such documentation must be comparable to that required of a producer who sources their own seed.

4.4 Role of Certifying Agents

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

a. If sufficient progress is not demonstrated, a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed.

b. Non-compliances should be issued for repeated lack of progress in sourcing organic seed over time.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of at-risk crops.

Vote in Crops Subcommittee

Motion to accept all additions as described in the proposal section above, to both the National Organic Program Regulation and the National Organic Program 5029 Guidance.
Motion by: Francis Thicke
Seconded by: Jesse Buie
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair to transmit to NOSB, February 17, 2017

National Organic Standards Board
Crops Subcommittee Proposal
Marine Algae Listings on the National List

February 15, 2017

I INTRODUCTION

During its recent five year sunset review of almost 200 materials, the NOSB and public comment noted that the listings of the nine (9) marine materials on the National List includes overlap in species and lack of scientific clarity. A discussion document was posted and substantive public comment received in Fall 2016. Based on public comment from a broad cross-section of stakeholders, this proposal recommends that the marine algae materials be annotated with Latin binomials where possible, or by Class, and that the NOP review the word "kelp" as used in organic production and clarify if marine materials on the List should be classified as agricultural or non-agricultural.

II BACKGROUND

There are nine separate listings for marine materials on the National List that are the subject of this document and an identical proposal brought forward by the Handling Subcommittee:

1. **Aquatic plant extracts** (Technical report [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) is in the *Fucaceae*, a brown seaweed, Class *Phaeophyceae.*

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, Saccharina* (various northern hemisphere oceans), and *Macrocystis* (California and Mexico), with lesser sources from *Lessonia* (South America), *Durvilea* (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 Eucheuma 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 carrageen-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 (TR 2015). Of the species in the class of brown seaweeds, 41 species are used for extracting alginates, including: *Ascophyllum nodosum* from Ireland, Norway, and the UK; *Cystoseira barbata* from Egypt; *Durvillaea potatorum* from Australia; *Fucus serratus, F. vesiculosus* from Ireland; *Laminaria digitata* from France and Ireland; *Laminaria hyperborea* from Ireland, Norway, Spain, and the UK; *Laminaria japonica* from China*; Laminaria ochroleuca* from Spain; *Lessonia nigrescens* from Chile and Peru; *Lessonia trabeculata* from Chile; *Macrocystis integrifolia* from Peru; *Sargassum crassifolium, S. gramminifolium, S. henslowianum, S. mcclurei, S. siliquosum,* and *S. vachelliannum* from Vietnam; *Sargassum ilicifolium, S. myriocystum, S. wightii, Turbinaria conoides, T. decurrens,* and *T. ornata* from India; *Sargassum polycystum* from Indonesia and 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 β-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).

7. **Kelp** (TR 2016) 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.*

   NOP 5027 states that kelps are brown algae and are among the most common seaweeds consumed as food. Stationary kelps/seaweeds rooted via a holdfast are wild harvested from the intertidal (eulittoral zone) and deeper (sublittoral zone) waters throughout the world's oceans.

   However the term "kelp" as used in fertilizer means ANY macroalgae seaweed, brown (*Phaeophyceae*), red (*Rhodophyceae),* or green (*Chlorophyceae)* (Assoc. of American Plant Food Control Officials (AAPFCO)).

   To further confuse the definition of kelp, the American Association of Feed Control Officials (AAFCO – as distinct from AAPFCO) approves dried kelp from the families *Laminariaceae* and *Fucaceae* for use as ingredients in livestock feed (see also NOP 5027).

   NOTE: Kelp used in organic livestock production must be certified, but for use in processing/handling for humans non-organic kelp is allowed.

   The FDA lists 4 species under the definition of Kelp: *Macrocystia pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni* (21 CFR 172.365).

   OMRI definition of Kelp:
   (1) Crop production- The dried marine algae of the botanical divisions of Rhodophyta (red algae) Phaeophyta (brown algae) and Chlorophyta (green algae) (AAPFCO).

(2) Livestock production – Seaweed of the families Laminariaceae and Fucaceae (American Association of Feed Control Officials (AAFCO).
(3) Processing and Handling – The dehydrated, ground product prepared from the brown algae species *Macrocystis pyrifera*, *Laminaria saccharina*, and *Laminaria coustoni* (21 CFR 172.365).

Kelp classification: The NOP received comments asserting that kelp is not agricultural and should be permitted only as a nonsynthetic, nonagricultural ingredient in organic livestock feed as per § 205.237(a). This position implies that kelp should not have to be certified organic to be used in organic livestock feed. However, kelp is currently listed as an agricultural product under § 205.606 of the National List of Allowed and Prohibited Substances (National List). Because kelp is listed at § 205.606, the NOP considers kelp an agricultural product, and therefore, kelp must be certified organic to be included in livestock feed (see comments received in response to publication of draft guidance, NOP 5022 – Wild Crop Harvesting. 70 FR 62693 [October 13, 2010]).

Pacific Kombu and *Undaria innatifida,* listed separately on the National List*,* are also Kelp species.

8. **Seaweed - Pacific Kombu** is a kelp, often *Laminaria japonica or Saccharina 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, FDA, NOP GUIDANCE, NOP POLICY MEMO, OMRI

§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 does 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.

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

NOP 5020, effective 1/15/16, Guidance: Natural Resources and Biodiversity Conservation. Purpose: To clarify organic regulations at 7 CFR 205.200, which states, "to maintain or improve the natural resources of the operation….".

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 for the limited scope TR in 2016. Questions were posed to the public in the subsequent NOSB discussion document (November 2016), and thousands of pages of public comment and peer reviewed scientific research articles were received, providing the NOSB with a substantive body of documented research from a number of perspectives.

Public comment included concerns for the following:

- Lack of clarity as to which species are allowed on the National List and confusion over names used.
- Desire to encourage organic cultivation and wild harvesting of marine materials.
- 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 and cultivated algal species.

Public comment from all sectors strongly supported a proposal to clarify and annotate the marine algae listing through use of Latin binomials as far as possible and recommended NOP Guidance.

V PROPOSAL:

Motion to annotate the marine algae listings as follows, shown in underline:

§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 does not contribute to contamination of crops, soil, or water...

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed) derived from brown seaweeds, class *Phaeophyceae*. –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction.

Vote in Crops Subcommittee:
Motion by: Emily Oakley
Seconded by: Jesse Buie
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair to transmit to NOSB, February 17, 2017

National Organic Standards Board
Crops Subcommittee Discussion Document
Aeroponics/Hydroponics/Aquaponics

February 15, 2017

Introduction

The National Organic Standards Board (NOSB) has taken up the issue of hydroponics several times in the past, and has made several recommendations to the National Organic Program (NOP). To date, the NOP has not undertaken rulemaking based on any of the NOSB recommendations. This discussion document suggests some language that could be used for rulemaking in the future and solicits comments from organic stakeholders on the suitability of that language and on other considerations that the Crops Subcommittee should take into account as it prepares a proposal for the NOSB meeting in fall of 2017.

This document was originally written as a proposal, with recommendations to be voted on by the full NOSB at the spring 2017 meeting. The proposal was reformatted as a discussion document in order to give new NOSB members more time to study the issues. Therefore, parts of this discussion document may read somewhat like a proposal; however, the Crops Subcommittee invites and will consider all comments that stakeholders wish to offer.

Background

In 1995, in the NOSB *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 the Organic Foods Production Act (OFPA) to guide them. Also, the statement indicates that an analysis had not been made of whether or not hydroponics met the provisions of OFPA.

In 2010 the NOSB issued a recommendation titled *Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses).* The recommendation contained the following statement:

> "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...certainly 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."

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."

Accredited organic certification agencies have been permitted to certify hydroponic operations as organic by the National Organic Program, with some agencies certifying hydroponic operations and some choosing not to certify this distinct production system. The lack of clear and detailed standards for this water-based nutrient delivery growing system has led to the need for the National Organic Standards Board to review this issue in a holistic way, and recommend a path forward to the National Organic Program.

In 2015, the NOP established a Hydroponic/Aquaponic Task Force (henceforth referred to as Task Force) to further explore this issue and write a report giving guidance to the 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[1].

In consideration of the information presented in the Task Force Report and from past NOSB recommendations, the Crops Subcommittee prepared a proposal for consideration by the full NOSB at the Fall 2016 NOSB meeting. The proposal included the following motion:

> "Motion to allow bioponic[2] (including hydroponic, aeroponic, or aquaponic) as consistent with organic production under the provisions and recommendations to be developed by the NOSB in 2017."

The motion was worded "to allow bioponic" in order to require a 2/3 majority of the board to overturn the previous NOSB recommendation (in 2010) that soilless production is not consistent with organic production. The Crops Subcommittee vote on the motion to allow bioponics failed by a vote of two in favor and five opposed.

At the fall 2016 NOSB meeting, questions were raised about the wording of the motion. Particularly, it was noted that if the vote were to result in a failed motion, there would be no recommendation going forward from the NOSB to the NOP. Therefore, the NOSB did not vote on the proposal, but voted to send it back to the Crops Subcommittee for further work. However, the NOSB did pass the following resolution at the fall 2016 meeting:

> "The NOSB respects the efforts of the former NOSB that led to their 2010 recommendation on terrestrial plants in greenhouses. The NOSB recognizes that the foundation of organic agriculture is based upon a systems approach to producing food in the natural environment, which respects the complex dynamic interaction between soil, water, air, sunlight, plants and animals needed to produce a thriving agro-ecosystem.
>
> "At the heart of the organic philosophy is the belief that our responsibilities of good stewardship go beyond production of healthy foods and include protection of natural resources, biodiversity and the ecosystem services upon which we all depend. We encourage future NOSB to consider this wider perspective as the board undertakes the challenges of assessing and defining innovations in agriculture that may be compatible in a system of organic production.

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[1] Hydroponic and Aquaponic Task Force Report, July 2016

[2] While "bioponics" was used in the Fall 2016 NOSB proposal, that term is not used in this proposal. Operations popularly referred to as "bioponic" fit within the definitions of hydroponics, aeroponics and aquaponics used in this proposal.

"In the case of the hydroponic/bioponic/aquaponic issue, it is the consensus[3] of the current members of the NOSB to prohibit hydroponic systems that have an entirely water based substrate. Although that was the original intent of the proposal before us today, the current proposal as structured does not achieve this objective.

"While the NOSB does not believe that the liquid substrate systems should be sold under the USDA organic label, these growers deserve the chance to promote their very commendable qualities and objectives in their own right."

Relevant areas in the Rule
Organic Foods 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.

[3] Because two members of the NOSB did not support this resolution, the resolution was amended to substitute the word "majority" for "consensus." However, it wasn't recognized until later that that word change confused the sentence syntax. It should also be noted that the two NOSB members who did not support the resolution went on record as being opposed because they did not think the resolution was strong enough, but they too were opposed to "hydroponic systems that have an entirely water based substrate."

§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.

§205.200 General.

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

§205.202 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

Arguments for Hydroponics

As is pointed out in the Task Force report and in public comments received in preparation for the Fall 2016 NOSB meeting, hydroponics has a long history in agriculture from societies that worked with limited resources in challenging conditions. Hydroponics is an innovative system that results in efficient water and nutrient use. Due to its controlled environment, hydroponic operations have been able to lessen use of pesticides, and operators have been able to develop systems that rely on organically approved inputs for crop nutrition and health.

Hydroponics can be an appropriate way to address challenges in farming as a whole, such as drought, food safety, limited access to arable land, and provide food in urban areas by using indoor growing systems. Practitioners have developed some innovative systems that are integrated, use only materials on the National List, and in some cases incorporate 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 with an integrated system.

In the Organic Integrity Quarterly Newsletter from May 2014, a publication from NOP, it is noted that organic hydroponic production is allowed as long as the producer can demonstrate compliance with the USDA organic regulations. The hydroponic proponents of the Task Force cited this, and the fact that some certifiers are accepting Organic System Plans for such operations, as approval. However the NOP publication did state that there may be additional guidance issued in the future for these methods. The allowance of hydroponic certification without organic hydroponic production standards has led to inconsistent approval by certifiers and confusion in the organic marketplace.

The hydroponic proponents on the Task Force contended that advantages of hydroponic systems included water conservation, food safety, disease suppression, nutrient conservation and retention, and soil conservation (because of lack of soil). They argued 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 hydroponic systems comply with §205.203 (soil fertility and crop nutrients) and §205.205 (rotations) have been given 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 (hydroponic) 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 (hydroponic) production." (Task Force report, p. 149).

Arguments Against Hydroponics

Natural soils are generally 95% or more 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 a great diversity of 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 which 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 systems that are input-based rather than soil-based. Also, when hydroponic operations pave over soil with cement or gravel, soil and natural resource conservation can be compromised.

Loss of arable land and the need to feed a growing world population are cited by pro-hydroponic advocates. However, organic agriculture, with its focus on soil building and protection or enhancement of natural resources, offers the opportunity to continually improve soil productivity and the natural resource base while producing crops. Additionally, it can transform land, which has been degraded by poor farming practices or is of low productive capability, to sustainable farming systems. Moreover, productivity *per se* is not a measure of the legitimacy of organic agriculture. Maintenance and improvement of the natural resources of the operation is also mandated under the organic regulation. On soil-based organic farms, the production of food and fiber is accomplished in concert with improving habitat for wildlife of all types, including pollinators, mammals, amphibians and soil microbes. Increased soil organic matter, cover crops, rotations, contour strips, reduced tillage and other activities continually improve the soil's structure and lessen erosion, which negatively affects water and soil quality. This integration of working lands with ecosystem stewardship is a foundational principle of organic agriculture.

While production of a crop in an aeroponic or hydroponic system can in some cases require less water 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. Furthermore, many farmers grow in temperate climates where annual rainfall provides most or all of a crop's water needs during all or part of the year.

Hydroponic production is highly dependent on continual use of fertilizer inputs to the production system, rather than relying on a productive soil and natural recycling of nutrients through decaying organic matter to regenerate the fertility needs of the crop. The "input substitution" approach of hydroponics has long been considered incompatible with a system of organic agriculture.

Another consideration is that unless there is careful attention paid to managing water runoff when siting and building hoophouses 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 hoophouses are present[4].

[4] http://www.rcdmonterey.org/pdf/RCDMCValleyRunoffandErosion.pdf

Specific language from OFPA and the Organic Rule that disqualify soilless production (hydroponic) from organic certification include the following:

- §6513 Organic Plan: "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…An organic plan shall not include any production or handling practices that are inconsistent with this chapter."
- § 205.200 General: "Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality."
- § 205.203 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…"

Aeroponic, hydroponic, and aquaponic production systems can be productive cropping systems which can be appropriate and well adapted to specific situations. However, that does not mean those systems are compatible with the principles of organic production or should quality them for organic certification.

Public Comments

Numerous comments were received from the public in response to both the Task Force report and the NOSB crops subcommittee proposal on Hydroponics/Aquaponics/Bioponics of September 6, 2016.

Those in favor of allowing hydroponics to carry the organic label in the marketplace discussed the efficient use of water and nutrients as important considerations. They also stated that there were fewer disease and pest problems in their controlled-environment production systems, leading to lower use of organically approved pesticides – although organic growers using soil in greenhouses disputed that claim. Soil and water were considered to be equally acceptable as a conductor of nutrients to plant roots. Food safety, worker health, providing food to urban food deserts, or aiding inexperienced or small scale growers were also cited as benefits of hydroponics, although some organic growers argued that organic production in soil in greenhouses provides similar benefits. Also, those are not factors that are used to determine a system's compliance with organic principles and regulations.

Those against allowing hydroponics to carry the organic label in the marketplace discussed the foundational principles of organic as originating with care and improvement of the soil and the overall ecosystem. Longer term improvements such as the use of nitrogen fixing crops, cover crops for improved organic matter, and an overall regenerative system that protects water and wildlife as well as supporting biodiversity, were also noted in numerous comments. The OFPA and organic regulations were cited, illustrating where soil- and ecosystem-based production systems are in the basic description of certified organic production. Many agreed hydroponics can be an innovative system of production, but did not agree that it met the letter nor spirit of the organic law or regulations.

Suggested Recommendations for Discussion

The Crops Subcommittee has divided the suggested recommendations in this discussion document into three parts: aeroponics, hydroponics, and aquaponics. This discussion does not refer to the production of edible sprouts or to aquatic plants growing outdoors in their native ecosystems.

Further research will be done that will result in a Crops Subcommittee proposed recommendation on container-based systems that deal with plants grown in soil or soil and substrate mixes. The proposal will examine the various systems of growing crops to maturity in containers and address minimum soil requirements as well as the amount of plant nutrients that can be supplied from liquid nutrients. Particular attention will be given to the needs of annual plants versus perennials. The standards of Canada, the EU, and other countries will be examined, and a proposal will be developed to try to provide consistent standards for growers and ease of trade for the organic produce industry.

The following are suggestions for additions to 205.105
§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in §205.601 or §205.603;

(b) Nonsynthetic substances prohibited in §205.602 or §205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

(e) Excluded methods, except for vaccines: *Provided,* that, the vaccines are approved in accordance with §205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.

Aeroponics
Discussion: Aeroponics does not require a root-zone medium. The roots are intentionally suspended in midair, in part to expose them to more atmospheric oxygen to aid plant growth. The roots are regularly sprayed with water that contains water-soluble nutrients.

Are aeroponic production systems – that do not include the use of soil or incorporate biological processes that mimic the biological processes that occur in soil – compatible with organic farming systems?

Suggested language for a new definition to be added to 205.2 Terms defined.

Aeroponics
Definition: A variation of hydroponics in which plant roots are suspended in air and misted with nutrient solution.

Suggested language to amend §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

Add (h) Aeroponics.

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Hydroponics

Discussion: In its 2010 recommendation, the NOSB stated that hydroponics "cannot be classified as certified organic growing methods due to their exclusion of the soil-plant ecology." The definition of hydroponics used for that recommendation was "The production of normally terrestrial, vascular plants in nutrient rich solutions or in an inert, porous, solid matrix bathed in nutrient rich solutions."

Today, plant-based materials – like coconut coir, wood shavings, and peat – are often used in place of inert materials for the solid matrix for hydroponics. These plant-based materials serve as effective matrix materials for hydroponics because they are porous, hold water well, allow for aeration of the plant roots, and do not biologically degrade readily. These plant-based materials are not technically inert (will not chemically react with anything under normal circumstances)[5] but are biologically recalcitrant (resistant to microbial attack)[6]. They will break down slowly over time but do not serve as a substantive source of nutrients for the plants being grown.

The term "recalcitrant" is used by soil scientists to describe organic materials that are resistant to microbial degradation, but will degrade slowly over time. For example, most models of soil organic matter describe three pools of organic matter: 1) the "active pool," comprised of microbial biomass and labile organic compounds (e.g., fresh plant residues), 2) the "slow pool," where much of the plant-associated nutrients reside for mineralization, and 3) the "recalcitrant pool," associated with the humus fraction of soil organic matter, that degrades very slowly (Rice, 2016)[7].

Are hydroponic production systems that use growing media comprised of inert or recalcitrant materials consistent with organic farming systems? Are production systems that rely on outside liquid fertility inputs for all or most of their fertility needs compatible with organic principles or a system of sustainable agriculture?

Suggested language for a new definition to be added to 205.2 Terms defined.

Hydroponics
Definition: The production of normally terrestrial, vascular plants in nutrient-rich solutions, or in a medium of inert or biologically recalcitrant solid materials to which a nutrient solution is added.

Suggested language to amend §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

Add (i) Hydroponics.

[5] http://www.biology-online.org/dictionary/Inert
[6] http://www.biology-online.org/dictionary/Recalcitrant
[7] Rice, C.W., Organic Matter and Nutrient Dynamics. pp. 1080-1081. *In* Lal, R., Encyclopedia of Soil Science. 2016 CRC Press, 3rd edition.

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Aquaponics

Discussion: Aquaponic systems use rooting media similar to hydroponic systems but get some or all of the plant nutrients from fish waste. Common rooting media include coconut materials, coconut/vermiculite mix, clay pellets, expanded shale, and lava rock (Task Force report).

The NOP has strict standards for handling animal manure in terrestrial organic production, but no such standards exist to ensure the safety of plant foods produced in the fecal waste of aquatic vertebrates. Also, the NOP has not yet issued standards for organic aquaculture production, upon which aquaponic plant production would be dependent.

Suggested language for a new definition to be added to 205.2 Terms defined.

Aquaponics: A recirculating hydroponic system in which plants are grown in nutrients originating from aquatic animal waste water, which may include the use of bacteria to improve availability of these nutrients to the plants. The plants improve the water quality by using the nutrients, and the water is then recirculated back to the aquatic animals.

Suggested language to amend §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

Add (j) Aquaponics.

Discussion Questions

1) The soil science term "recalcitrant" is used in the definition of hydroponics to identify substrates that are used in some hydroponic systems that are not completely "inert" but do not contribute substantive plant nutrition. Is this term and the intent of including it in the definition understood by the organic community, and should it be included in the definition?

2) Please provide feedback on the definitions of aeroponics, hydroponics, and aquaponics used in this proposal.

3) Some stakeholders have proposed an option of alternative labeling under OFPA for organic hydroponics. Please address opportunities or weakness to this suggestion.

4) Some proponents of hydroponics have stated that some commercial organic in-ground farmers may rely on liquid fertility inputs for most of their fertility needs. Please provide information to either support or refute this statement. Should that issue be addressed in the future?

Discussion Questions Regarding Container Production

At the fall 2016 meeting, the Crops Subcommittee (CS) presented a discussion document on Container and Greenhouse Production. The CS posed some questions for public comment there, and would like to follow up with additional questions here for consideration as a proposal on container production is developed for the fall 2017 meeting.

The CS recognizes there are numerous operations that are using containers for both annual and perennial plants. However, in order to develop standards for this production system, which has different needs and practices than in-ground production, the CS would like more information from the organic stakeholder community. In addition, the CS will be looking at organic standards in place by our trading partners in Canada and the European Union to inform our final recommendation on growing crops in containers. This container discussion will not pertain to plants grown in pots for eventual replanting into a field or in-ground situation, instead this container discussion pertains to plants that are grown to maturity to produce a final crop for sale to consumers.

The following questions refer to systems of annual and perennial terrestrial plants grown in containers in soil and/or compost-based mixes. Terrestrial plants growing in inert or recalcitrant substrates, with reliance predominantly on liquid nutrient solutions, are considered to be hydroponic.

When answering the questions below, please provide information that relates to your current practices, or to practices you know to be in use when growing annual and perennial crops in containers. You may also comment on what you think should be allowed and not allowed for organic certification.

Container Discussion Questions:

1. For both annual and perennial container growing, can you clarify if you rely on artificial lighting and/or artificial heating for the majority of the plant's needs?

2. For both annual and perennial container growing, do you use plastic mulch or petroleum-based landscape cloth under your containers? If so, when is this removed; once per year when it starts to decompose, or does it have organic mulch on top of it to prevent decomposition and it is never removed?

3. For both annual and perennial container growing, is this done inside a greenhouse situation or under hoops that are covered for part of the year by plastic?

4. Crops that grow to maturity for sale within a 12 month period are considered annuals. Do you grow annuals in containers? Could you meet a standard such as the Canadian container regulation? If not, how would you modify this standard?

   Excerpt from Canadian Standards:

   7.5.5 *The following conditions apply to containerized, staked crops (for example, tomatoes, sweet peppers, cucumbers, and eggplant):*

   a) at the start of production, the total volume of soil shall consist of at least 10% compost;
   b) compost shall be included in the fertility program;
   c) the soil volume shall be at least 70 L/m² (15.4 gal./10.8 ft²), based on the total growing area.

5. Plants that produce crops for sale after 12 months, and produce crops each year thereafter are considered perennials. It is understood that over time, the container-grown plants will be more reliant on outside nutrient sources, as the plants grow and the original soil or compost substrate will lose its fertility and nutrient availability.
   A. Could these perennial plants meet the Canadian container standard described in question 4? If not, how would you modify this standard?
   B. Would there need to be additional requirements beyond this Canadian container standard to address long-term perennial plants?

C. How many years are your perennial plants producing crops in these containers?

6. Some organic standards limit the amount of liquid nutrients that can be added after planting. The Task Force Subcommittee that reviewed the 2010 recommendation recommended that liquid nutrients be limited to 20% of the total nutrients supplied. Should there be a maximum amount of liquid fertility inputs allowed in organic container production? If so, what should that maximum be?
7. Most European countries do not allow container production to be certified organic, with the exception of a few kinds of plantings. They require that organic crops be grown in the ground, except for transplants, ornamental potted plants, and potted herbs, which can be grown in containers. Should the NOP adopt that European standard?
8. Would a decision tree be useful for evaluating the various systems of production to determine how an operation would be classified?

Vote in Crops Subcommittee:
Motion to accept the discussion document on aeroponics/hydroponics/aquaponics
Motion by: Francis Thicke
Seconded by: Emily Oakley
Yes: 6 No: 0 Abstain: 2 Absent: 1 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair to transmit to NOSB, February16, 2017

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Glossary of terms

Aeroponics—A variation of hydroponic in which plant roots are suspended in air and misted with nutrient solution.

Aquaponics—A recirculating hydroponic system in which plants are grown in nutrients originating from aquatic animal waste water, which may include the use of bacteria to improve availability of these nutrients to the plants. The plants improve the water quality by using the nutrients, and the water is then recirculated back to the aquatic animals.

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.

Greenhouse—Permanent enclosed structure that allows for an actively controlled environment used to grow crops, annual seedlings or planting stock.

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".

Hydroponics—The production of normally terrestrial, vascular plants in nutrient-rich solutions, or in a medium of inert or biologically recalcitrant solid materials to which a nutrient solution is added.

Inert material—A material that will not chemically react with anything under normal circumstances

Nutrient solution—Growing solution used in traditional hydroponic production that is commonly composed of immediately plant-available soluble mineral salts in water

Recalcitrant— Resistant to microbial attack.

Soil—The unconsolidated mineral or organic material on the immediate surface of the earth that serves as a natural medium for the growth of land plants. (ii) The unconsolidated mineral or organic matter on the surface of the earth that has been subjected to and shows effects of genetic and environmental factors of: climate (including water and temperature effects), and macro- and microorganisms, conditioned by relief, acting on parent material over a period of time. A product-soil differs from the material from which it is derived in many physical, chemical, biological, and morphological properties and characteristics (Soil Science Society of America Glossary).