National Organic Standards Board Meeting
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National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee Proposal
Eliminating the Incentive to Convert Native Ecosystems to Organic Production
August 29, 2017

I INTRODUCTION

The Organic Food 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 include a clear bias towards protection of the natural resources present on an organic operation, including the physical, hydrological, and biological features of the farm. The soil, water, wetlands, woodlands, and wildlife must be maintained or improved by the organic operator through production practices implemented in accordance with the Act and Regulations. Organic agricultural systems rely upon the soil health, biodiversity, and conservation of ecosystem-based benefits such as pollinator habitat, for crop health, vigor, protection from pests, and more. Materials approved for use in organic agriculture are strictly reviewed before approval to determine their effects on the environment during manufacture, use, and disposal to represent the least toxic choice. This bias towards ecosystem preservation is also found within the organic marketplace with consumer expectations that organic farms and ranches will be examples of excellent land stewardship.

Along with this strong environmental protection within the regulatory framework that oversees organic production, is the requirement that land cannot produce organic crops or livestock until 36 months have passed between the application of a prohibited substance and the harvest of an organic crop. This three-year transition can be a challenge for farm operators who must follow organic regulations but cannot enter the organic marketplace with their production. Using land that has not had any prohibited substances applied to it provides an immediate entry into the organic marketplace for crops or livestock, without the three year wait. Fallow land that had previously been cropped can meet this requirement, as well as land that has never been cropped. There is a risk that native ecosystems, many of which provide habitat for endangered, threatened, and at-risk species of all types, could be destroyed if they are converted to organic agricultural crop or livestock production. The lack of the three-year transition timeframe is an incentive to convert these native ecosystems to immediate agricultural production.

Over the last two and a half 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 incentives and disincentives to reduce conversion of native ecosystems.

The NOSB discussion document from January 10, 2016, provided background and encouraged public comment from a wide cross-section of stakeholders to determine if the NOSB should recommend to the NOP a Rule change, Guidance, or other mechanisms to address this issue.

II BACKGROUND

The NOP provided Guidance on Biodiversity in 2016 (NOP 5020) encouraging the protection and maintenance of a high level of biodiversity on farms because it brings benefits not only to the entire ecosystem in that geographic area, but also to the farmer. Advantages to certified organic operations that implement these types of production practices include: 1) decreased dependence on outside fertility inputs; 2) reduced pest management applications and costs; 3) more reliable sources of clean water; and 4) better pollination (NOP 5020).

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

The Organic Food Production Act (OFPA) of 1990, as amended, 7 U.S.C., Chapter 94:

7 U.S.C. 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 U.S.C. 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 U.S.C. 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." (65 FR 80547, December 20, 2001)

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 U.S.C. 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.

While there is no specific reference to the protection of native ecosystems in the Organic Foods Production Act of 1990, 7 U.S.C. 6506 General Requirements (11) states the program established under this title can "require such other terms and conditions as may be determined by the Secretary to be necessary and consistent with this title".

The National Organic Standards Board (NOSB), in Section 2119 (7 U.S.C. 6518) can "advise the Secretary on any other aspects of implementation of this title".

The proposal below is an NOSB recommendation to the Secretary, advising him of a need to address this important issue. The discussion document provided numerous instances of unaltered native ecosystems that are either at risk or have been destroyed for agricultural production, illustrating this issue is real and should be addressed. Numerous examples were provided that this destruction is occurring on land that subsequently is used for organic production.

There are other regulations within the U.S. law that seek to protect specific areas, such as the "sodsaver" provision[1], which specifically addresses the protection of prairie potholes in the United States.

IV DISCUSSION and PUBLIC COMMENT

The discussion document preceding this proposal listed organic standards from other countries and organic control bodies that protect native ecosystems including Australia, Argentina, Bolivia, IFOAM, (International Federation of Organic Agricultural Movements) and New Zealand. The NOP has Memoranda of Agreement and Equivalencies with several of the above listed countries. In addition, there are other ecolabels around the world providing consumers the assurance that high conservation value ecosystems were not destroyed in the production of their food or fiber.

The control bodies listed above can 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 in the United States.

This issue of conversion of native ecosystems to agricultural production has been discussed through public comment and on the Board for two years. The discussion document received only positive comments supporting the need to address this issue in a timely manner. Consumers, retailers, scientists,

[1] https://www.rma.usda.gov/data/pothole/,
https://www.ers.usda.gov/webdocs/publications/44876/7105_err120_reportsummary.pdf?v=41056

environmentalists, organic producers, and certifiers all agreed that the time has come to address this issue.

The NOSB puts forward the proposal below to provide protections for these ecosystems through removal of the incentive to immediately gain access to the organic market after the destruction of these native ecosystems. It is understood that the operator requesting organic certification may not be the entity that destroyed the ecosystem. Organic production is more environmentally beneficial in many cases than nonorganic production practices. Taking these situations into account, the NOSB does not wish to ban the use of this land forever from organic agricultural production. However, the NOSB does want to provide a strong disincentive for both the production of annual and perennial crops on land where this loss of biodiversity and species has occurred. A 10-year "wait period" provides a strong disincentive for perennial crops such as tree fruits, nuts, and others, which can need five to ten years in order to produce a crop. Any shorter timeframe would not provide a sufficient disincentive to these perennial crop operators to destroy native ecosystems since they would be waiting for their crops to mature to productive levels during that shorter time period anyway. The proposal below does not prevent operators from wild harvest of crops from these native ecosystems, such as collection of prairie seed, as long as they meet the wild harvest requirements of 7 CFR 205.207. In addition, this wait period would not affect lands that have been enrolled in the Conservation Reserve Program, since these lands have all been previously cropped.

The NOSB, along with the NOP, will continue working on this issue with the goal of providing future NOP guidance and further information on how to identify native ecosystems and their conversion date to agricultural production.

V QUESTION

The NOSB would like to receive feedback from certifiers on possible economic impact this rulemaking may have on their certified operations:

> *How many operations, crops, and acreage would have been impacted if this rule had been in place in 2016?*

VI PROPOSAL

Add the following in italics to the organic regulation.

Subpart C- Organic Production and Handling Requirements
205.200 General
The producer or handler of a production or handling operation intending to sell, label, or represent agricultural production as "100 percent organic", "organic" or "made with organic (specified ingredients or food groups (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.

(a) A native ecosystem site that has not been previously grazed or cultivated cannot be certified as organic as provided for under this regulation for a period of 10 years from the date of conversion to crop or livestock production.

Motion to approve the proposal on eliminating the incentive to convert native ecosystems to organic production" for rulemaking.
Motion by: Harriet Behar
Seconded by: Tom Chapman
Yes: 4 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB August 29, 2017

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Excluded Operations in the Supply Chain Proposal
August 29, 2017

I. INTRODUCTION

Since the passage of the Organic Foods Protection Act into law in 1990, organic trade has grown to a nearly $50 billion market. Integral to past and future growth is consumer confidence in the integrity of the USDA organic label as the gold standard. Just as integral is trust in the certification services of USDA-accredited certifiers, a third-party system that evaluates the production and flow of products from farm to market.

Under USDA certification, most operations in the organic market are subject to certification. Operations that produce, process, or further handle organic product fall under the scrutiny of certification. Within the system of certification, integrity of the product relies on a strong record trail to transparently verify an organic product has remained intact and been handled in accordance with the regulations. However, certain operations are presently excluded under the current USDA organic regulations (7 CFR 205.101(b)):

- A handling operation that handles products that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation and remain in the same package or container and are not otherwise processed while in the control of the handling operation.
- A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as organic.

The second example above is of less concern as the organic product has essentially reached its end user. However, when a product passes through an excluded handling operation, such as a broker or distributor, a complete and transparent audit trail can become challenging to follow. The regulations require a certified operation to verify organic status by tracing back to the last organic certificate holder. Excluded operations may present gaps in this trail as they fall outside of the scrutiny of certification.

This discussion document seeks to explore a means to strengthen these audit trails by further clarifying what operations are excluded from certification. It also seeks to clarify the requirements of labeling bulk packages and containers, as well as what constitutes an enclosed package or container.

II. BACKGROUND

With consumer demand and the premium organic receives, market growth has created opportunity for U.S. farmers and businesses. This opportunity continues as U.S. demand now outstrips supply in certain commodity crops such as corn, wheat, and soybeans. With increased demand comes the increase of imported grain and other products.

Much of the imported product passes through at least one—and sometimes many more—handlers, brokers, and distributors excluded from certification. Additionally, fresh produce from both domestic and imported sources often passes through similar entities not subject to certification. Operating outside of certification, these operations may be in compliance but present a gap in maintaining strong audit trails and transparent recordkeeping.

At the Fall 2010 NOSB meeting, the NOSB passed a recommendation entitled *Clarifying the Limitations of 205.101(b)*. This recommendation asked the National Organic Program to articulate their interpretation of existing regulations with respect to specifying those handling activities that are inside and outside the scope of §205.101(b), thereby implicating handling operations undertaking those activities and their eligibility or ineligibility, respectively, for exclusion from mandatory organic certification. Specifically, the NOSB recommended the following:

> This notice is provided to inform the general public and interested parties that the National Organic Program (NOP) staff has determined that the limitations to the applicability of §205.101(b) have not been adequately observed and that a number of uncertified handlers have been operating in a manner inconsistent with 7 CFR Part 205 and the National Organic Program.
>
> Handling operations selling or otherwise representing (organic) commodities such as grains, soybeans, hay, or cattle and commonly referred to as brokers, traders, or distributors of those commodities, are not excluded from the requirements of 7 CFR Part 205, including but not limited to organic certification, unless such an operation only sells organic agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" that:
>
>> (i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and
>> (ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.
>
> Hay is typically sold or transported in bales of various sizes and configurations on trailers without packaging; cattle are sold on the hoof in trailers. These activities are inconsistent with §205.101(b)(1)(i). Brokers, traders or distributors of such organic goods are therefore required to be certified organic operators, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.
>
> Commodities such as grains and soybeans are typically not packaged and are received from one container or vessel and transported in another container or vessel; this is inconsistent with §205.101(b)(1)(ii). Brokers, traders or distributors of such organic commodities are therefore required to be certified organic operations, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.
>
> Handlers currently engaged in brokering, trading or distribution activities in a manner inconsistent with §205.101(b) are not in compliance and may be subject to penalties and fines as per §205.100(c)(1).

In February 2012 and July 2013, the Office of Inspector General (OIG) conducted audits of the NOP. The OIG audits stated that the NOP needs to ensure that organic milk is not coming into contact with prohibited substances while being transported. In OIG's recommendations, it stated that the NOP should ensure that transporters are either certified or included in the responsible parties' Organic System Plan (OSP).

In response to this finding and the NOSB recommendation, the NOP, in January 2014, finalized guidance entitled Certification Requirements for Handling Unpackaged Organic Products as NOP 5031, which is a part of the Program Handbook. This document provided guidance to clarify the following:

> In regards to 205.101(b)(1),] An operation is excluded from certification if:
> - It only handles organic products that are enclosed in a package or container;
> - The products remain in the same package or container for the entire period handled; and
> - It does not process organic products.
>
> In other words, the excluded operation must receive certified organic products in wholesale or retail containers and distribute them in the same wholesale or retail containers without opening, reconstituting, altering, repackaging, processing, or relabeling the products.

The guidance goes on to describe several types of operations that don't require certification, operations that are excluded (don't need to be certified), and operations that are not excluded (need to be certified):

Examples of operations that are not required to be certified:

- Transportation companies that move certified organic hay or straw (wrapped or unwrapped) or milk from a certified organic farm to a certified organic buyer or processing facility;
- Transportation companies that transport certified organic grain from certified operations to a certified handling facility; and
- Transportation companies that move certified organic livestock from a certified organic farm to a certified organic slaughter facility.

And:

Excluded examples (those that do not need to be certified):

- Wholesale distributors, brokers, and traders that sell boxed or otherwise sealed containers of certified organic products (e.g., sealed tote bags, 55 gallon juice drums, boxed cereal, milk in cartons);
- Trucking or other transportation companies that transport boxed or otherwise sealed containers of certified organic products; and
- Produce handlers who do not open, repack, trim, or re-label certified organic products (e.g., bagged salad greens, boxed produce).

As well as examples of non-excluded operations (those that must be certified):

- Operations that handle certified organic hay or straw (wrapped or unwrapped) by combining or splitting loads or lots;
- Operations that handle unpackaged grain (including combining or splitting loads or lots), package, or otherwise handle the product other than for transport; and
- Fruit and vegetable wholesalers that package or label containers of certified organic produce for sale as organic.

The program also published NOP 5031-1 *Response to Comments Certification Requirements for Handling Unpackaged Organic Products*. In this document, there is a discussion of changes requested but not made to Guidance NOP 5031. Some of these changes requested but not made are as follows:

1) Define "enclosed in a container" to mean impermeable with a tamper proof seal. A number of certifying agents requested that we clarify that the exclusion from certification described at section 205.101(b) applies only to products that are enclosed in tamperproof, impermeable containers. While we recognize that these types of containers and sealing systems are an important tool for prevention of contamination and loss of integrity for some distribution systems (e.g. rail cars hauling grain and milk tankers), we have not further defined "enclosed in a container" or "packaged". For example, produce brokers who do not open boxes, repack, trim, re-label or otherwise handle the product are excluded from certification because they handle "packaged" products. Such products do not necessarily use impermeable boxes or seals, but these products are still considered "packaged". Any change to specify that produce boxes are not considered "packaged" or "enclosed in a container" would require review of the impacts on the produce industry.

2) Handlers who take ownership should be certified. A number of commenters, including processors, a trade organization, and certifying agents stressed that brokers, traders, distributors or other handlers that take ownership or are directly paid for unpackaged (i.e., unsealed) organic product should be certified. The comments stated that without such a requirement, there is a gap in the audit trail and the integrity of the product becomes difficult to verify. In the final guidance, we have not specified that ownership determines whether a handler (e.g., broker, trader, distributor) should be certified. The exclusion from certification provided for at section 205.101(b) of the regulations is not dependent on ownership, but is based on whether the product remains enclosed in a container and is not further processed. Therefore, the final guidance specifies that if you handle (i.e., sell, package, or process) unpackaged organic product, and you are not exempt or excluded (per section 205.101), then you must be certified. We have clarified that producers and owners of certified organic products must be able to provide adequate records and audit trail for products shipped via non-certified transporters.

3) Include a reference to section 205.307 of the USDA organic regulations. A commenter suggested providing a reference to section 205.307: "Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food groups)." While this is a related topic, and applies to labeling of all non-retail packaging, it is beyond the scope of this guidance. This guidance focuses on the requirements for certification of packaged and unpackaged products, and does not address labeling.

Recent press revealed conventional product fraudulently sold as organic. Investigations conducted by the NOP have since shown at least one instance of fraudulent trade took place within the scope of certification. This news has made national headlines and has been raised in Senate Agricultural Committee hearings. It is important that consumers are confident in the integrity of the NOP control system, and it is prudent to re-review rules and guidance about excluded operations. Clarification of what operations are truly exempt from certification, the requirements of labeling bulk packages and containers, and what constitutes an enclosed package or container can aid in overall integrity and greater transparency in the supply chain.

III. RELEVANT AREAS OF THE RULE

§205.2 Terms defined.

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

§205.101 Exemptions and exclusions from certification.

(b) *Exclusions.* (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in §205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in §205.272; and

(ii) The labeling provisions of §205.310.

§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.

§205.201 Organic production and handling system plan.
(a)(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§205.303 Packaged products labeled “100 percent organic” or “organic.”
(b) Agricultural products in packages described in §205.301(a) and (b) must:
(1) For products labeled “organic,” identify each organic ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient

statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.
(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§205.306 Labeling of livestock feed.
(b) Livestock feed products described in §205.301(e)(1) and (e)(2) must:
(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

§205.401 Application for certification.
A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:
(d) Other information necessary to determine compliance with the Act and the regulations in this part

§205.406 Continuation of certification.
(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:
(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

NOP Guidance 5031 Certification Requirements for Handling Unpackaged Organic Products

NOP 5031-1 Response to Comments Certification Requirements for Handling Unpackaged Organic Products.

IV. DISCUSSION
This discussion will seek to build upon the scope and applicability of NOP 5031. Readers should refer to this document to understand why transport operations that do not sell, label, or repack organic product do not require certification. Additionally, if not specifically clarified in this proposal, current guidance in NOP 5031 should remain. For example, NOP 5031 makes clear that operations involved in the sale of unenclosed product need to be certified. We agree with this interpretation, and such guidance should remain in place.

Upon further review of standards and guidance, the NOSB suggests the following clarifications to NOP Guidance 5031 to further strengthen organic integrity in the supply chain.

An operation is excluded from certification if:

- It only handles organic products that are enclosed in a package or container;
- The products remain in the same package or container for the entire period handled; and
- *The package or container is labeled as “organic”. When labeled as “organic”, products must also contain the “certified organic by” certifier statement and name the handler and ingredient list (if applicable).*
- It does not process organic products

The NOSB finds these additional recommendations are compliant with the standards as currently written and help to maintain organic integrity by limiting loopholes in supply chain documentation and labeling. This would clarify the following:

To be exempt, product must not only be enclosed in a package or container, but that package, container, or product must be labeled as "organic" and include the "certified organic by" certifier statement next to the name of the handler, as well as an organic ingredient list (as applicable). We find the labeling of product or containers to be required based on the text of §205.101 (b)(1). This section states the exemption only applies to operations or the portion of the operation that sells "organic agricultural products **labeled** as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" …" The requirement that products be labeled makes fraud, commingling, and contamination more difficult given the clear statement to all who come into contact with the product. Furthermore, §205.303 Packaged products labeled "100 percent organic" or "organic", requires that packaged production labeled as organic also "**identify each organic ingredient** in the ingredient statement with the word "organic"; "below the information **identifying the handler or distributor of the product** and preceded by the statement, "**Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler** of the finished product" [emphasis added]. For livestock feed, similar requirements are outlined in §205.306. These additional labeling requirements are referred to as "accompanying requirements" for the remainder of this document.

The term label is defined by the NOP in section 205.2:

> ***Label:*** *A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed or graphic material which contains only information about the weight of the product.*

The definition makes the elements of a label clear. To be a label it must be "written, printed or graphically displayed" and must meet one of the following elements:

- Be on the immediate a container, or
- Affixed to the agricultural product, or
- Affixed to a bulk container containing an agricultural product [applies to retail only, see bulk below]

Bulk is also defined and is clearly limited to retail sale situations. Section 205.2 defines bulk as "the **presentation to consumers at retail sale** of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased." Since bulk labeling only applies in the retail environment, handlers of unpacked and unlabeled products in a non-retail environment must meet one of the other elements (a label on the immediate container or affixed to the agricultural product) to be considered labeled and thus eligible for exemption.

Operations involved in the sale and distribution of retail-labeled organic products would be exempt if such products were already packed, remained in the same packaging, and were not further processed or packaged. This remains true regardless of how the non-retail containers containing retail-labeled products are packed. However, such non-retail containers must comply with the requirements of §205.307, and retail-labeled product must comply with §205.303. Similarly, operations involved in the sale of labeled and packaged organic livestock feed products would be exempted if such products were already packed, remained in the same packaging, and were not further processed or packaged; however, such packaging would need to comply with §205.306.

This interpretation does not require transport operations that do not sell, package, or process (such as rail cars of grain or tankers with liquid products) to be certified. Both operations that load and unload organic products into the rail car/tanker would need to maintain proper audit trail documentation of the organic products they receive and package (loading/unloading), including documenting that organic integrity was maintained throughout transit. In the example of a rail car/tanker, the rail car or tanker itself would be considered the container, so transit and physical handling of the rail car/tanker itself would not need to be certified. However, operations involved in the loading and unloading of product into the rail car/tanker would need to be certified since the §205.101 (b)(1)(i) and (ii) exemption only applies when the products "are packaged or otherwise enclosed in a container **prior** to being received or acquired by the operation, and remain in the same package or container and are not otherwise processed while in the control of the handling operation." Additionally, the rail car or tanker would also need to be physically labeled as organic with the accompanying requirements for any operation in the supply chain that is selling the product in order to be exempted from certification. If the rail car or tanker is not labeled, then any operation involved in selling, packaging, or processing would need to be certified since they did not meet the definition for exemption; this would include brokers/traders who sell these products regardless of their ownership of the product. We find it prudent for the NOP, under the authority of §205.401 and §205.406, to require that the same labeling information be included on packing slips as necessary to determine compliance with the regulations during audits. This would be an additional requirement and cannot be completed in lieu of physically labeling the product/container.

If products were packed and remained packed in discrete containers like sacks, boxes, pails, drums, totes, etc. and labeled as organic with the accompanying requirements, then operations involved in the product's sale, but not processing or packaging, are exempt operations per §205.101(b)(1). However, in this case, operations purchasing or receiving these products for further processing or packing would need to maintain audit trial documents that verify the organic compliance and integrity of the product as labeled. If the same containers were not labeled as organic with the accompanying requirements, then operations involved in the sale of the same product packed in the same containers would need to be certified since they do not meet the "labeled" requirement of §205.101(b)(1). In this case, the selling party would be the same as the party providing evidence of organic certification. Operations purchasing or receiving these products for further processing, packing, or sale would need to maintain audit trial documents that clearly demonstrated that the selling party is certified organic.

V. RECOMMENDATIONS

The NOSB recommends the NOP make the following change to Guidance document NOP 5031:

1. Revise to make clear that exemption only applies to packaged and labeled product:
   An operation is excluded from certification if:
   - It only handles organic products that are enclosed in a package or container;
   - The products remain in the same package or container for the entire period handled; and
   - *The package or container is labeled as "organic". When labeled as "organic", products must also contain the "certified organic by" certifier statement and name the handler and ingredient list (if applicable).*
   - It does not process organic products
2. Revise to make clear that unlabeled, unenclosed produce handlers in a non-retail environment must be certified.
3. Provide additional examples of operations that need to be certified and those excluded. An example of a template that can be expanded upon is provided in Attachment A.
4. Provide additional training to certifiers and certified handlers on proper ways to verify that organic certification documents of purchased products matches product as labeled when

purchased from a non-certified operation. Certifiers should be trained on how to audit to this requirement.

5. Provide additional guidance to certified handlers and certifiers on proper audit trail documentation for purchases of unpackaged, unlabeled product from certified operations. Such documentation must be sufficient to connect sale, receipt, and integrity of unlabeled product. Certifiers should be trained on how to audit to this requirement.
6. Include in the accreditation audit of certifiers a verification that this policy is properly interpreted by the certifier.

VI. REQUEST FOR PUBLIC COMMENT

While it is uncommon for the subcommittee to seek questions in a proposal, the NOSB believes action is needed urgently to further ensure the integrity of organic products in the marketplace and maintain continued consumer confidence. The NOSB believes the NOP will be able to make any needed modifications to this NOSB recommendation based on a summary of the comments received when the NOP publishes draft guidance.

The NOSB is requesting public comment from the community on these clarifications, implementation by certifiers, and impacts on existing trade. Please respond to the following questions, as well as provide any other information that would be helpful in moving this issue forward:

1. What negative impact might there be on the trade and movement of organic product with these clarifications?
2. What economic impact might there be based on these clarifications?
3. What impact will these clarifications have on maintaining organic integrity?

Subcommittee vote

Motion to approve this proposal on excluded operations in the supply chain
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Scott Rice, CACS Chair, to transmit to NOP August 29, 2017

Attachment A – Template for clarification

#	Handling Action of operation	Product already enclosed in a container?	Product already labeled organic?	Does Operation need to be certified?	Example
1	Process a product	n/a	n/a	Yes	Bakery making bread
2	Package a product	n/a	n/a	Yes	Labeling blank cans of already packed soup
3	Sell a product	No	No	Yes	Brokering Grains (whether or not taking physical possession) or Fruit distributor where fruit is in open trays and fruit itself **is not** stickered
4	Sell a product	Yes	No	Yes	Distributor of enclosed product that is not specifically labeled as organic.
5	Sell a product	No	Yes	No – but still comply with 272	Fruit distributor where fruit is in open trays and fruit itself **is** stickered
6	Sell a product	Yes	Yes	No – but still comply with 272	Distributor of packed and organically labeled product in discreet enclosed containers.
7	Transit a product	n/a	n/a	No – but still comply with 272	Operations that load and unload unlabeled products would need to be certified as required under #4. However, the operation transporting would not require certification.

Attachment B

NOP 5031: Guidance - Certification Requirements for Handling Unpackaged Organic Products

Attachment C

NOP 5031-1: Response to Comments - Certification Requirements for Handling Unpackaged Organic Products

Sunset 2019
Meeting 2 - Review
Crops Substances
November 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.

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

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)

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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).

Public comments were received during the 2019 review indicating that chlorine materials are necessary in organic crop production, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, preventing the spread of disease, and controlling pathogens detrimental to human health. Some commenters said it was important to have several types of sanitizers available for use in case resistance develops to any of them.

Some public commenters expressed concerns that chlorine sanitizers can be harmful to human health and the environment, and that alternatives should be used when possible. Commenters also suggested that chlorine sanitizers, and all sanitizers, should be reviewed as a group to identify if all sanitizers currently on the National List are needed, and if the use of chlorine sanitizers could be limited to use only where other sanitizers that are less harmful to human health and the environment are not adequate.

Subcommittee vote:

Motion to remove calcium hypochlorite from §205.601(a) based on the following criteria in the Organic

Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Francis Thicke
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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 10 (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).

Public comments were received during the 2019 review indicating that chlorine materials are necessary in organic crop production, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, preventing the spread of disease, and controlling pathogens detrimental to human health. Some commenters said it was important to have several types of sanitizers available for use in case resistance develops to any of them.

Some public commenters expressed concerns that chlorine sanitizers can be harmful to human health and the environment, and that alternatives should be used when possible. Commenters also suggested that chlorine sanitizers, and all sanitizers, should be reviewed as a group to identify if all sanitizers currently on the National List are needed, and if the use of chlorine sanitizers could be limited to use only where other sanitizers that are less harmful to human health and the environment are not adequate.

Subcommittee vote:

Motion to remove chlorine dioxide from §205.601(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Francis Thicke
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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 (Na_2CO_3) (TR lines 199-202).

Public comments were received during the 2019 review indicating that chlorine materials are necessary in organic crop production, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, preventing the spread of disease, and controlling pathogens detrimental to human health. Some commenters said it was important to have several types of sanitizers available for use in case resistance develops to any of them.

Some public commenters expressed concerns that chlorine sanitizers can be harmful to human health and the environment, and that alternatives should be used when possible. Commenters also suggested that chlorine sanitizers, and all sanitizers, should be reviewed as a group to identify if all sanitizers currently on the National List are needed, and if the use of chlorine sanitizers could be limited to use only where other sanitizers that are less harmful to human health and the environment are not adequate.

Subcommittee vote:
Motion to remove sodium hypochlorite from §205.601(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Francis Thicke
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review
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 (NH_3) or ammonium hydroxide (NH_4OH) 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 issues, 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, MAFF, and IFOAM 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.

The Crops Subcommittee supports relisting soap-based herbicides at §205.601(b).

Subcommittee vote:

Motion to remove soap based herbicides from §205.601(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Sue Baird
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 2 Absent: 2 Recuse: 0

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: Added to National List effective 10/30/14 (79 FR 58655)

Sunset Date: 10/30/19

Subcommittee Review:

Biodegradable biobased mulch films were approved for placement on the National List of approved synthetics without detailed information about the how much non-biobased content would be allowed. The vast majority of mulch films in this category contain 20% or less of 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, clarifying 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. This supplemental TR was inconclusive, since research on these materials is currently limited.

There have been numerous public comments requesting the NOSB work with the NOP to allow a biodegradable biobased mulch that contains these unique polymers. Some noted that having a degradable plastic mulch is more environmentally friendly than using landfills for the non-degradable plastic mulches. Commenters also acknowledged that there are currently very few options (other than difficult to use paper mulch), for 100% biobased mulch, but felt the listing should remain. This could encourage development of mulch that would meet the NOP regulations, or solicit information that could change the directive in the policy memo. The fact this product is derived from petroleum, led to negative comments asking for its removal from the National List of approved synthetics.

There are studies now in progress that could provide more information in the future, which could result in a proposed annotation change or other mechanism to allow the use of a mulch containing some percentage of these synthetic polymers. The research may also support the current NOP regulations and policy memo that no synthetic polymers are allowed in degradable mulch. Our current understanding of the unique synthetic polymers used in these biodegradable mulches is they are recognized by the soil biological life as food, and readily consumed and degraded when incorporated into the soil. However, there are fossil fuel-based fertilizers, used in nonorganic agriculture, that also break down in the soil and provide nutrients for plants as well, but they are not allowed. The Crops Subcommittee will keep biodegradable, biobased mulch film on our work agenda. We will revisit it again once we have more information and can determine if the polymers used in these biodegradable mulch films are compatible with the approved synthetic materials criteria in the Organic Foods Production Act.

The Crops Subcommittee favors keeping biodegradable biobased mulch film on the National List at 205.601(b).

Subcommittee vote:

Motion to remove biodegradable biobased mulch film as defined in §205.2 - Must be produced without organisms or feedstock derived from excluded methods.
Motion by: Harriet Behar
Seconded by: Emily Oakley
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse:

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

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.

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 it is good to have as a means for control and as a back-up with insect problems. Comment was received that natural alternatives do exist, and that management changes rather than a material application is the best if problems do occur.

At the Fall 2015 NOSB meeting, the Crops Subcommittee proposed a vote to remove boric acid from §205.601(e) on the basis of not fully meeting all sub-components of OFPA criteria in regards to: criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency. The motion to remove failed after receiving 1 "Yes" and 134 "No" votes. While boric acid does not fully meet the OFPA criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency, the alternatives often have equally challenging issues.

This material is often used in packing sheds and other facilities. Many times it is used as a powder introduced into cracks and crevices, and is essential for controlling ants and roaches. A number of members of the public did comment regarding the listing of boric acid, and the majority supported re-listing. Numerous distributors, food processing businesses, certifiers and farmers recommended relisting, as a necessary tool for control of ants and roaches in packing houses and food handling facilities. One certifier noted it was not used by any of their certified operations. A few organizations recommended changing the annotation to read: "For use only as bait in traps or in gel formulations". The CS would consider a petition requesting an annotation change.

Subcommittee vote:

Motion to remove boric acid - As insecticides (including acaricides or mite control) (3) Boric acid- structural pest control, no direct contact with organic food or crops from 205.601(e) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Harriet Behar
Seconded by: Francis Thicke
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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 (completed in 2015), 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 as a permitted synthetic given both product availability and effective insect control.

During this sunset review, no additional information was requested. As in the previous review, there was broad support for relisting sticky traps/barriers from farmers, certifiers, and trade organizations. There was some concern that non-target animals can get caught, with a suggested annotation stating that traps and barriers must be used in a way that prevents non-target trapping.

Subcommittee vote:
Motion to remove sticky traps from §205.601(e) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Emily Oakley
Seconded by: Sue Baird
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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.

In the review of copper materials in Spring 2017, several public comments expressed concern about the overuse of copper, particularly near harvest time, when copper residues could still be seen on harvested produce. There was a question of whether an additional annotation should be added that no visible residues of copper be present at harvest. Several certifiers commented that this would be very difficult to enforce since it would require an inspection visit during the actual harvest. In general, comments during the Spring 2017 Review supported relisting of copper materials and that the current annotation is adequate.

Given the extensive use and documented need for copper sprays, the Crops Subcommittee thinks these materials should be renewed.

Subcommittee vote:

Motion to remove coppers, fixed from §205.601(i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Steve Ela
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

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."

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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.

In the review of copper materials in Spring 2017, several public comments expressed concern about the overuse of copper, particularly near harvest time, when copper residues could still be seen on harvested produce. There was a question of whether an additional annotation should be added that no visible residues of copper be present at harvest. Several certifiers commented that this would be very difficult to enforce since it would require an inspection visit during the actual harvest. In general, comments during the Spring 2017 Review supported relisting of copper materials and that the current annotation is adequate.

Given the extensive use and documented need for copper sprays, the Crops Subcommittee thinks these materials should be renewed.

Subcommittee vote:

Motion to remove copper sulfate from §205.601(i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Steve Ela
Seconded by: Francis Thicke
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

Humic acids, which naturally exist in soils, can be supplemented by manufactured humic acids from oxidized lignite. Humic acids are used as a component of traditional fertilizers, and do not provide additional nutrients to plants, but rather affect soil fertility by making micronutrients more readily available to plants. "Humic acids 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 and lignite. 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 majority of comments were in favor of keeping humic acids on the National List. At the Spring 2017 NOSB meeting the majority of commenters were also in favor of keeping humic acids. Several objections focused on environmental concerns related to humic acids as fertility tools manufactured, in some cases, from low grade coal (lignite).

However, as reiterated in public comment, humic acids are viewed as a critical and necessary element of nutrient management in organic farming. Concerns were raised that removal from the National List would negatively impact many growers.

Based on the Subcommittee review and public comment, the NOSB finds humic acids compliant with OFPA criteria, and does not recommend removal from the National List.

Subcommittee vote:

Motion to remove humic acids from 205.601(j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Ashley Swaffar
Seconded by: Dave Mortensen
Yes: 0 No: 9 Abstain: 0 Absent: 0 Recuse: 0

Micronutrients: Soluble boron products.

Reference: 205.601(j)(6) - As a plant or soil amendment. 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 sunset recommendation; 10/2015 micronutrient annotation change
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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 yet been implemented by the NOP or printed in the Federal Register. The NOSB crops supports this annotation change.

All public commenters were supportive of relisting this micronutrient, calling it essential. Certifiers, distributors, food processing businesses, and many individual growers stated their need for this material and that it is very commonly used. One commenter felt that there should be a way to address over-accumulation of all micronutrients used by organic growers. Others felt that if testing must be done before micronutrients are used, the application may be too late to save the crop or perennial plant.

The Subcommittee supports the proposed annotation change recommended by the NOSB in October 2015. Removing the requirement that there be soil testing before allowing application is problematic for both perennial and annual crop producers. There are numerous ways of documenting a deficiency, other than soil testing. By the time the deficiency is noted through soil testing, it may be too late to save the perennial plant or crop. This is an essential micronutrient, used across all types of crop production.

The Crops Subcommittee supports relisting micronutrients: soluble boron products at §205.601(j)(6).

Subcommittee vote:
Motion to remove micronutrients: soluble boron products from §205.601(j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Micronutrients 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 the 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 plant or soil amendments.

(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 plant or soil amendments.

(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 published in the Federal Register.

All public commenters were supportive of relisting these micronutrients, calling them essential in a variety of cropping systems. Certifiers, distributors, food processing businesses, and many individual growers stated their need for these materials and one or more of them are commonly used. One commenter felt that there should be a way to address over-accumulation of all micronutrients used by organic growers. Others felt that if testing must be done before micronutrients are used, the application may be too late to save the crop or perennial plant.

The Crops Subcommittee supports renewing micronutrients with the proposed annotation change recommended by the NOSB in October 2015. The requirement that there be soil testing before allowing application is problematic for both perennial and annual crop producers. There are numerous ways of documenting a deficiency, other than soil testing. By the time the deficiency is noted through soil testing, it may be too late to save the perennial plant or crop. Many of these are essential micronutrients, used across all types of crop production.

Subcommittee vote:

Motion to remove micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt at §205.601 (j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 3 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

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 review, 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 (Organic Materials Review Institute) product search for each of the three vitamins resulted in zero entries. An OMRI generic materials database search indicated that nonsynthetic plant hormones such as gibberellic acid, indole acetic acid (IAA), and cytokinins might 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 review, the Crops Subcommittee requested a technical review.

The 2015 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.

During the 2019 sunset review, additional information was requested on the efficacy and use of vitamin B1, given that the 2015 TR stated that it is not generally effective at reducing transplant shock or stimulating new root growth outside of a laboratory setting. Public comments were solicited as to whether vitamin B1 should be removed or if there are there other benefits attributed to it that necessitates its continued listing as a plant or soil amendment. Specific information was invited regarding its use in the tree fruit industry and if there is a need for vitamin B1 to assist in transplant shock or replant disease issues.

Public comments were received from certifiers, material reviewers, organizations, and farmers supporting the continued listing of the vitamins. In response to the questions posed, stakeholders again noted that there are products in use containing multiple vitamins, particularly in blended fertilizers. There was some concern that the vitamins could be made from excluded methods; however, there are vitamins available from non-GMO sources, and material reviewers can obtain affidavits attesting to that. There was very limited feedback regarding the efficacy and use of vitamin B1, particularly in relation to the tree fruit industry.

The 2015 TR reveals that it is the auxins indole butyric acid (IBA) and naphthylacetic acid (NAA) that "contribute to root regeneration of transplanted trees by suppressing crown growth to effectively redirect resources to developing roots", rather than vitamin B1 (TR lines 102-111). Additionally, multiple studies of vegetable transplants, trees, and flowers concluded that vitamin B1 had no impact on seedling vigor, size, color, or root development (TR lines 111-117). The TR was unable to describe a mode of action for the substance "in the absence of significant *in vivo* results correlating vitamin B1 applications with enhanced root growth" (TR lines 212-219). The TR provides broad reference to alternative substances for Vitamin B1 (TR lines 643-692). There are no OMRI approved brand name crop inputs containing Vitamin B1 in the final product.

The Crops Subcommittee chose to separate the vitamins for voting purposes, as indicated below.

Subcommittee votes:

Motion to remove vitamin B1 from §205.601(j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: incompatible with a system of sustainable agriculture due to its unproven efficacy or need and a lack of essentiality.

Motion by: Emily Oakley
Seconded by: Steve Ela
Yes: 6 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Motion to remove Vitamins C and E from §205.601(j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Emily Oakley
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 3 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:
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.

Public comments received were in favor of keeping lead salts on the list of nonsynthetic substances prohibited for use in organic crop production.

The NOSB recommends keeping lead salts in its prohibited status on the National List.

Subcommittee vote:
Motion to remove lead salts from §205.602 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Francis Thicke
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:
Tobacco dust, nicotine sulfate, has been present on the National List as a prohibited substance since the inception of the USDA organic regulations. This natural product can be used as a pesticide and as 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 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.

Public comments indicated that certifiers, businesses and public interest organizations agree that this product should remain listed as a prohibited nonsynthetic. It was noted by two certifiers and OMRI that this is currently allowed as a natural agricultural product to be incorporated into the soil, while tobacco dust, tea and smoke are prohibited by USDA organic regulations. Clarification had been requested to better draw the line between where it is allowed and where it is prohibited. It was noted that this product is no longer commercially available as a crop pest control product, however it could still be homemade.

The Subcommittee recognizes there are questions as to where to draw the line in respect to the use of tobacco, tobacco dust, smoke, and tea. The Subcommittee is researching the use of various tobacco products as soil amendments, compost feedstocks, etc. in organic agriculture as well as future actions needed, if any, to clarify these allowed or prohibited uses.

The Crops Subcommittee supports keeping tobacco dust on the National List at §205.602.

Subcommittee vote:
Motion to remove tobacco dust from §205.602 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Joelle Mosso
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Fatty Alcohols (Octanol/Decanol mix)
August 1, 2017

Summary of Petition

Green Ag Supply, LLC has petitioned for inclusion of natural fatty alcohols in Section 205.601 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances. The petitioner intends to use this substance as sucker control on organic crops.

Category: Synthetic Substance Allowed for Use in Organic Crop Production
NOP Reference: 205.601 - Synthetic substances allowed for use in organic crop production.
NOP Section: 205.601(k) - As plant growth regulators
Requested Annotation: As a sucker control on organic crops

Rather than filing separate petitions for octanol (C8) and decanol (C10), the petitioner chose to submit a single petition to focus on the blend of C8C10 fatty alcohol since it is the product that is specifically manufactured for use in the end products N-TAC (EPA Reg. No. 51873-20) and O-TAC PLANT CONTACT AGENT (EPA Reg. No. 51873-18). This blend of fatty alcohols is also marketed under the product name ALFOL 810 (EPA Reg. No. 63896-1). The only other registered uses for individual fatty alcohols is the C10 (decanol) and it is not included in this petition. There is no EPA registered use for C8 (octanol) fatty alcohol.

Summary of Review:

Fatty alcohols (Octanol and Decanol) are monohydric aliphatic alcohols containing 8 and 10 carbons respectfully with a single (-OH) group. The Octyl-Decyl alcohol blend refers to a blend of C8 and C10 alcohol (42.6%/56.7%). According to the petitioner, raw material for the alcohols are derived primarily from Palm Kernel Oil and Palm Oil, not synthetic alcohol.

The petitioner proposes to use the fatty alcohol blend for topping and sucker control on organic crops. The Technical Review indicates the specific use of this fatty alcohol substance is to chemically remove flower buds and suckers from tobacco plants. This process prevents seed formation and causes the plant to focus on leaf production. This is important because tobacco sells by weight, so the heavier the leaves, the greater the profit.

There is no reference in the National List for fatty alcohols. The proposal to add fatty alcohols to the National List specifies 7 CFR 205.601 (k) under the heading plant growth regulator. This section of the National List currently describes the use of the synthetic substance ethylene in organic crop production as a plant growth regulator for regulation of pineapple flowering. Fatty alcohols as aqueous emulsions inhibit terminal or axillary bud growth of tobacco plants. Contact with meristematic tissue affects plant development by preventing the growth flower buds and suckers. The EPA only registers products containing fatty alcohols for tobacco sucker control.

EPA has only approved fatty alcohols for use as a growth regulator on tobacco, and the technical review only covered use of fatty alcohols for use on tobacco.

Category 1: Classification

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

   Fatty alcohols can be produced from natural fats from plants or animals, or from petroleum sources. In either case, chemical changes are required to produce fatty alcohols.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   Fatty alcohols do not fall into any of the OFPA categories. Fatty alcohols produced as a mixture of four aliphatic alcohols are not considered inert by the Environmental Protection Agency nor are they included in List 4. Fatty alcohols may be registered with the EPA only for tobacco sucker control. N-decyl alcohol (decanol) and n-octyl alcohol (octanol) are individually approved by the US Food and Drug Administration (FDA) for food and non-food use as solvents or co-solvents.

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?
   There appears to be no known detrimental chemical interactions between fatty alcohols and other materials used in organic farming systems. Mineral oil, cooking oil or paraffin oil are currently the only topping and suckering substances used by organic crop producers and there is no proven adverse impact with these substances.

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 log Kow is an indicator of a chemical's tendency to bioaccumulate. The TR reports log Kow's for octanol and decanol at 3.15 and 4.57 respectively, which are moderately low.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]
   According to the Safer Choice determination of the EPA, 1-decanol, 1-octanol, 1-dodecanol and the C_6-C_{12} alcohols are expected to be of low concern for environmental contamination based on experimental and modeled data. Linear fatty alcohols in general are easily biodegradable. The solubility of fatty alcohols in water decreases with an increasing C-chain length. Fatty alcohols possess only moderate acute toxicity for aquatic organisms. In general, in their range of water solubility no toxic effects are observed.

The fatty alcohols from both natural and manufactured sources represent a low risk for environmental contamination.

4. Discuss the effect of the substance on human health.

   There is no evidence to suggest that the aliphatic alcohols cause increased susceptibility to health problems in infants and children. Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human risks of concern for aliphatic alcohols. TR lines 396 – 399.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   When fatty alcohols are applied to tobacco plants for suckering with a surfactant, an average residue of 1.6 parts per million (ppm) of the applied fatty alcohols and 1.0 ppm of the surfactant remain on the cured leaves. Over 7000 ppm of naturally occurring fatty alcohols are also present in and on the cured leaves. Fatty alcohols induce a low incidence of polynucleate root tip cells or root tip cells with fragmented nuclei. The fatty alcohols are produced naturally, in all living organisms, from bacteria to man, and thus, are widely present throughout the natural world. In any agro-ecosystem, fatty alcohols will be present from natural sources. The introduction of C_6-C_{12} fatty alcohols for topping and suckering may produce short term toxicity to many organisms in the range of 1-100 milligrams/liter, however; because the application rate is intermittent and biodegradability and removal rate are high for this substance no readily observable effects occur in the agroecosystem. TR lines 342-352.

6. Are there any adverse impacts on biodiversity? (§205.200)
   Fatty alcohols are chemicals that naturally occur in all plants and animals. They are known for their high level of biodegradability in the environments. Their derivative products are additionally designed to rapidly degrade after use and are not considered endocrine disrupters.

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)]

   Topping may be done by hand or with special machines that cut the flower heads and sacrifice a few leaves. Topping requires two or three trips over the field to catch all the plants. Suckers can be removed by hand as well as stunted by carefully applying approved soybean oil or mineral oil to the top of the plant. Topping and suckering are the most time-consuming tasks associated with growing organic tobacco, and may be necessary every week for 10 weeks.

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

   No. The Crops Subcommittee does not think that use of a synthetic growth regulator is compatible with a system of sustainable and organic agriculture.

Classification Motion:

Motion to classify fatty alcohols (octanol/decanol mix) as petitioned as synthetic.
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add fatty alcohols (octanol/decanol mix) as petitioned at §205.601(k)(2) for use in organic crop production.
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 16, 2017

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Anaerobic Digestate
August 15, 2017

Summary of Anaerobic Digestate Petition:

Cenergy USA, Inc. submitted a petition "to establish a separate classification for anaerobic digestate on the National list of Allowed and Prohibited Substances". The petition requests that anaerobic digestate fiber, or digestate, produced without synthetic materials, be allowed for use in organic production exclusive of days-to-harvest restrictions following application.

The petition states: "the section for inclusion of substance: §205.600 as plant or soil amendments"; however, the material does not include any synthetic materials and so would not fall under §205.601, Synthetic substances allowed for use in organic crop production. The petition requests that anaerobic digestate materials not be classified as raw manure and therefore not be subject to pre-harvest intervals. If approved, an inclusion of anaerobic digestate would likely involve an amendment to 205.203(c), with a new listing defining a standard for anaerobic digestate.

The petition is for anaerobic digestate derived from plant and animal products in a two stage mixed plug-flow digester. Anaerobic digestate fiber is currently used in horticultural products, crop production, and landscape applications as a soil amendment and fertilizer with the same restrictions required of raw manure, when used in organic production. The fiber is an ingredient in potting soils, is used in fertilizers, and serves as an alternative to peat moss in the commercial greenhouse industry.

In this petition, anaerobic digestate fiber is manufactured by collecting animal manure and/or food scraps in a receiving pit. The petition states: "the waste is collected throughout the day, chopped as needed, and pumped directly into the anaerobic digester vessel". During the first stage of production, the raw waste is mixed and heated to 101 °F. Either reclaimed waste heat or a boiler is used to maintain the digester temperature for the growth of methanogenic bacteria. Waste materials from the first stage gravity flow into the second stage of the vessel. Here "the methanogenic bacteria convert volatile fatty acids and acetic acids produced in the first stage of the anaerobic digestate vessel into a biogas". Heat mixes the material in a rotational motion, and it is held at 101 °F for 21 days. Next the waste flows into an effluent collection pit for additional processing. The liquid and solids are separated, and a fiber of 30-35% solid material is produced.

The petitioner states that digestate is not raw manure or compost, is virtually pathogen free, and therefore should not be restricted. They suggest that the two stage mixed plug-flow anaerobic digester produces a material that is equivalent to OMRI's classification of processed manure (based on NOP Guidance NOP 5006 Processed Animal Manures in Organic Crop Production). While this classification specifies a minimum temperature of 150 °F for at least one hour and maximum moisture content of 12%, the petitioner proposes that these temperature, duration, and drying criteria are unnecessary for pathogen kill when using their digestion process.

Summary of Review:

The NOP first sent the petition to the Materials Subcommittee before making an eligibility determination. In agreement with the NOP, the MS determined that the petition should be sent to the Crops Subcommittee for review.

The CS requested a comprehensive technical review (TR) for all anaerobic digestate system technologies and feedstocks and posed the following supplemental questions:

1. Define anaerobic digestion (AD) and its end products.
2. Describe commercially available AD technologies and how the different technologies affect the end products.
3. Discuss differences between anaerobic digestate products and compost.
4. Provide a summary of all the methods in use for creating this material, with feedstocks, ingredients, and end products. The TR should also describe any materials (e.g., acids, bases, microorganisms, etc.) typically added during the anaerobic digestion process, and discuss the fate of these additives (e.g., if they are used up, removed, or contribute to the nutrient profile for the end product).
5. Explain a typical nutrient cycle for the feedstocks into end products from these processes, focusing on nitrogen.
6. Describe available data concerning pathogen (e.g., E. coli, Salmonella) control using anaerobic digestion and describe documented microbiological risks from use of AD products.

The TR provides a broad review of anaerobic digestate, looking at Plug Flow, Complete Mix, the Chinese Dome Digester, and the Indian Gobar System in addition to the Two Stage Mixed-Plug Flow method. It examined only the digestate fiber, not the liquid that is also an end product. There is broad variability in the physical and chemical properties of digestate fiber depending upon the feedstocks and fermentation process. The three products of anaerobic digestion are biogas, digestate fiber, and liquid (also referred to as the liquor).

According to the TR, “anaerobic digestate is best characterized as friable, flocculated organic matter” (LINES 96). “Application of AD recycles nutrients in a way that is similar to the application of raw manure and compost. However, a review of the literature indicates that the nitrogen in AD will have higher levels of ammonium (NH_4^+-N) nitrogen” (TR LINES 136-138). “Sulfur amino acid decomposition under reducing conditions—such as in the absence of oxygen—increases the production of hydrogen sulfide gas, which is usually vented with the biogas unless it is precipitated prior to release. More research would be needed to investigate how the soil sulfur cycle is changed by anaerobic digestion technologies, and whether the reduced forms of sulfur from AD have an impact on plant availability and soil microorganisms” (TR LINES 185-189).

“While the anaerobic digestion process can take place without chemical additives, various substances are used to pre-treat the feedstocks, adjust the substrate during the digestion process, and treat the finished AD. Various other ingredients may be blended with the feedstocks before or injected during the digestion process, which may include acids and bases to adjust the pH, surfactants to dissolve and separate fatty acids, and sequestrants and chelating agents to precipitate and remove toxic metals. The fate of these various additives would depend on how they are partitioned when the digestate is removed. At least some can be reasonably expected to remain in either the digestate or the liquor. While it is possible to make some predictions about the likely fate of the additives based on their structure, function and activity, these predictions would need to be empirically tested by third-party peer-reviewed studies to see if these predictions are scientifically valid. Such studies are not available in the literature” (TR LINES 412-421).

“Adsorbents and surfactants may also be added to remove the scum from the liquor, both during the wastewater pretreatment process as well as after the gas is vented and the effluent is released. Some surfactants, such as sodium lauryl sulfate, polyethylene sorbatan fatty acids (Tween), and polydimethyl siloxane polyethers (Tegoprens) may accelerate digestion and increase the methane yield (Madamwar, Patel, and Patel 1991; Madamwar et al. 1992). Others, such as the alkyl sulfonates, appear to inhibit some of the organisms responsible for the digestion process and lower the methane yield (Hobson and Wheatley

1993). Some commercial sources of AD will add nitrification inhibitors. Most of these are proprietary products, and the active substances are trade secrets" (TR LINES 199-208).

Because this petition is for manure that does not meet the compost practice standard in 205.203(c)(2) and is requesting an exemption to the raw manure application practice standard in 205.203(c)(1), it is helpful to review some history for these two standards. The Preamble to the Final Rule published in 2000 (65 FR 80547) addresses the issues surrounding applications of manure that were discussed during the rulemaking process. The 120-day interval for crops in contact with the soil and the 90-interval for other food crops were both supported by the NOSB. It explains on page 80567 that "commenters stated that the lengthy intervals between application and harvest would not impose an unreasonable or unfeasible burden on organic producers". Additionally, "other commenters stated that the provisions were consistent with the requirements in existing organic standards and added that the restrictions were justifiable because they reflected responsible management practices".

In 2010, the NOP published Guidance 5006 Processed Animal Manures in Organic Crop Production. It specifies guidelines for manure treatment to reduce pathogens that allow for such products to be applied without a pre-harvest interval.

Some manufacturers subsequently inquired if their manure treatment methods not specified in NOP 5006 could be viewed similarly. On May 9, 2016, the NOP sent a Memorandum to the NOSB on Guidance for Treated Manure Products. The memo notes, "Stakeholders have … asked AMS to clarify if anaerobic digestate made with manure as a feedstock requires an application interval". The memo goes on to request that the NOSB "evaluate if the prescribed application intervals apply when these products are used". This proposal seeks to provide clarification on this request.

In addition to anaerobic digestate, other manufacturers employ heat without drying or a moisture reduction process without heating to treat manure. NOP 5006 requests that the CS also evaluate these treatment processes to determine if they should be allowed without a preharvest interval. Following the adoption of the Food Modernization Safety Act, the Food and Drug Administration (FDA) undertook a risk assessment of produce grown with manure. The CS is awaiting the outcome of the FDA's assessment and will then determine how to evaluate these other manure treatment methods as a separate work agenda item.

Category 1: Classification

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

   No; the TR is not asking for a digestate listing using any synthetic materials.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No. The substance is not being petitioned as a synthetic, and these categories only apply to synthetic substances.

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.

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)]

   Heavy metals and other chemical contaminants may be present in digestate fiber. According to the TR, “the metal contaminants of greater concern in livestock systems are copper and zinc” (LINES 616-617), as would also be the case when such manure is used raw in field applications or as an ingredient in compost. Other chemical contaminants may include phthalates from degraded plastics and pesticides (TR lines 622-623).

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

   Digestate is often made using manure from concentrated animal feeding operations (CAFOs), and as noted above, it is also sometimes used in raw manure field applications or as an ingredient in compost. “CAFOs are a significant source of environmental pollution and pose risks related to water contamination, greenhouse gas emissions, aerosol pollutants, heavy metal contamination, and farm chemicals such as pesticides, antibiotics, and growth hormones. Manure is also a vector for human and animal pathogens” (TR LINE 667-670).

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

   “The principal human health concern from AD is food-borne pathogens” (TR LINE 791). “Several peer-reviewed papers document that foodborne pathogens commonly survive the anaerobic digestion process, as summarized in Table 2. In particular, spore-forming pathogens are the most likely to remain viable after the anaerobic digestion process (Franke-Whittle and Insam 2013; Nkoa 2014)” (TR LINES 797-799).

   “While the anaerobic digestion process is documented to reduce certain pathogens, anaerobic conditions pose a different set of foodborne pathogen risks than would be found under aerobic conditions. Field validation of treatment processes is needed to verify that pathogens are not able to survive the anaerobic digestion process and migrate onto harvestable plant parts (Gerba and Smith 2005). That is because several pathogens are able to survive or at least remain viable after the anaerobic digestion process, but would be unlikely to survive aerobic composting. The indicator species used for aerobic compost, *E. coli* and *Salmonella* spp. may not be appropriate for anaerobic conditions. The indicator pathogens used for quality assurance of digested residues in Denmark are *Salmonellae*, *Listeria*, *Campylobacter* and *Yersinia* (Sahlström 2003)” (TR LINES 804-813).

Digestate fiber made from agricultural feedstock may be contaminated with *Listeria monocytogenes* as well as other common foodborne pathogens mentioned above (TR LINES 820-821, 824-831). *Clostridium perfringens* was not reduced in anaerobic digestion in several cases (TR LINE 830).

“Another foodborne pathogen of concern with AD is *Campylobacter jejuni.* While *Campylobacter* is a microaerophile, meaning that it requires some oxygen, it also thrives in oxygen-poor conditions. Anaerobic digestion was found to have little effect on *Campylobacter jejuni* populations after 112 days of digestion (Kearney, Larkin, and Levett 1993)” (TR LINES 833-836).

“*Bacillus anthracis*, the vector responsible for anthrax, was observed to survive anaerobic digestion of slaughterhouse wastes (Franke-Whittle and Insam 2013). The organism can be grown in either aerobic or anaerobic conditions, and also forms spores that can remain viable after thermophilic temperatures (J. E. Olsen and Larsen 1987). Prions, the vectors that transmit bovine spongiform encephalopathy (BSE), are not considered to be adequately digested in the fermentation process (Franke-Whittle and Insam 2013)” (TR LINES 844-850).

“The petition claims that the pathogen reduction in plant and animal materials properly processed in a two stage mixed plug-flow anaerobic digester produced an equivalent heating process to aerobic composting as specified in the NOP regulations at §205.203(c)(2) (Joblin 2016). The petition requests that such AD not be subject to a days-to-harvest interval after application. Laboratory analyses were included in the petition, but the sampling methodology was not described. The results were not peer-reviewed. While AD is not raw manure, it is not aerobically composted. The temperature reported in the petition is 38°C (101°F) (Joblin 2016). This is in the mesophilic range and below the temperature of 131°F specified in the NOP regulations for composting manure at §205.203(c)(2)” (TR LINES 854-861). In the production of anaerobic digestate from sewage sludge, the EPA requires that the material go through aerobic composting under the same conditions stipulated in §205.203(c)(2), a process to further reduce pathogens (PFRP). Aerobic composting of the digestate is a process to significantly reduce pathogens (PSRP) (TR LINES 918-924).

“The carbon-to-nitrogen ratio for the system is not specified. The patent does not make a pathogen reduction claim or provide any evidence that the system reduces foodborne pathogens equivalent to aerobic composting (Dvorak 2012) (TR LINES 861-863). The petition does not address risks/fates of anaerobic pathogens that may be present following the anaerobic digestion process that may not be relevant to those normally studied in aerobic composting. “No peer-reviewed studies were found to support that the petitioned PFRP was effective to a degree equivalent to the aerobic composting requirements for livestock manure specified in the NOP regulations at §205.203(c)(2). Independent research to determine whether the process is equivalent would require original research and third party review of the findings and is beyond the scope of this report” (TR LINES 863-867).

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)]

   As a source of organic matter, digestate fiber is generally beneficial to soil health; however, the salt content may be higher than in compost (TR LINES 729-730).

"The majority of trials with agronomic and vegetable crops show that AD is beneficial for plant growth, at least compared with mineral (chemical) fertilizer and with no fertilizer; there were some contrary results in a review of the literature (Möller and Müller 2012). In situations where yields were reduced and quality degraded by the AD treatment, there was evidence that the amendment was phytotoxic. Germination has been negatively correlated with ammonia nitrogen, fatty acids, and volatile organic acids, suggesting these constituents in AD may be harmful to crops when applied in excess (Poggi-Varaldo et al. 1999; Walker, Charles, and Cord-Ruwisch 2009; Prays and Kaupenjohann 2016)" (TR LINES 738-744).

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

   Depending on the source of the materials for the feedstock, there may be a detrimental impact on overall biodiversity. For example, "with systems that produce biofuel co-products, the continuous production of corn (maize) has led to a loss of biodiversity. In these cases, the solid biomass left after the fermentation of corn to make bioethanol is anaerobically digested to produce biogas, frequently co-digested with pig slurry collected from CAFOs. The anaerobic digestate is returned to the corn fields. The ecological efficiency of such a system has been questioned (Svoboda et al. 2015). Efforts to find alternative biofuel crops that increase biodiversity and reduce dependence on fossil fuel inputs have had limited success (Mast et al. 2014)" (TR LINES 746-751).

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)]

   Organic producers employ a wide range of practices to foster soil health and fertility, including cover cropping, incorporating crop residue, crop rotation, and conservation and no-tillage techniques. There are numerous alternative materials to digestate fiber, including "compost, vermicompost, raw manure, heat-treated and processed manure, mulches, and organic fertilizers such as blood meal, bone meal, fish meal, soybean meal, alfalfa meal and cottonseed meal" (TR lines 876-878). In addition, anaerobic digestate may currently be used in organic production as an ingredient in compost or as a manure subject to the required preharvest intervals required of raw manure inputs in §205.203.

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

   Because of the potential for negative effects on human health through food-borne pathogen, the unproven safety of digestate fiber, and the many alternative practices and materials already in use in organic production, this substance as petitioned without preharvest application intervals is not compatible with a system of sustainable agriculture.

Classification Motion:

Motion to classify anaerobic digestate produced from nonsynthetic feedstocks as nonsynthetic
Motion by: Emily Oakley
Seconded by: Harriet Behar
Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion to amend section 205.203(c) as follows:

§205.203 Soil fertility and crop nutrient management practice standard.

* * * * *

(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. Animal and plant materials include:

(1) Raw animal manure, which must be composted **<u>or undergo an anaerobic digestion process</u>** unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced though a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

<u>(4) Anaerobic digestion products that have been processed to reduce pathogens.</u>

Motion by: Emily Oakley
Seconded by: Steve Ela
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 29, 2017

National Organic Standards Board
Crops Subcommittee Proposal
Strengthening the Organic Seed Guidance
August 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 which 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[1] and 2008[2] 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 the guidance was 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 it seems like a good time for the NOSB to re-visit the important topic of organic seed.

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[1] https://www.ams.usda.gov/sites/default/files/media/NOP%20Rec%20Commercial%20Availability%20of%20Organic%20Seed.pdf

[2] https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Seed%20Commercial%20Availability.pdf

Relevant Areas of the Rule and Guidance

From the USDA organic regulations:

§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 (OSP). 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 briefly will be if a rule change might be appropriate to consider for some of these issues.

<u>A. Crops at risk from GMO contamination might need to be acknowledged, emphasized and have additional requirements for sourcing seeds.</u>

The NOSB has worked for almost four years on trying to assure 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 guidance does not even mention this subject is of concern to many stakeholders.

Commenters provided good 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 looking in a more general way of several possible places where seed purity from excluded methods could be brought up in the structure of NOP 5029.

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 have 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. (Language in italics is proposed new language).*

iii. An alternative idea to this specific addition in number ii would be to add a section 4.1.7 which specifies that non-organic seed must be produced without excluded methods. While both these ideas are good, the first one of amending 4.1.2 is cleaner and where the authors are leaning at this time.

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 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 CS 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) 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 on 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 guidance. However much of the discussion section above about OSP goals applies here. Nowhere in the NOP regulations are there statements that mandate 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 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 be 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 what sufficient improvement would be, either as percent increase in acreage per year planted to organic seed, increased sourcing efforts, etc.

D. Documentation of quality, quantity and equivalent variety

Working within the existing meaning of a practice standard still leaves room for increased efforts on the part of producers to source organic seed and increased 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 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 not just explanations of what form, quality and quantity meant, but more explicit guidance on what would not be allowed. It is not totally 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:

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:

a. 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 truly determine equivalence and quality of other organic varieties. Many growers perform variety trails, 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 were 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 to change this was to require five sources, with other ideas being to limit 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 than 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 revision of §4.2.1(b)(1) (changes in <u>*underlined italics*</u>):
1. Evidence of efforts made to source organic seed, including

    <u>*a.*</u> documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. <u>*Five sources must be contacted for seed of at-risk crops.*</u>

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

    <u>*c. Failure to demonstrate improvement in sourcing organic seed over time may result in additional seed sources being required or additional steps taken to procure organic seed.*</u>

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 from this is that the Role of Certifying Agents, as described in section 4.4 of NOP 5029, is not doing a complete job or is not being followed carefully enough. Much of this issue is training for ACAs rather than changing section 4.4, but if it were possible to put some specific language about what constitutes non-compliance, the ACAs would really appreciate it.

viii. §4.4.4 is the statement that justifies asking for progress in obtaining organic seeds compared to previous years and 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
<u>*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.*</u>

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 (NOP 5029-1):

> **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 NOSB 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 as way so 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 for that crop. 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 both hold trainings tailored for their audiences, at a minimum 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 this 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 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 must be demonstrated every year until full compliance with (a) is achieved.

2. Changes to NOP 5029 Guidance (Section 4)
The Guidance for Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production should be amended as follows:

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, Annual Seedlings, and Planting Stock

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 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.
>
> 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.*
>>
>> *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 specific varieties sourced every year.*
>>
>> *iii. Failure to demonstrate improvement in sourcing organic seed over time may result in additional seed sources being required or additional steps taken to procure organic seed.*

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.

Subcommittee Vote:
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: Harriet Behar
Seconded by: Emily Oakley
Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 29, 2017

National Organic Standards Board
Crops Subcommittee Proposal
Hydroponics and Container-Growing Recommendations
August 29, 2017

Introduction

Over the past year the Crops Subcommittee has prepared—and received many public comments on—two discussion documents and a proposal covering the range of growing systems in which nutrient delivery to plants is water based, including aeroponics, hydroponics, aquaponics, and plants grown in containers. We have learned that the public is divided on these issues, as are members of the NOSB. Some think that organic certification should require plants be grown in soil that is connected to the earth's surface. Others think that organic certification should allow the growing of plants in pure nutrient solution, without the presence of any soil or compost. Others favor positions somewhere in between.

Accredited organic certification agencies have been permitted to certify hydroponic operations as organic by the National Organic Program (NOP), with some agencies certifying hydroponic operations and some choosing not to. The lack of consistency among certifying agencies and lack of standards for water-based nutrient-delivery growing systems 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.

The purpose of this proposal is to delineate the range of growing systems, from soil to soilless, and make recommendations on a middle ground within that range, which we hope the NOSB and the organic community can support. To do that, we first summarize pertinent past discussions and legal considerations.

Background

The 1995 NOSB recommendation *Standards for Greenhouses* contains the statement:

> Hydroponic production in soilless media to be labeled organically produced shall be allowed if all provisions of the OFPA have been met.

This was before there was an NOP rule so the NOSB only had OFPA to guide them. Also, that statement indicated that an analysis had not been made of whether or not hydroponics met the provisions of OFPA. The brief dialogue at the 1995 meeting indicates that while some board members were supportive of hydroponics, others had concerns about soilless production:

> Kahn concluded his report by reading the hydroponics recommendation that would allow organic labeling for products from soilless media if all other National Program requirements are satisfied. Baker expressed his concerns about the philosophical problems associated with soilless production. Kahn noted that the recommendation only allows for the possibility of an organic hydroponics industry developing. Kahn recognized that hydroponics is a practice that is dependent on synthetic inputs and wants to open up dialogue with its proponents. Crossley moved and Weakley seconded a motion to accept lines 101-105 as a Board Final Recommendation. Friedman first offered a friendly amendment that was accepted to strike "other applicable" from the document. Vote: Unanimous aye.[1]

A revised proposed rule for the National Organic Program was published in March 2000 revising the initial

[1] NOSB Meeting Minutes - April 24-28, 1995. Orlando, Florida.

proposed rule published in December 1997. In the supplemental information, the following was stated:

> (13) We have amended the term, "system of organic farming and handling," to "system of organic production and handling" and retained the original definition in this proposal. The original definition was crafted to be consistent with the requirements of the Act. We have changed "farming" to "production" to provide a more encompassing term, which may come to include such diverse activities as hydroponics, green house production, and harvesting of aquatic animals. The purpose of the original definition was to describe practices and substances consistent with systems of organic farming and organic handling as required by the Act and to provide an explicit reference point for determining which practices and substances are most consistent with these systems. Several commenters suggested that the definition include the concepts, "agroecosystem health," "ecological harmony," and "biological diversity." Commenters also suggested including definitions for "organic agriculture," "organic farming," and "transition to organic." This definition is intended to clarify regulatory provisions in this proposal and is not intended as a broad philosophical statement. The terms "organic agriculture," "organic farming," and "transition to organic," are not used in this proposal and, therefore, are not defined[2]

The final rule for the National Organic Program was published in December 2000 (65 FR 80547). In the supplemental information, the following was stated:

> The proposed rule treated mined substances of high solubility as a single category of soil amendment and allowed their use where warranted by soil and crop tissue testing. Many commenters objected to the general allowance for this category of substances and were particularly disappointed that the NOSB annotations on two such materials, sodium (Chilean) nitrate and potassium chloride, were not included. Commenters cited the potential detrimental effects of these highly soluble and saline substances on soil quality and stated that several international organic certification programs severely prescribe or prohibit their use. One certifying agent recommended that natural substances of high solubility and salinity be handled comparably to similar synthetic materials such as liquid fish products and humic acids that appear on the National List, complete with their original NOSB annotations.
>
> At its June 2000 meeting, the NOSB recommended that the NOP delete general references to mined substances of high solubility from the final rule, and incorporate the NOSB's specific annotations for materials of this nature. We have adopted this recommendation by retaining a place for mined substances of high solubility in the soil fertility and crop nutrient management practice standard but restricting their use to the conditions established for the material as specified on the National List of prohibited natural substances. Under this approach, mined substances of high solubility are prohibited unless used in accordance with the annotation recommended by the NOSB and added by the Secretary to the National List.[3]

At the Spring 2002 Meeting the NOSB Crops Subcommittee brought forward a new proposal on hydroponics stating:

> Hydroponic production in soilless media shall be allowed if all other provisions of the Organic Food Production Act and NOP final rule have been met. However, the Crop Committee recommends that the principles of organic production as presented by the NOSB Board be met by any certified

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[2] Federal Register Volume 65 Number 49. Page 13521. Docket Number: TMD-00-02-PR2, RIN 0581-AA40. National Organic Program Proposed Rule. Agricultural Marketing Service, USDA. March 13, 2000

[3] Federal Register Volume 65 Number 246. Page 80565. Docket Number: TMD-00-02-FR, RIN 0581-AA40. National Organic Program Final Rule. Agricultural Marketing Service, USDA. December 21, 2000

organic hydroponic system.

> We recognize it will be a challenge for many hydroponic operations to meet some of the principles, that is, promoting biological cycles, recycling materials, minimizing use of non-reusable resources, et cetera. And we recommend that hydroponic operations that do not meet such principles be denied organic certification.

Discussion went on to note that this proposal followed recommendations made on greenhouse management, which allowed for waivers of certain NOP requirements. It was further noted that the intent of the proposal was to allow hydroponics if they meet all parts of OFPA/NOP other than soil requirements. Board members debated this motion and some questioned if exempting operations from soil was consistent with organic principles. Input was sought from the program if hydroponics were allowed under the NOP as currently written:

> MR. BANDELE: Rick, maybe it would be helpful to get a clarification on, is hydroponics already covered?
>
> MR. MATHEWS [NOP Program Manager]: The policy statement that is on the Web with regard to the scope of the National Organic Standards includes hydroponics.[2]

After input from the program, the board decided to table the matter stating:

> Hydroponic -- based on a discussion yesterday, the crops committee will reconsider that it was pointed out by Rick that hydroponics is already covered as far as the existing rule is concerned. So what the crops committee will do is try to provide some -- a guidance document… to the hydroponic situation at a later date.[4]

At the October 2002 meeting there was some discussion of hydroponics being on the Crops agenda but no additional information.[5] At the May 2003 NOSB meeting a draft discussion document about hydroponic and soilless production techniques and questions was circulated and at the meeting the following statement was recorded in the minutes:

> Draft guidance document regarding certification of hydroponics and other soil-less production systems. The draft will be forwarded to the strategic planning committee and NOP for feedback and to determine if further work on the document is a priority.[6]

The topic of hydroponics was next discussed at the October 2004 meeting. In the context of a draft NOP scope document, the policy sub-committee stated the following:

> [In regards to the scope document] …the sixth area, which was mushrooms, apiculture and honey, greenhouse operations and greenhouse products, hydroponic agriculture; these are areas that the NOSB has had -- has addressed. These products from the April directive, the products may be certified to the existing NOP regulations which will be amended in future rulemaking to cover any unique production and handling requirements. NOSB has provided recommendations and the NOP is saying they'll publish at the earliest possible date through notice and comment rulemaking any additional standards needed for these commodities. So the Policy Development Committee recommends that the NOSB agree with the NOP for a position that mushrooms, apiculture and greenhouse operations can be certified organic and the products, as such, can be labeled as organic and carry the USDA Organic logo. We point out that the NOSB adopted the support of an April 25, 1995 greenhouse recommendation, a section entitled "Specialized Standards for Hydroponic Production in Soil-less Media" and that their recommendations stated, "Hydroponic production and

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[4] NOSB Meeting Transcripts – May 6-8, 2002. Austin, Texas

[5] NOSB Meeting Minutes – October 19-20 2002. Washington DC

[6] NOSB Meeting Minutes – May 13-14 2003. Austin, Texas

> soil-less media to be labeled organically produced shall be allowed if all provisions of OFPA have been met." And though the issue has been discussed, the NOSB has not yet submitted a recommendation on hydroponic standards since a Final Rule was released, so we request that the Crops Committee place the item on its work plan and that rulemaking standards should not proceed until the NOSB has submitted a final recommendation.

Furthermore, during an exchange between Barbara Robinson (Agricultural Marketing Service Deputy Administrator) and a board member, the following was said:

> MR. BANDELE: I just have a kind of related question in terms of the -- just a point of clarification. Like something like hydroponics, which is -- can be covered by the rule but in which no guidance has yet been given, than at this point a USDA accredited certifier could certify an operation that's organic. Is that right?
>
> MS. ROBINSON: Yes. Yes. We believe that hydroponics are covered under the standards. They fall under the crop standards. But we recognize that, you know, there may be additional details that need to be added to the standards.[7]

Hydroponics was not discussed again until the August 2005 meeting and only to say there was no update[8]. At the November 2005 meeting hydroponics was discussed again with frustration being expressed over this being a work agenda item for multiple years with no progress. It was noted that hydroponic operations were being currently certified organic and the next steps would be to survey certifiers on how they were meeting the regulations.[9] At the April 2006 NOSB meeting the following update was given:

> Hydroponics is still on the list. Gather information and fact-finding on how and if hydroponics should have or could have standards, organic standards.

At the October 2006 meeting the NOSB discussed potential issues with hydroponics and OFPA around soilless production and aquatic plants. A survey of certifiers was proposed by the Crops Subcommittee.[10] In March 2007 the NOSB approved recommendations for aquaculture standards that included aquatic plants. As part of this recommendation the following definition was proposed:

> Aquatic plant. Any plant grown in an aquaculture facility, including microscopic or macroscopic algae, and excluding vascular aquatic plants such as watercress, rice, water hyacinth, and hydroponically produced vascular plant crops."

Additionally, the following was proposed regarding aquaculture effluent:

> (2) Metabolic products of aquaculture species are not considered animal manure under §205.2 Terms Defined, Manure, and § 205.239 (c) Livestock Living Conditions.
>
> (3) Metabolic products of one species are recognized as organic resources for one or more other species in an aquaculture production system. The Organic System Plan of facilities producing aquatic animals must consider measures to recycle or biologically process metabolic products. Where feasible, the Organic System plan must include the polyculture of two or more different species grown in the same body of water, and the integration of additional species as water moves through the aquaculture facility or into adjoining discharge areas.
>
> (4) The feasibility of using water discharges and filtered metabolic products as nutrients for vascular plants in agricultural crops and constructed wetlands must be considered in Organic System Plans.

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[7] NOSB Meeting Transcripts – October 12-14, 2004. Washington DC
[8] NOSB Meeting Transcripts – August 15-17 2005. Washington DC
[9] NOSB Meeting Transcripts – November 16-17 2005. Washington DC
[10] NOSB Meeting Transcripts – October 17-19 2006. Arlington, Virginia.

> The quantities of such discharges and filtered products applied shall not exceed the requirements of targeted plants in the receiving area, and shall not be discharged into unplanned areas. Vascular agriculture crops using nutrients from certified organic aquaculture operations may be certified organic if in compliance with other regulations in this Subpart.[11]

At the May 2009 board meeting the Crop Subcommittee brought forward a discussion document on hydroponic production systems. This document generated substantial public comment and board debate about the compatibility of hydroponics with organic principles.[12] At the November 2009 NOSB meeting, Barbara Robinson (Deputy Administrator Transportation and Marketing Programs USDA) talking in the context of Canadian Equivalence stated the following:

> I told Canada that although we do not specifically prohibit hydroponic production, that it was my understanding that we don't approve hydroponic what I referred to as crops in a bucket in this country.[13]

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.

In 2010, the NOSB issued a recommendation entitled *Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses).* The recommendation contained the following statements:

> 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 <u>cannot</u> 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.

And,

> Although the regulations do not specifically state 'soil only production', the exclusion of soil from organic production of normally terrestrial, vascular plants violates the intent of the regulations.

In the May 2014 Organic Integrity Quarterly the following was stated about hydroponic operations:

> Organic hydroponics is a method of growing plants using mineral nutrient solutions, in water, without soil. Terrestrial plants may be grown with their roots in the mineral nutrient solution only or in an inert medium, such as perlite, gravel, biochar, or coconut husk…Organic hydroponic production is allowed as long as the producer can demonstrate compliance with the USDA organic regulations…Accredited certifying agents are certifying organic hydroponic operations based on the

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[11] NOSB Recommendation on Aquaculture Standards – March 29, 2007
[12] NOSB Meeting Transcripts - May 4-6, 2009. Washington DC
[13] NOSB Meeting Transcripts - November 3-5, 2009. Washington DC

> current organic regulations and the operation's Organic System Plan. In the future, the NOP may provide additional guidance regarding organic hydroponic production and how the regulations apply to such methods…The NOSB's 2010 recommendation included a provision for not allowing organic hydroponic production. The NOP continues to work on evaluating and implementing a backlog of older NOSB recommendations including the greenhouse recommendation.[14]

In 2015, the NOP established a Hydroponic and Aquaponic Task Force to further explore this issue and summarize their findings in order to provide additional information to guide the NOSB's deliberations on whether hydroponic and aquaponic production should be allowed under the current organic regulations, and if not, how the regulations could or should be changed. At the April 2015 NOSB meeting Miles McEvoy, Deputy Administrator of the NOP, stated the following about the 2010 recommendation:

> …in order for us to do something to not allow organic hydroponics, we would have to do a rule change, which is, as you know, quite challenging… So, in order to move this topic forward, we did not have enough information from the NOSB 2010 recommendation to do a proposed rulemaking to prohibit organic hydroponics. We need more information to be successful.[15]

The NOP Task Force report was completed in July 2016[16]. The Task Force was divided in their discussions and recommendations, so much so that the Task Force report was divided into two separate subcommittee reports, one named the "2010 NOSB Recommendation Subcommittee," which proposed that organic certification require that plants get all or most of their nutrition from soil or compost, and one named the "Hydroponic and Aquaponic Subcommittee," which favored allowing water-based nutrient delivery systems in organic certification. A third subcommittee of the Task Force explored options for labeling of hydroponic and container-based systems.

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[17] (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 failed by a vote of two in favor and five opposed to allowing "bioponic."

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, making the vote meaningless. Therefore, the NOSB did not vote on the proposal

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[14] Organic Integrity Quarterly, May 2014, page 13 "Organic Hydroponics"
[15] NOSB Meeting Transcripts – April 27-30, 2015. San Diego, California
[16] Hydroponic and Aquaponic Task Force Report, July 2016
[17] 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, aquaponics, and container growing used in this proposal.

but instead 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.
>
> In the case of the hydroponic/bioponic/aquaponic issue, it is the consensus[18] 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.

For the Spring 2017 meeting, the Crops Subcommittee prepared a discussion document titled “Aeroponics/Hydroponics/Aquaponics,” which solicited additional public input on these types of growing systems as well as container-based growing systems.

Relevant areas in the Rule

<u>Organic Foods Production Act of 1990 (OFPA)</u>

§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

[18] 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.”

(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.

USDA Organic Regulations

§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;

Discussion

This discussion section provides background information in support of the voting motions that follow. Arguments in favor of allowing hydroponic systems to be certified organic are in a minority view at the end of this document.

The role of the NOSB centers on making recommendations that underpin the integrity of the USDA organic label. Consumers entrust the NOSB with the important role of critically assessing what constitutes organic production and processing. The NOSB understands that many production systems and brand labeling exist outside of the organic label; however, our role is as gatekeepers of the organic label. As such, it is our responsibility to recommend production practices that uphold the integrity of the USDA organic seal, that are built on the primacy of soil stewardship, that are managed to emulate ecological processes of productive ecosystems, that support and enhance biodiversity, and that minimize to the extent possible the downside effects of farming while at the same time producing safe, nutritious, and tasty foods.

The organic designation, with its roots in the teachings of Sir Albert Howard, is based on soil. This fact is evident throughout the *Organic Foods Production Act* (OFPA). Section 6513 of the Organic Plan under the Crop Production section begins with Soil Fertility, detailing the critical role that managing organic matter plays in the plan, then finishes (section (G)) stating "an organic plan shall not include any production or handling practices that are inconsistent with this chapter". There are a number of other reasons not to include hydroponic agriculture within the organic designation.

Field-grown plants are physiologically different from hydroponically grown plants for a number of reasons. Hydroponic, greenhouse plants are not stressed the way field-grown plants are. Secondary plant metabolites, for example, frequently increase in concentration in stressed plants.[19] Secondary plant metabolites have also been found to be higher in organic crops than conventional, in soil-based systems.[20]

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[19] Ramakrishna, A. and Ravishandar, G.A., 2011. Influence of abiotic stress factors on secondary metabolites in plants. Plant Signal Behav. 2011 Nov 1; 6(11): 1720–173.

[20] Benbrook, C.M., 2005. Elevating antioxidant levels in food through organic farming and food processing. An Organic Center State of Science Review. https://www.organic-center.org/reportfiles/Antioxidant_SSR.pdf

Field-grown plants will also be symbiotic with sets of microbial communities that are distinct from those found in hydroponically grown plants, and there are many consequences of this. The endophytic fungi living in stems and leaves will also be very different in hydroponic container-grown and field-grown plants. These fungi influence a number of physiological variables including secondary metabolism, with consequences for flavor and nutrition.

In addition to bypassing naturally occurring, co-evolved relationships between plant roots and the many functional trait types of rhizospheric organisms, nutrient bathing is an unbuffered system. For example, nutrient solutions contain high concentrations of nitrate, which plants can accumulate beyond their requirement, storing excess nitrate in leaf (and root) vacuoles. This is particularly problematic for some species like spinach and chard. Nitrate is toxic in food, has been linked to stomach cancer, and can kill livestock. Meta-analyses have shown that organically produced produce has lower nitrate levels than conventionally grown produce, an example of a clearly documented health benefit of organic production. Nitrogen regimes in organic systems are slow release, making them more synchronized with plant demand, which is better for the environment (less leaching and volatilization) as well as better for consumers. The problem with solution culture in this context is that N and P regimes are orders of magnitude more concentrated than those found in soil solution which is naturally highly buffered (meaning only a fraction of the nutrients that exist in the soil are available at any one time). Nutrient solutions are unbuffered, so high N and P concentrations are needed, which could result in unnatural and (in the case of N) problematic mineral nutrient accumulation. High P regimes will also reduce phytoavailability of Fe and Zn, two nutrients deficient in many human diets.

An added concern about the difference between a buffered soil--where nutrients are built up over a long period of time with the bulk of the mineral nutrition coming from manure, crop rotation, cover cropping, compost, and nutrient capture from rainwater--is that for a number of hydroponic systems, the principle source of fertility comes from highly soluble sources such as hydrolyzed soybean meal. Today, approximately 95% of the soybeans grown in the U.S. are genetically modified, using molecular methods prohibited by the NOP. The engineered trait used in GM soybean has brought about a dramatic rise in herbicide use on the backs of the so-called *transgene facilitated herbicide treadmill* (Mortensen et al. 2012).[21] Hydroponic growers who use hydrolyzed soybean meal have indicated that they source it from Europe, to avoid GMO soybean meal. Are the environmental costs of importing this nutrient factored into the claimed environmental benefits of hydroponic production?

In a 2015 paper purporting to be “the first quantitative comparison of conventional and hydroponic produce production” (Barbosa et al. 2015),[22] the authors compared the yield, water use efficiency, and energy use efficiency of the two production systems. The paper contained some misleading assumptions about the yield of the two systems. Specifically, the paper concludes that lettuce yield would be 11 times higher in the hydroponic production system. Only at the end of the paper is it clarified that the analysis is built on the assumption that lettuce is grown year round in the hydroponic system while “warm season crops” would be grown in the field, and the analysis only compared lettuce production and not those additional warm season crops. In effect, the paper far understates the yield of the “conventional, soil grown” crops. However, the energy required to produce the crops compared across the hydroponic and soil grown systems is revealing. The paper concludes that the pumps, heating and cooling, filtration, lighting

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[21] Mortensen, D.A., Egan, J.F., Maxwell, B.D., Ryan, M.R., and R.G. Smith, 2012. Navigating a critical juncture for sustainable weed management. Bioscience Volume 62:1. pp75-84.
[22] Barbosa, G.L., Gadelha, F.D., Kublik, N., Proctor, A. Reichelm, L. Weissinger, E. Wohlleb, G.M. and R.U. Halden, 2015. Comparison of land, water, and energy requirements of lettuce grown using hydroponic vs. conventional agricultural methods. Int. J. Environ. Res. Public Health **2015**, 12(6), 6879-6891

etc. would result in an approximately 100-fold increase in energy use per unit of lettuce produced. By the author's own admission, energy analyses of this kind are surprisingly rare.

In a study of indoor *Cannabis* production, Mills (2012)[23] found that energy consumption for this practice in the United States is 1% of national electricity use, or $6 billion each year. One average kilogram of final product was associated with 4600 kg of carbon dioxide emissions to the atmosphere, or that of 3 million average U.S. cars when aggregated across all national production. The paper goes on to state, "the unchecked growth of electricity demand in this sector confounds energy forecasts and obscures savings from energy efficiency programs and policies".

In addition to these systems being energy inefficient, they lack resiliency. During a recent visit to an aquaponics facility in the northeastern U.S., one NOSB member observed staff replanting lettuce and other greens and awaiting a shipment of new fish. An ice storm had moved through the region and knocked power out for nine hours. During that time, the daytime heat load, coupled with the lack of nutrient delivery and oxygenation of the roots of the plants and fish tanks, resulted in most of the lettuce dying and all of the fish dying. In terms of systems resilience, this aquaponics system with its high dependence on electricity, predisposed the system to be very brittle. A system built on a high degree of external energy use is not in keeping with the spirit of the organic label.

Hydroponic proponents argue that as many bacteria and fungi are found in hydroponics as are found in soil-based systems. However, they are not able to cite data to indicate that hydroponic systems have the ecological complexity of soil-based systems. How soils are managed does affect microbial diversity. In a comparison of organic and conventional soil-based systems, it was found that the "Organically managed system increased taxonomic and phylogenetic richness, diversity and heterogeneity of the soil microbiota when compared with conventional farming system."[24]

It is not surprising that hydroponic systems would have high numbers of decomposing microorganisms when labile feedstocks like hydrolyzed soybean or fish meal are fed into the system. Populations of microorganisms will multiply quickly when given such an easily degraded food source. However, those should not be considered equivalent to the diverse populations of microorganisms present in a soil-based rhizosphere.

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

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[23] E. Mills, 2012. The carbon footprint of indoor cannabis production. Energy Policy 46 (2012) 58–67.
[24] Lupatini, M., Korthals, G.W., de Hollander, M., Janssens, T.K.S., and Kuramae, E.E., 2016. Soil microbiome is more heterogeneous in organic than conventional farming system. Front Microbiol. 2016; 7: 2064.

rock powders (Task Force report p. 14). For these reasons, many organic producers reject hydroponic systems that are input-based rather than soil-based.

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, as well as to transform land which has been degraded by poor farming practices or is of low productive capability into 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 are 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 soil 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.

Hydroponic production is highly dependent on continuous 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 used in hydroponics has long been considered incompatible with a system of organic agriculture. Some of the major fertility inputs used in hydroponic production are transported long distances to the hydroponic production site, negating the purported environmental benefits of hydroponic production.

Specific language from OFPA and the Organic Rule that justify disqualifying soilless production from organic certification includes 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 from Previous Proposal and Discussion Documents

Numerous comments were received from the public in response to the Hydroponics Task Force report and the NOSB Crops Subcommittee proposal and two discussion documents on hydroponics and container growing over the past year.

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. Soil and water were considered by them to be equally acceptable as a medium to deliver 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. Hydroponic growers were also concerned that if hydroponics were no longer allowed, current hydroponic growers would lose their organic market.

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 or spirit of the organic law or regulations. Organic growers using soil in greenhouses contended that it is the greenhouse environment, not hydroponics, that allows for lower pesticide use, improved food safety, worker health, and providing food to urban food deserts.

Rationale for Proposed Recommendations on Aeroponics, Hydroponics, Aquaponics, and Container Growing

At the first meeting of the Hydroponic/Aquaponic Task Force in January 2016, the NOP presented information about potential gaps and inconsistencies in the past NOSB recommendations, both for hydroponics and for greenhouse growing systems in general. The NOP presentation included the following statement, "Further analysis and clarification is necessary because regardless of what position the NOSB ultimately takes on the issue of hydroponics and aquaponics, the NOP will likely need to undertake rulemaking. Rulemaking requires a comprehensive recommendation from the NOSB that addresses grey areas left by past recommendations."

The grey areas and gaps include the following (paraphrased from original):

- A clear explanation of the basis for each recommendation made.
- Acknowledging the continuum of production methods from field/soil to hydroponic and the role of compost or other biological growing media. Recommendations on each type of production and reasons for allowing or prohibiting.
- Guidelines are needed on exactly how different production types comply with provisions in regulations for soil fertility, rotation, and cover cropping.
- Definitions of vague terms including container, hydroponics, soil-less media, "compost-based", and soil ecology.
- How are OFPA and the NOP rule able to be consistent on other soilless production such as mushrooms, sprouts, aquatic plants and greenhouse in-ground systems?
- What is the justification for requiring soil (as opposed to cycling of resources, promoting ecological balance, and conserving biodiversity) but making an exception for cover crops, crop rotation, etc. when soil is not explicitly required in the regulations, but crop rotation is a MUST?
- Aquaponic systems are not specifically addressed in previous NOSB recommendations.

The lengthy report from the Task Force contains much more background information; too extensive to cover here. Selected portions are referenced throughout this proposal.

For clarity, terms used in this proposal, as well as some of the most common definitions taken from the NOSB 2010 Recommendation and the Task Force Report are appended in a glossary, amended for this discussion.

1. Consistency with mushrooms, aquatic plants, seedlings, and other "soilless" culture.
The 2010 Subcommittee of the Task Force report points out the following,

> From this subcommittee's perspective, the recommendation could be bettered, and more easily accepted by the NOP, if it explained how each of these exceptions to the premise that crops be grown in soil; 1) are linked to soil, or 2) are not naturally living or growing in soil so there is no reason for farming them in soil. Furthermore, how each meets the Principles of Organic Production and Handling (NOSB, 2001) should be made clear.

They continue by pointing out that sprouts and wild harvest aquatic plants are addressed in the current organic regulations, and the Preamble to the final rule specifically states that additional standards would be needed for mushrooms and greenhouses.

The Crops Subcommittee concurs with this analysis. Sprouting seeds is similar to a processing step for an organic product. Therefore the ingredient (seeds) must be certified organic. There are no inputs to the seeds to make them grow besides water, an exempt handling ingredient. The essential elements otherwise needed for plants to complete their lifecycle are not added because all the nutrition they need to the point of harvest is provided by the seed.

The 2010 NOSB recommendation *Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses)* includes the statement "naturally aquatic plant species and non-vascular plant species such as mushrooms come from different (non-soil) ecological niches and would be handled separately. Sprouts (the sprouted radicle and hypocotyl of seeds) are produced without soil by design and are not subject to this recommendation."

Wild Aquatic plants are covered under the wild crop section of the rules, and the preamble specifically points out that the term "site" was used to replace "from land" in the proposed rule. This clarifies that wild aquatic plant certification was intended. However, there is now a large amount of aquatic plant farming occurring that would not be considered wild, and this is not covered in the current rules.

Seedlings, or transplants, are also specifically mentioned in the organic rules and must be certified organically grown but are considered acceptable if raised in soil-less media. These are future crops that will spend most of their time growing in soil, and the time to produce the transplant is short compared to the time spent in the ground.

Mushrooms are fungi, not plants, and that justifies that they don't have a direct link to soil. They are more similar to yeasts and microorganisms that may be grown on substrate that does not depend on minerals from soil. The parameters of their production may eventually need additional rulemaking, but so far many mushrooms are able to be certified organic under the existing rules.

2. Land Considerations and Natural Resources
Regardless of where the container production is occurring, the land underneath the containers and the surrounding environment must be considered. The land underneath an outdoor operation must comply with the same provisions of the rule regarding land history and transition as other land. It must also be maintained or improved with respect to avoiding contamination. Land that has a building on top of it with an impermeable floor must comply with whatever practices are adopted for greenhouse or enclosure production.

The 2010 Subcommittee of the Task Force asked the NOSB to consider limiting the use of land where crops could be grown in the soil from being converted to container production. It also suggested limiting the conversion of non-organic container plants to organic by re-potting them in organic growing media.

Natural resource conservation includes the resources of soil, water, and wildlife. This must be addressed in an Organic System plan for a container growing system. This includes maintaining the condition of land underneath the container production, fate of any water or nutrient run-off from container production, and any positive actions taken to encourage biodiversity, such as installing hedgerows, planting insectary plants amongst the containerized crop plants, and other similar techniques.

3. Rotation
The 2010 NOSB recommendation noted that the intent of the rotation and cover cropping clauses in the rule could be met by similar practices with the same functions or goals as the crop rotation that are applicable to the operation. Such techniques might include mulching, replacing growing media (thus replenishing the soil system), planting hedgerows, adding microbial inoculants to stimulate existing populations, and recycling and composting used growing media. It was noted by the 2010 Recommendation Subcommittee of the Task Force that the crop rotation requirement is already not enforced by some certifiers on greenhouse crops grown in soil and on perennial crops with limited water.

Similarly, Canadian standards 7.5.12 states:

> Soil regeneration and recycling procedures shall be practiced. The following alternatives to crop rotation are permitted: grafting of plants onto disease-resistant rootstock, freezing the soil in winter, regeneration by incorporating biodegradable plant mulch (for example, straw or hay), and partial or complete replacement of greenhouse soil or container soil, provided it is re-used outside the greenhouse for another crop.

4. Containers & Growing Media
The 2010 NOSB recommendation on Terrestrial Plants in Containers does partially address production in containers. It specifies that the substrate in the container be based on compost and reiterates the previous NOSB opinion that compost was equivalent to soil.

The weakness of the 2010 recommendation was that it didn't quantify "compost-based", nor did it specify upper or lower limits for the volume of soil or compost in a container to achieve a level of biological activity comparable to that found in soil. There was also no consideration of whether non-synthetic, carbon-based materials such as coir or peat moss could serve the same functions as soil in a container.

The statement from OFPA that fertility come "primarily through the management of the organic content of the soil" has been interpreted to mean that soluble fertilizers should not be the primary source of nutrients but only a supplement to an overall program focused on crop rotations, cover crops, and amending with compost or manure. This is reflected consistently throughout NOSB recommendations from the past, from limitations on sodium nitrate or potassium chloride, to many rejected petitions centered on adding soluble forms of nutrients to the National List.

In order to specify an appropriate size of container or characteristics of the growing media that are appropriate for organic production, there needs to be a comparison of the characteristics of container system versus the soil system. The 2010 Recommendation Subcommittee of the Task Force uses bulk density as point of comparison to assess important distinctions between the two systems. Mineral soils have a bulk density of about 1.3 grams per cubic centimeter, while non-organic peat or coir-based media are only 0.13 gm/cubic cm, one tenth as much. With compost or other high organic matter media, the bulk density increases and so will the nutrient-supplying capacity.

A raised bed that has a liner between it and the ground is considered a container, regardless of the depth of the growing media. However, containers as referred to in this discussion are limited to those containing a solid substrate only[25].

By making the containers large enough, the nutrients in the organic matter fraction will be able to supply the majority of the nutrition for the plant. What is large enough, and how can it be explained in a way that is appropriate for different plants? The 2010 Recommendation Subcommittee of the Task Force cites the work of Dr. Martine Dorais of Laval University and the Agassiz Research and Development Centre. At a volume of 100 to 180 liters of soil per m^2, she has demonstrated that no liquid feeding is necessary, and fertility can be provided by the biological activity of the growing medium in the beds.

Both Canada and Sweden permit container growing while requiring minimum soil volumes based on growing area (although proposed new EU rules would prohibit container growing in the future). Canada requires a minimum soil volume of 70 liters[26] per m^2 of growing area. For staked crops like tomatoes and peppers, they require at least 10% compost at the start of production, and containers must be at least 30 cm (12 inches) high. They state, 7.5.4:

> Soil used in a container system, with the exception of transplants, shall provide nutrients to plants continuously. The soil (growth media) shall contain a mineral fraction (sand, silt or clay) and an organic fraction; it shall support life and ecosystem diversity.

The Canadian standards do not specify an amount of compost or soil for other crops such as lettuce or blueberries. They do not account for breakdown and settling of soil volume. It is unclear how certifiers can measure the soil volume, and the term "growing area" is not well defined.

In Sweden, at least 30 liters of soil per m^2 are required for annual crops with long seasons and 0.2 liters per pot for other plants, such as herbs, lettuce, and strawberries. However, as mentioned above, proposed new EU rules would prohibit container growing in Sweden.

The 2010 Recommendation Subcommittee of the Task Force report states, "Transplant and container growing methods would have more clarity if container growing media had a defined initial and temporal water and nutrient holding capacity and biology carrying capacity." It is possible to have a compost- or soil-

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[25] Container troughs in which water is recirculated are considered hydroponic. Similarly, container systems with troughs under the pots that collect, filter, and recirculate the water after adding additional liquid nutrients are considered hydroponic unless they meet the container standard in the Container Production Systems motion below**.**

[26] For reference a 5-gallon pot holds 25 liters and a 10-gallon pot holds 40 liters.

based growing media with adequate aeration and water holding capacity that can provide enough fertility for production of annual plant crops or a season in the growth of perennial plants.

The 2010 Recommendation Subcommittee of the Task Force proposed that organic growing media must have a minimum of 20% compost.

5. Nutrition

The 2010 Recommendation Subcommittee of the Task Force Report states, "The key distinction between organic fertility management and conventional fertility management is that under organic management the source of the bulk of the crop nutrients are from the biological activity of decomposing complex organic molecules (compost, manures, seed meals, etc.) and the mineral fractions." Soil is important due to the interactions of the physical, chemical, and biological properties together.

While hydroponic systems can be efficient in nutrient recycling and water conservation, they do not have the complex interactions found in an organic soil-based system. The backbone of organic production is the complex interactions between soils, plants, animals (from tiny insects to large herbivores and carnivores), and humans.

It would seem logical to assess the continuum between grown in the ground and fully liquid-based systems by determining where the plant nutrition is coming from. If the nutrients are primarily coming from soil or compost and solid amendments, then they would be considered equivalent to in-ground production whereas a container production system that relies primarily on liquid fertilizers would not be within the requirement for soil-based systems.

The NOSB recognizes that some soils contain very little inherent fertility and crops are being grown and certified organic which rely in large part on liquid fertilizers. While that is an area that the NOSB and NOP should examine to see if higher standards should be set to improve the inherent fertility of those soils over time, that is outside the scope of this attempt to set standards for crops grown in containers. Container producers have more flexibility to create a minimum level of fertility in the container substrate mix before beginning production, compared to producers growing in the ground.

The 2010 Recommendation Subcommittee of the NOP Hydroponics Task Force proposed to “Limit organic certification to what is grown in the ground, with the exceptions of transplants, ornamental, and herbs.” That subcommittee further proposed that if organic certification were to include crops grown in containers, there should be a “limitation of no more than 50% of the required fertility being added after planting, and no more than 20% to be added as a liquid fertilizer after planting. For perennials these limitations should be on an annual basis.

“The British Soil Association specifies that at least 51% of the nutrition for the crop must come from the soil at the time of planting” (Task Force Report p. 54). That applies to crops grown in the ground. Other standards for greenhouses limit liquid nutrients to 25% of the total nutrients supplied. A recent revision to the Canadian standards[27] also proposes limits on liquid fertilizers by stating that for small soil volumes, 70% of the nitrogen and phosphorus must be supplied by solid organic soil amendments that require an active soil ecosystem.

The suggestion of the 2010 Recommendation Subcommittee of the Task Force that liquid nutrients be limited to 20% of the total nutrients supplied is consistent with the current annotation for the use of the

[27] 2016 amended draft of Canada Organic Standards, pp 44-45: General Principles and Management Standards

highly soluble Chilean nitrate, which is listed at 205.602: “Sodium nitrate (is prohibited)—unless use is restricted to no more than 20% of the crop’s total nitrogen requirement.”

The policy on Chilean nitrate sets a precedent for the use of highly soluble inputs. How that policy came about is worth exploring here because it illustrates how the principles of organic agriculture influenced that policy.

As mentioned above, in the Preamble to the Final Rule of the NOP of December 21, 2000, the Proposed Organic Rule of 1997 had allowed the use of mined substances of high solubility (e.g., Chilean nitrate). The Preamble to the Final Rule goes on to say “Many commenters objected to the general allowance for this category of substances.” Therefore, the Final Rule included the June 2000 recommendation of the NOSB, which is the annotation at §205.602 that sodium nitrate be “restricted to no more than 20% of the crop’s total nitrogen requirement.”

In April 2000, the NOSB recommended complete prohibition of sodium nitrate. The NOP has yet to fulfill that recommendation but issued a policy memo in September 2011[28] that states:

> Organic producers must meet the requirements of 7 CFR 205.200 which states that production practices must maintain or improve the natural resources of the operation, including soil and water quality. Under 7 CFR 205.203(b), producers must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal nutrients. Organic producers who use sodium nitrate need to ensure that the use of sodium nitrate is aligned with the requirements of 7 CFR 205.203(b).

The principle of limiting soluble Chilean nitrate to 20% of a crop’s nitrogen requirement in order to remain aligned with the soil fertility requirements of the organic standards is consistent with a principle of limiting soluble fertility sources to 20% of a crop’s needs in container production systems.

A requirement that would limit liquid feeding of crops is complicated by the number of essential elements needed by crops, and that some micronutrients may need higher percentages of supplemental feeding than macronutrients like nitrogen. Nitrogen is generally the most dynamic crop nutrient in the soil/substrate, and managing nitrogen in accord with organic principles will likely ensure that all nutrients are managed well. Also, limiting the requirement to just one indicator element (nitrogen) makes monitoring for compliance much easier.

Chilean nitrate is generally about 16-0-0 (16% nitrogen). Hydrolyzed soybean meal (which is commonly used as a nitrogen source in hydroponic container systems) is also sold as 16-0-0 (16% nitrogen), and like Chilean nitrate, is completely water-soluble. Limiting use of soluble nitrogen feeding to 20% of crops’ needs will help ensure that container growing is aligned with the requirements of 7 CFR 205.203(b), as outlined in the quote from the NOP above.

Hydroponics proponents claim that the mineralization of nutrients into forms that plants can take up can be performed by microbial digestion in a hydroponics system with carbon-based substrate, and that the microbial population and dynamics are equivalent to a "diverse soil ecology". The Crops Subcommittee questions those statements because simple, labile nutrient sources are used in container systems, and no definitive data has been provided to back up the claim that microbial dynamics are equivalent to a diverse soil ecology. Saying that "soil biology" can happen without soil is not substantiated by definition or data.

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[28] https://www.ams.usda.gov/sites/default/files/media/NOP-Notice-12-1-SodiumNitrate.pdf

6. Other issues
The Task Force report included discussion about other issues related to indoor production. In a separate discussion document to be presented at the Fall 2017 meeting in Jacksonville, the Crops Subcommittee discusses three of those issues: use of artificial light; use of synthetic mulches; and disposal of crops, substrates, and containers at the end of the crops' production cycle. The Crops Subcommittee seeks input from the organic community on those issues.

Some have expressed concern that if hydroponic and aquaponic production are prohibited from organic certification, it would be a hardship for those hydroponic and aquaponic operations currently certified. Certainly, some currently certified operations would lose certification, but the numbers would be quite small relative to the total number of operations certified through the NOP.

At the April 2016 meeting of the NOSB, Deputy Administrator Miles McEvoy, presented the results[29] of a 2016 survey to certifying agents regarding the certification of hydroponic, aquaponic, and container-based systems. Of the 80 accredited certifying agents worldwide at the time of the survey, 17 certified hydroponic and aquaponic operations. Stated as a percentage, 21% of certified agents are certifying these operations. Similarly, of the approximately 31,000 certified organic operations, 30 (or less than 0.1% of all certified organic operations) were certified organic hydroponic. There were 22 certified organic aquaponic operations, or 0.07% of all certified organic operations. Finally, there were 69 certified organic container-based operations, or 0.2% of all certified organic operations. As is clear from these figures, certified organic hydroponic, aquaponic, and container-based systems constitute an extreme minority of all certified organic operations, or less than 0.4% when combined.

Regarding the location within the organic standards where aeroponics, aquaponics, and hydroponics could be addressed, if any of the motions below to remove organic certification from a specific method of production are passed by the NOSB, the National Organic Program could add those prohibitions to 205.105, as well as adding the definitions of the various methods to 205.2 Terms Defined.

An example would be:
205.105 To be sold or labeled as "100% organic", "organic", or "made with organic (specified ingredients or food groups)", the product must be produced and handled without the use of:
(h) aeroponics
(i) aquaponics
(j) hydroponics

Crops Subcommittee Proposed Recommendations:

Aeroponics
Discussion: Aeroponics systems do not require soil or 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.

The Crops Subcommittee is opposed to allowing aeroponic production systems to be certified organic because they do not meet the requirements of OFPA or the Organic Rule.

Subcommittee vote:
Motion to prohibit aeroponic production systems from organic certification.
Motion by: Emily Oakley

[29] https://www.ams.usda.gov/sites/default/files/media/McEvoy%20NOSB%20April%202016.pdf

Seconded by: Harriet Behar
Yes: 8 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Aquaponics

Discussion: Aquaponic production is a form of hydroponics in which plants get some or all of their nutrients delivered in liquid form from fish waste. Aquaponics is defined here as “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.”

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.

The Crops Subcommittee is opposed to allowing aquaponic production systems to be certified organic at this time. If aquaculture standards are issued in the future, and concerns about food safety are resolved, aquaponics could be reconsidered.

Subcommittee vote:

Motion to prohibit aquaponic production systems from organic certification.
Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 7 No: 2 Abstain: 0 Absent: 0 Recuse: 0

Hydroponics and Container Growing

Discussion: The word “hydroponics” comes from two Greek words: hydro, meaning water; and ponos, meaning labor. In popular use of the term, hydroponics means growing plants by providing the plants’ nutrition in liquid form. The Merriam-Webster Dictionary definition of hydroponics is “the growing of plants in nutrient solutions with or without an inert medium (such as soil) to provide mechanical support.”

Proponents of allowing hydroponic production to qualify as certified organic have created confusion in the hydroponics discussion by attempting to redefine some forms of hydroponic production as “container growing.” That creates confusion because, in fact, all hydroponic production is done in containers, and as noted above, hydroponics has traditionally been defined by the use of nutrient solutions to feed plants, not by the particular type of rooting medium used.

In particular, hydroponic producers who want to be certified organic claim that if plants are grown in certain rooting media, the growing system is no longer hydroponic, even if all, or virtually all, of the plants’ nutrition is provided as a liquid feed. That belies both common usage and dictionary definitions of “hydroponics.”

A common rooting medium that is used in hydroponic container production is coconut coir. One of the advantages of coir as a growing medium is that coir is resistant to microbial decomposition, so it will maintain its structure and water-holding capacity in the container longer than some other rooting materials. Hydroponic advocates argue that coir is not inert. However, the NOP, in the May 2014 Organic Integrity Quarterly (cited above), included “coconut husk” in a list of examples of an “inert medium.”

In a research paper investigating decomposition rates of coir, Prabhu and Thomas[30] point out "Coir pith with high C:N ratio (about 100:1), lignin and polyphenol contents is highly resistant to easy decomposition…Lignin prevents the easy decomposition and mineralization of coir pith…making it a recalcitrant biopolymer."

Coir is a good rooting medium for hydroponic production because it has high air- and water-holding capacity and because it is recalcitrant. Coir pith also has a cation exchange capacity of 20-30 meq/100g (Ravindranath)[31]. However, "As a nutrient source, coir pith has not much value" (Prabhu and Thomas). The nitrogen content of coir pith ranges from 0.26% (Ravindranath) to 0.57% (Bethke)[32]. Given the C:N ratio of 100:1 for coir pith, the small amount of nitrogen in coir will not serve as a nitrogen source for growing plants, which means that in a hydroponic system using coir as the rooting medium, all of the plants' nitrogen needs will have to be supplied by liquid feeding.

It is interesting to note that the Merriam-Webster definition of hydroponics noted above parenthetically equates soil to an inert medium in a system in which plants' nutrient needs are being fulfilled through liquid feeding. Of course, we know that in a soil-based cropping system--in which the plants' nutrient needs are being supplied by the soil--the soil is not inert, but dynamically supplies and cycles nutrients. However, any rooting medium—including soil—will not serve as an adequate or long-term source of fertility to grow plants unless it is managed to do so.

The majority of the Crops Subcommittee believes that providing most of a plant's nutritional needs through liquid feeding in a container should be defined as hydroponics, regardless of the rooting medium used. The Crops Subcommittee further supports the suggestion of the 2010 Recommendation Subcommittee of the NOP Hydroponics Task Force, which stated that there should be a "limitation of no more than 50% of the required fertility being added after planting, and no more than 20% to be added as a liquid fertilizer after planting." In order to make monitoring simpler, and because nitrogen can serve as an indicator nutrient to demonstrate the nutrient-supplying power of a soil/compost system, the Crops Subcommittee proposes that this fertility requirement of container systems apply to nitrogen only.

The majority of the Crops Subcommittee believes that this standard is sufficient to ensure that crops grown in containers are not merely being fed hydroponically but have an active soil biology and ecology that can supply nutrients to the crops. This is in keeping with the 2010 NOSB recommendation, which states:

> "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."

Universities and crop consultants who advise hydroponic growers can provide tables of the nitrogen requirement (or nitrogen removal) of crops, which can be used to calculate the 20% and 50% limits on liquid feeding of nitrogen. For example, Knotts Handbook for Vegetable Growers indicates that a 30-ton

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[30] Prabhu, S.R. and G.V. Thomas, 2002. Biological conversion of coir pith into a value-added organic resource and its application in Agri-Horticulture: Current status, prospects and perspective.
[31] Ravindranath, Chief editor, Coir Pith Wealth from Waste, a Reference. 2016. Coir Board, Ministry of MS&ME, Govt. of India.
[32] Bethke, C.L., 2008. Nutritional properties of agrocoir. Horticultural Soils and Nutrition Consulting 77 Granite Road Williamston, Michigan 48895.

tomato yield will require 180 lb/acre of nitrogen.[33] The crop consulting firm Yara estimates (online)[34] that the nitrogen requirement (removal) of tomatoes is 5 to 5.3 lbs of nitrogen per ton of yield. A grower would need to use a nitrogen requirement value appropriate for the region, growing conditions, and expected yield of the operation. Similar calculations are already commonly used to determine the 20% limit for Chilean nitrate allowed in organic crop production.

Subcommittee vote, container production:
Motion that for container production to be certified organic, a limit of 20% of the plants' nitrogen requirement can be supplied by liquid feeding, and a limit of 50% of the plants' nitrogen requirement can be added to the container after the crop has been planted. For perennials, the nitrogen feeding limit is calculated on an annual basis. Transplants, ornamentals, herbs, sprouts, fodder, and aquatic plants are exempted from these requirements.

Motion by: Francis Thicke
Seconded by: Steve Ela
Yes: 6 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Subcommittee vote, hydroponics:
Motion that any container production system that does not meet the standard of a limit of 20% of the plants' nitrogen requirement being supplied by liquid feeding, and a limit of 50% of the plants' nitrogen requirement being added to the container after the crop has been planted is defined as hydroponic and should not be allowed to be certified organic. For perennials, the nitrogen feeding limit is calculated on an annual basis. Transplants, ornamentals, herbs, sprouts, fodder, and aquatic plants are exempted from these requirements.

Motion by: Jesse Buie
Seconded by: Dave Mortensen
Yes: 6 No: 3 Abstain: 0 Absent: 0 Recuse: 0

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Glossary of terms

Aeroponics: A variation of hydroponic plant production in which plant roots are suspended in air and misted with nutrient solution.

Aquaponics: A recirculating hydroponic plant production 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.

Recalcitrant: Resistant to microbial attack.

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

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[33] Maynard, D.N. and G.J. Hochmuth. Knotts Handbook for Vegetable Growers, 5th ed., 2007. John Wiley and Sons Inc., Hoboken, New Jersey.
[34] http://www.yara.us/agriculture/crops/tomato/key-facts/nutritional-summary/

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 (for the purposes of this proposal): Any container production system that does not meet the standard of a limit of 20% of the plants' nitrogen requirement being supplied by liquid feeding, and a limit of 50% of the plants' nitrogen requirement being added to the container after the crop has been planted.

Nutrient solution: Growing solution used in traditional hydroponic production that is commonly composed of immediately plant-available soluble mineral salts in water

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).

<u>Minority View:</u>

Summary of Pro-Hydroponic Arguments

As is pointed out in the Aquaponics/Hydroponics Subcommittee of the Task Force report and in public comments received over the past year, hydroponics has a long history in agriculture from societies that worked with limited resources in changing conditions. Hydroponics is an innovative system that results in efficient water and nutrient use. This efficient use of water allows for conservation of vital water resources which have been scarce recently due to climate change and recent droughts. Due to its controlled environment, hydroponic operations—like other greenhouse operations—have been able to lessen the 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 production of food in urban areas or on un-arable land. Hydroponics operations are quite diverse and can be stand-alone operations or part of a larger in-ground farming operation. Critics contend that hydroponics are reliant on off-site nutrients and while the site specific conditions will dictate the level and type of nutrient cycling that occurs, proponents would argue the same is true for most organic in-ground farmers as well, including reliance on off farm manure. Practitioners have developed systems that are integrated, use only materials on the National List, and incorporate microbial action to provide plant health and nutrition. The introduction of fish to create an aquaponic system can address production of a protein source and integrate *in situ* fertilizer production with an integrated system.

Hydroponic proponents argue that as much bacteria and fungi are found in hydroponics as is found in soil-based systems. They cite studies that look at the microbiology in hydroponics systems and find about 10,000,000 bacteria per milliliter of nutrient solution[35] [36]. Soil microbiology varies quite a bit, but compost consistently comes in at 100,000 to 1,000,000,000 colony forming units - or cfu- a measure of the viable bacterial and fungal cells - per milliliter of dry compost[37] [38] [39]. These systems are also rich in fungi-- a study that looked at both fungi and bacteria in hydroponic systems found 1,000,000 cfu/ml bacteria and 10 to 1000 fungi cfu/ml in the system[40]. They supply research that shows suppression of plant disease by root flora and other microflora in hydroponics. A review of these studies in 2011 found suppressive flora in rockwool, NFT, peat, and other hydroponic methods[41] [42] [43] [44] [45] [46] [47] [48] [49] [50] [51]. It should be noted that

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[35] Berkelmann, B., W. Wohanka, and G. A. Wolf. 1994. Characterization of the bacterial flora in circulating nutrient solutions of a hydroponic system in rockwool. Acta Hortic. 361:372–381.

[36] Waechter-Kristensen, B., S. Caspersen, S. Adalsteinsson, P. Sundin, and P. Jensén. 1999. Organic compounds and micro-organisms in closed, hydroponic culture: Occurrence and effects on plant growth and mineral nutrition. Acta Hortic. 481:197–204.

[37] Bess, V. 2008. Evaluating Microbiology Of Compost 83–85.

[38] Chandna, P., L. Nain, S. Singh, and R. C. Kuhad. 2013. Assessment of bacterial diversity during composting of agricultural byproducts. BMC Microbiol. 13:99.

[39] Hassen, A., K. Belguith, N. Jedidi, A. Cherif, M. Cherif, and A. Boudabous. 2001. Microbial characterization during composting of municipal solid waste. Bioresour. Technol. 80:217–225.

[40] Berkelmann, B., W. Wohanka, and G. A. Wolf. 1994. Characterization of the bacterial flora in circulating nutrient solutions of a hydroponic system in rockwool. Acta Hortic. 361:372–381.

[41] . Clematis, F., A. Minuto, M. L. Gullino, and A. Garibaldi. 2009. Suppressiveness to Fusarium oxysporum f. sp. radicis lycopersici in re-used perlite and perlite-peat substrates in soilless tomatoes. Biol. Control. Elsevier Inc. 48:108–114.

[42] Folman, L. B., J. Postma, and J. a. Veen. 2001. Ecophysiological characterization of rhizosphere bacterial communities at different root locations and plant developmental stages of cucumber grown on rockwool. Microb. Ecol. 42:586–597.

[43] Minuto, A., F. Clematis, M. L. Gullino, and A. Garibaldi. Induced suppressiveness toFusarium oxysporum f.sp.radicis lycopersici in rockwool substrate used in closed soilless systems. Phytoparasitica 35:77–85.

[44] Muslim, A., H. Horinouchi, and M. Hyakumachi. 2003. Control of fusarium crown and root rot of tomato with hypovirulent binucleate Rhizodonia in soil and rock wool systems. Plant Dis. 87:739–747.

[45] Postma, J., M. J. Willemsen-de Klein, and J. D. van Elsas. 2000. Effect of the Indigenous Microflora on the Development of Root and Crown Rot Caused by Pythium aphanidermatum in Cucumber Grown on Rockwool. Phytopathology 90:125–33.

[46] Postma, J. 2004. Suppressiveness of root pathogens in closed cultivation systems. Acta Hortic. 644:503–510.

[47] Postma, J., B. P. J. Geraats, R. Pastoor, and J. D. van Elsas. 2005. Characterization of the Microbial Community Involved in the Suppression of Pythium aphanidermatum in Cucumber Grown on Rockwool. Phytopathology 95:808–818.

[48] Tu, J. C. ., A. P. . Papadopoulos, X. Hao, and J. Zheng. 1999. The relationship of Pythium root rot and rhizosphere microorganisms in a closed circulating and an open system in rockwool culture of tomato. Acta Hortic. 481:577–583.

[49] Vallance, J., F. Déniel, G. Floch, L. Guérin-Dubrana, D. Blancard, and P. Rey. 2011. Pathogenic and beneficial microorganisms in soilless cultures. Agron. Sustain. Dev. 31:191–203.

[50] . van Os, E. A., and J. Postma. 2000. Prevention of root diseases in closed soilless growing systems by microbial optimisation and slow sand filtration. Acta Hortic. 532:97–102.

[51] Zhang, W., and J. C. Tu. 2000. Effect of ultraviolet disinfection of hydroponic solutions on Pythium root rot and non-target bacteria. Eur. J. Plant Pathol. 106:415–421

compared to soil, there have been many less studies on suppressive flora in hydroponics. The fact that of these few studies, so many have found strong evidence of suppressive flora in hydroponics is important.

While there has been ambiguity over the years on the position of the NOSB related to organic hydroponic production, the NOP has noted in 2002, 2004, 2009, 2014 and 2016 that organic hydroponic production is allowed as long as the producer can demonstrate compliance with the USDA organic regulations However, an NOP publication (the Organic Integrity Quarterly of May 2014) 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.

The hydroponic proponents of 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 not using any soil and use of land unsuitable for cultivation). They argued that these production systems abide by the definition of 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. Additionally, proponents contend they comply with applicable areas of the rule, including writing and implementing an Organic System Plan, keeping records, preserving and cycling natural resources, and using compliant inputs. Precedence for exemptions for non-applicable areas of the standards has already been set by NOSB recommendations on greenhouse production, mushroom production, aquaculture production and others.

Organic production systems

The justifications for how hydroponic systems comply with §205.203 (soil fertility and crop nutrients) and §205.205 (crop rotation) have been given as follows (see rule wording above):

- §205.203 (a) – Depends on the site specific conditions but generally, if the system interacts with soil these requirements apply as they would to in-ground farms. If production is soil-less then the non-use of soil maintains the site's soil. Operations are still responsible for not degrading soil.
- §205.203 (b), (c) and 205.205 – In lieu of crop rotation and cover cropping, soil regeneration and recycling practices are implemented and documented in order to demonstrate that the required functions/goals of crop rotation and cover cropping listed in 205.205 (a, b, c, d) have been achieved through these alternate practices, as applicable to the operation. Specifically, by maintaining or improving organic matter content, providing for pest management in crops, managing deficient or excess plant nutrients, and by providing erosion control. Exemptions for crop rotation and cover cropping have been recommended by the NOSB in the past for specific types of operations like greenhouses.

Minority Discussion

This minority view is a byproduct of numerous hours of debate, research, and contemplation about the diversity of the organic community. The industry is comprised of a variety of producers, processors, certifiers, retailers and consumers that all have evolved to define what compliant organic production systems look like under current NOP regulation. During many rounds of public comment, the NOSB has listened to the community and their opinions on the applicability and legality of hydroponic, aeroponic and aquaponic systems under the organic label. As with all complex issues, there are various viewpoints regarding the meaning and interpretation of the organic regulation. The minority position celebrates this diversity and respects all shareholders' interpretations.

There are some who believe that proper soil management following principles outlined in the standards are foundational to what organic certification should mean. Many founding farmers of the organic movement shared this perspective as they pioneered new methods of agricultural production as an alternative to conventional production. We agree that soil is historically linked with organic production and should be as well in its future – we are pro soil. However, we do not view this as a mutually exclusive decision – being pro soil does not mean there is not a home for other production methods that "respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."

Members of the organic community were drawn to organic foods and production for various reasons, including but not limited to: Environmental impacts of agriculture, resource conservation, avoidance of highly toxic synthetic pesticides and fertilizers, believed health benefits, local agriculture, etc. Some of these aspects were included in the law and regulations, while others were left out. Most members of the organic community are motivated by these concerns and more, each to varying degrees. Each of these concerns have tradeoffs which need to be balanced. Determining where this balance lies has unfortunately confounded the NOSB since its inception in 1995.

The 1995 NOSB recommendation *Standards for Greenhouses* contains the statement, "Hydroponic production in soilless media to be labeled organically produced shall be allowed if all provisions of the OFPA have been met." That statement indicated that an analysis had not been made of whether hydroponics met the provisions of OFPA. The brief dialogue at the meeting made it clear that while some board members were supportive of hydroponics, others had concerns about soilless production.

In March 2000, a revised proposed rule for the National Organic Program was published, revising the initial proposed rule published in December 1997. In the supplemental information, the following was stated:

> We have amended the term, "system of organic farming and handling," to "system of organic production and handling" and retained the original definition in this proposal. The original definition was crafted to be consistent with the requirements of the Act. We have changed "farming" to "production" to provide a more encompassing term, which may come to include such diverse activities as hydroponics, green house production, and harvesting of aquatic animals. The purpose of the original definition was to describe practices and substances consistent with systems of organic farming and organic handling as required by the Act and to provide an explicit reference point for determining which practices and substances are most consistent with these systems.[52]

In an 1807 communication from Thomas Jefferson to William H. Cabbell as to statutory interpretation, Thomas Jefferson stated,

> *"In the construction of a law, even in judiciary cases of meum et tuum, where the opposite parties have a right and counter right in the very words of the law, the Judge considers the intention of the lawgiver as his true guide, and gives to all the parts and expressions of the law, that meaning which will effect, instead of defeating, its intention. But in laws merely executive, where no private right stands in the way, and the public object is in the interest of all, a much freer scope of construction, in favor of the intention of the law, ought to be taken, and ingenuity ever should be exercised in devising constructions which may save to the public the benefit of the law. Its intention is the important thing:*

[52] Federal Register Volume 65 Number 49. Page 13521. Docket Number: TMD-00-02-PR2, RIN 0581-AA40. National Organic Program Proposed Rule. Agricultural Marketing Service, USDA. March 13, 2000

the means of attaining it quite subordinate." –Thomas Jefferson to William H. Cabbell, 1807.

The minority view does find some common ground with the majority proposal; however, we find it strays too far from the original intent of the previous NOSB recommendations. It is not consistent with previous Board decisions, nor its intent when crafting its recommendations. It would be difficult for the NOP to implement without additional justification.

The minority view holds that the 2010 NOSB recommendation entitled *Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses)* was generally complete in regards to addressing compliant characteristics of organic systems under the NOP regulation. However, as was discussed previously in the introduction and background section, the NOP returned to the NOSB following the 2016 Task Force report, asking for additional clarity regarding the 2010 NOSB hydroponics recommendation because the NOP felt the 2010 recommendation left too many aspects of compliant organic production systems open for interpretation. As such, the minority position below is an edited and redlined version of the 2010 NOSB recommendation intended to provide further clarity requested by the NOP.

The minority view notes that the 2010 recommendation allowed compost to be utilized in place of soil because it deemed it equivalent to soil. The foundation of this equivalency was stated as follows:

> The 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, protozoa, fungi, bacteria, actinomycetes, etc. 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.

As such, the minority view extends that if production systems, utilizing organically approved production techniques on majority carbon based substrate, can foster the proliferation of proper soil biology within their accompanying ecologies as evidenced by the presence of typical soil dwelling organisms, such as earthworms, protozoa, fungi, bacteria, actinomycetes then they should be eligible for organic certification. Therefore, we propose working on a production standard that requires verification of the presence of four trophic levels. We understand this concept is new and has not been reviewed or commented on by the organic community or industry. We welcome feedback from the community and industry on this concept, definition and feasibility.

The minority view is based upon the beliefs that organic production should enforce responsible stewardship practices, address sustainability and conservation of resources (e.g. land, water, on-farm inputs, energy, biodiversity), and allow for novel developments in organic food production systems that assist in providing greater access of organic food to consumers.

The minority is not supportive of taking either proposal (major or minority) through to a vote at the Fall 2017 NOSB meeting. Given the division of the community reflected in the division of the board, all stakeholders need to come to terms that a greater compromise will be necessary to make progress on this issue. The minority view finds merit in a discussion on hydroponic/soilless production standards and mandatory additional labeling with the organic label/claim. This concept has not been fully explored.

The minority view believes these proposed revisions to the 2010 recommendation require further refinement and as noted earlier we request additional feedback from the public on these proposed revisions.

Proposal – based on 2010 NOSB Recommendation

§ 205.2 Terms Defined
Greenhouse- Permanent enclosed structure that allows for an actively controlled environment used to grow organic crops, annual seedlings or planting stock used in organic production.

Hydroponics- The production of normally terrestrial, vascular plants in nutrient rich solutions or in an inert, porous, solid matrix bathed in nutrient rich solutions. Sprouts and fodder are considered a processed material and are not considered hydroponic.

Aeroponics- A variation of hydroponics in which plant roots are suspended in air and misted with nutrient solution.

Containers- 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.
~~*Growing media*- Material which contains sufficient organic matter capable of supporting the plant root system and a natural and diverse soil ecology.~~

Container Production- The production of normally terrestrial, vascular plants in containers. Can be certified organic if production requirements of section of 205.209 are met.

Trophic levels: The hierarchical levels of organisms within an ecosystem; each level consisting of organisms that share the same function and food source in the food chain of a defined ecosystem.

§ 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**:**
(h) Aeroponics and Hydroponics.

§ 205.209 Terrestrial Plants in Containers and Enclosures ~~(Greenhouses)~~
(a) Container and enclosure (such as a greenhouse) operations must meet all applicable requirements of subparts B (205.105) and C (205.200 – 205.206) except that:

(1) The producer operating a container or enclosure operation ~~greenhouse~~ with crops grown in containers using a growing media that does not include soil from the production site is exempt from requirements of 205.202(b)~~, 205.203(a).~~

(2) The producer operating with crops grown in containers shall comply with the applicable section of 205.203(a) based on site specific conditions.

(3) In addition, the ~~growing~~ container based producer is exempt from the crop rotation and cover cropping requirements in section 205.203(b) and 205.205. In lieu of crop rotation and cover cropping, soil regeneration and recycling practices shall be implemented and documented for the Accredited Certification Agent in order to demonstrate that the required functions/goals of crop rotation and cover cropping listed in 205.205(a, b, c, d) have been achieved through these alternate practices, as applicable to the operation. Specifically:

(i) Maintain or improve soil organic matter content (a)- Examples include, but are not limited to, recycling and re-use of growing media, addition of compost and other compostable materials, earthworm replenishment, microbial re-inoculation, etc.

(ii) Provide for pest management in crops (b)- Examples include, but are not limited to: Soil borne damping-off control through various low temperature heating methods; Soil inoculation using disease suppressant bacteria and fungi.

(iii) Manage deficient or excess plant nutrients (c)- Examples include, but are not limited to: Recycle excess plant nutrients contained in drain water from media containers, avoiding so called drain-to-waste systems. Recycled nutrients must be re-used in the greenhouse, or alternatively, on a growing crop outside the facility.

(iv) Provide erosion control (d)- Examples include, but are not limited to: Though erosion is not generally applicable to greenhouse production, recycling of drain water prevents off-site movement of nutrients, a common consequence of typical field erosion.

(4) The Container Organic System Plan must address how meets the requirements to conserve biodiversity and maintain or improve natural resources of the site-specific operations. The Organic System Plan should include the entire production site (containers and non-containers as applicable) as well as the surrounding environment.

(b) Growing media requirements:

(1) ~~ingredients~~ Inputs shall be verified by Accredited Certifying Agent and shall not include as ingredients any prohibited materials.

(2) Growing media shall ~~be comprised of ingredients that~~ allow for recycling and re-use as growing media within the operation, or alternatively, as a crop input outside the greenhouse.

(3) Growing media shall not be disposed of as waste, but should be recycled or reused whenever possible.

(4) Growing media shall contain sufficient organic matter capable of supporting natural and diverse soil ecology as evidenced by supporting four trophic levels. ~~For this reason, hydroponic and aeroponic systems are prohibited.Growing media used to produce crop transplants should also be capable of supporting a natural and diverse soil ecology.~~

(5) Growing media shall be a minimum of 50% carbon based material.

(c) Producers may use full-spectrum light sources.

(d) Plants and soil shall not be in direct contact with, or indirect contact with condensates from, wood treated with prohibited materials that are used for greenhouse structures or frames of raised beds.

(e) Producers must recycle or reuse containers at end of life.

~~(f) To comply with the provisions of 205.201(a)(5) to prevent commingling and contamination, organic and non-organic crops can be grown within the same structure only if the following conditions are met:~~

~~(1) An impermeable wall shall separate organic and non-organic production sites if prohibited materials are applied to the non-organic crop to ensure that cross contamination does not occur.~~

~~(2) The ventilation systems must ensure that prohibited materials cannot drift, or be otherwise conveyed to the organic~~

~~(3) Separate watering systems must be established if prohibited fertilizers and/or pesticides are injected within the watering system.~~

~~(4) Producers must ensure that no contamination occurs to the organic crop through cross-pollination with crops produced through genetic engineering~~

~~(5) Soil mixing machines and other equipment used for non-organic crop production must be thoroughly cleaned prior to use in organic production.~~

~~(6) Adequate physical facilities, as determined by the certifying agent, shall separate organic and non-organic crops and production materials in storage, production or holding areas.~~

~~(7) Organic and non-organic crops and production areas must be conspicuously labeled.~~

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 29, 2017

National Organic Standards Board
Crops Subcommittee Discussion Document
Field and Greenhouse Container Production
August 29, 2017

Introduction

Since 1995, the National Organic Standards Board has discussed the production of crops in greenhouses and/or containers, and grown in a variety of substrates. This has resulted in numerous recommendations that have not been incorporated into the USDA organic regulations. USDA accredited certifiers have been approved to develop standards for hydroponics and containers and certify operations to those standards, as long as their organic certification requirements do not conflict with current regulations. Many of the unique aspects of operations that are hydroponic in recirculating systems or hydroponic in containers, where the crop relies upon soluble nutrients due to the use of inert substrates in those containers, are not explicitly addressed in the current USDA organic regulations. This discussion document provides background on the issues and why there is a need to address various aspects unique to container operations, both hydroponic and soil-based.

In the equivalency agreements for organic trade between two of our major trading partners, the European Union and Canada, hydroponic crops are not allowed to carry the organic label and are an exception to the agreement. Other aspects of container and greenhouse growing are also covered by our trading partners. Bringing the USDA organic regulations more in line with international organic regulations could improve trade and lessen confusion in the marketplace.

Background

In a separate proposal to be voted on at the Fall 2017 NOSB meeting, the Crops Subcommittee has proposed the following standard for container production:

For container production to be certified organic, a limit of 20% of the plants' nitrogen requirement can be supplied by liquid feeding, a limit of 50% of the plants' nitrogen requirement can be added to the container after the crop has been planted, and the container substrate must be at least 50% soil and/or compost by volume. For perennials, the nitrogen feeding limit is calculated on an annual basis. Transplants, ornamentals, herbs, and aquatic plants are exempted from these requirements.

In the proposal, hydroponic is defined as

any container production system that does not meet the standard of a limit of 20% of the plants' nitrogen requirement being supplied by liquid feeding, and a limit of 50% of the plants' nitrogen requirement being added to the container after the crop has been planted is defined as hydroponic, and should not allowed to be certified organic. For perennials, the nitrogen feeding limit is calculated on an annual basis. Transplants, ornamentals, herbs, sprouts, fodder, and aquatic plants are exempted from these requirements.

Whether or not these items are recommended by the National Organic Standards Board and subsequently incorporated into the organic regulations by the National Organic Program, there are other aspects associated with these operations that are beyond requirements for nutrient and substrate

sources and percentages. These systems produce crops either in greenhouses or in field situations and rely on some practices that are not typical of a field grown operation.
The lack of standards overseeing these practices leads to inconsistency between hydroponic operations and field grown crop production.

Relevant Areas of the Rule and the Organic Foods Production Act (OFPA)

There are numerous areas of the OFPA and the USDA organic regulations that address growing crops and would address the need for hydroponic systems of all types to meet those requirements as well.

Organic Foods Production Act of 1990 (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.

.... (g) Limitation on content of plan

> An organic plan shall not include any production or handling practices that are inconsistent with this chapter.

USDA Organic Regulations
§205.2 Terms defined.
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.

§ 205.203 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....

Discussion

This document will address three areas:

1. Use of artificial light
2. Use of synthetic mulches including, but not limited to, plastic film and woven landscape cloth.
3. Disposal of crops, substrates, and containers at the end of the crop's production cycle.

Artificial Light

Artificial light used to grow plants is present in the organic standards of EU certification bodies and Canada. The EU Final Report on Greenhouse Production 2013 states the following:

> *In the Group's opinion, the provision of artificial light is in line with the objectives and principles of organic farming, if the normal daylight is insufficient for the normal growing of crops. It should only be allowed on dark, overcast days and for extending the daylight period, and only during autumn, winter and early spring. However, the intensity of artificial light used in overcast or short days should not exceed the Photosynthetically Active Radiation (PAR) of the country during a summer day (21st of June) and the number of hours should not exceed 12 hours of daylight including artificial light.*
>
> *Artificial light should also be allowed for the production of seedlings and herbs in pots, for the forcing of herbs, and for photoperiod induction of flowering.*
>
> *Large production units using artificial light can create a dome of light above the production units ('light pollution'), which can lead to the disruption of natural behavior patterns of birds, bats and insects.*

Lighting during night hours should therefore be avoided, and an appropriate dark period provided for the plants. Where possible, energy-efficient light bulbs, electricity from renewable sources and/or intelligent greenhouse management systems should be used[1].

In addition, here is an example of one EU certifier's standard (Ecocert) for the light spectrum of the artificial light used to grow organic crops:

The maintenance of the temperature of the culture medium and complementary artificial light with lamps adjusted to the light spectrum of the species are authorized over difficult periods (winter conditions in temperate zones, restart of strains, etc.) after approval by Ecocert[2].

The Canadian Organic Standards allow the following:

7.5.9 *Full-spectrum lighting is permitted*[3].

The use of artificial light can mimic the spectral quality of natural light and duration of natural light to these plants during the growing season. Artificial light is sometimes used to promote faster plant growth, or replace natural light altogether. This discussion will seek to determine what types of artificial light are compatible with the principles of organic agriculture.

There is a prohibition for organic livestock in 205.238 (c) (3) to administer hormones for growth promotion. The argument could be made that the use of artificial light designed to grow specific crops faster than can be performed in a natural setting might also need to be prohibited. The allowance to force herbs or induce flowering for the ornamental industry might be considered an exception, since these are necessary to the production of the crop. However, lettuce, other vegetables, and fruits would not require this artificial stimulant to produce a sellable crop.

Synthetic Mulch

Many container systems rely on the use of synthetic mulches to control weeds under the pots in the field, hoophouses or in greenhouses. Some may be impermeable and others are woven to allow some air and water infiltration. Typically, this synthetic mulch is not removed at the end of the harvest season as required of annual organic crops. Instead, it remains in the field for many years, even beyond a decade. For the woven landscape cloth, even though some water and air can infiltrate, it is not porous enough to absorb heavy downpours and can result in runoff and erosion beyond the edges of the synthetic mulch. In addition, the top few inches of the soil below the synthetic mulch can become sterile due to heat buildup beneath the mulch. Hundreds of acres are currently covered using these synthetic mulches for numerous years on organic farms. The adverse effects of synthetic mulches on the natural resources of the farm, as well as secondary effects on adjoining land, are issues that could be addressed.

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[1] https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/final_report_egtop_on_greenhouse_production_en.pdf

[2] http://www.ecocert.com/sites/default/files/u3/Ecocert-Organic-Standard.pdf

[3] http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/pgng-gpms-eng.html

A requirement that these synthetic mulches be covered by a biologically based mulch such as straw, wood chips, hay etc. would mitigate numerous issues associated with this use. The soil temperature underneath a wood chip covered landscape cloth is cooler, and mulch protects the fabric from UV radiation thereby prolonging the useful life of the synthetic mulch. Woodchips or straw (and other naturally derived mulches) are proven tools for reducing the impact of raindrops and thereby enhancing infiltration of rainwater and reducing surface water runoff. Snow and ice would be trapped in the "organic" mulch and lessen the incidence of runoff issues, since these would slowly melt and infiltrate down into the soil.

Another issue to be considered is the percentage of the land covered by the plastic film or cloth. Having large numbers of acres covered by synthetic mulches magnifies the issues mentioned above, and prevents the growth of habitat and food sources for beneficial insects and birds. A percentage of the growing area around the edges and pathways, and through the rows of containers sitting on the mulch, could be grass, beneficial insect habitat, or otherwise left uncovered by the synthetic mulch so the soil can absorb water and provide vegetation that promotes ecological balance and biodiversity.

Disposal of Crops and Containers at the End of the Crop's Production Cycle

The crops and substrate used in container operations will eventually lose their productive capabilities and will need to be disposed of in some manner. Sending dump truck loads of large plastic pots and plastic liners with dead annual or perennial crops to a landfill does not meet the definition of organic production since it does not recycle the nutrients still present in those containers. The EU is currently reviewing a requirement that the substrate and vegetative matter from containers be composted and incorporated on-site and eventually spread on fields that are part of the same operation. The plastic pots can then be reused or recycled. Whether or not the vegetative material and approved organic substrates found in containers is composted and spread on site or at another location, this discussion document asks if consideration should be given to what happens to both the plastic residues and organic matter generated once the containers have outlived their productive capacity.

Public Comments from Previous Proposal and Discussion Documents

In order to have a robust and transparent interaction, these issues are being brought to the public for discussion. While the examples and issues being considered in this document are part of a container production system, if the same issues are found in greenhouse or field grown crops, it would be assumed that any future proposed regulations would apply to them as well.

Discussion Questions

1. Should the use of artificial light be limited to a specific number of hours per day? Describe your rationale for how many hours should be permitted.

2. Should the spectrum and intensity of artificial light be limited to full spectrum, which is as close to natural daylight as possible, or should other types of lighting, such as those that emit the red or ultraviolet spectrum of light or modified intensities, be allowed? Describe your rationale for the spectrums and intensities of artificial light for use in container operations.

3. Should the use of synthetic mulches which remain in place for numerous years, especially in an outdoor production setting, address the issues of soil and water quality as well as natural resource maintenance and improvement elaborated in this discussion document? Please describe the issues you feel are important and how they might be addressed.

4. Should the composting and field spreading of crop residue and substrates from container operations, and the recycling of plastic or non-compostable containers, be addressed within the NOP organic certification system?

Appendix - Definitions

Container – Any rigid or collapsible 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".

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

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).

Subcommittee vote:
Motion to accept the discussion document on Field and Greenhouse Container Production
Motion: Francis Thicke
Second: Steve Ela
Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 29, 2017

Sunset 2019
Meeting 2 - Review
Livestock Substances §205.603
November 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 renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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 cause mastitis.

There are numerous synthetic disinfectants currently on the National List 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.

Questions for the public:

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?

Public comment:
Numerous certification agencies noted this to be an important material for organic livestock production. Chlorhexidine is useful as the active disinfectant in a teat dip in cold temperatures, as compared to iodine, which can be problematic in that type of situation. All commenters agreed chlorhexidine's use in

surgical procedures is essential. One public interest group noted that less toxic alternatives, such as vinegar, lavender essential oil, tea tree oil or hydrogen peroxide, might be better alternatives for the teat dip use, while another noted there are alternative teat dips to chlorhexidine.

The Subcommittee did not feel alternatives were present for this material, and were in favor of retaining it as an approved synthetic as annotated. This material fulfills specific functions and is a necessary livestock tool.

Subcommittee vote:
Motion to remove chlorhexidine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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).

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?

Discussion:
The Livestock Subcommittee has received several comments both supporting and opposing relisting.

Several commenters opposed to the relisting stated:
- There needs to be a comprehensive review of all sanitizers used.

Several commenters in support of relisting stated:
- Sodium hypochlorite is routinely used to sanitize many surfaces to kill pathogenic microorganisms. Chlorine dioxide is routinely used to kill pathogenic microorganisms in water lines because sodium hypochlorite is corrosive to the pipes. No alternatives currently allowed.
- Chlorine dioxide is very important in controlling the growth of microorganisms in our water lines. Sodium hypochlorite is not a suitable substitute in water lines because it is too corrosive.

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. While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of chlorine materials.

Subcommittee vote:
Motion to remove chlorine materials from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Ashley Swaffar
Seconded by: Sue Baird
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Background from Subcommittee: Glucose has been on the National List since 1995, with 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 cow. 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?

Public comment:

Numerous certifiers stated this is a commonly used material on their certified organic dairy operations, other said it was not used a lot, but still supported relisting. Its use for managing ketosis was noted as essential by farmers, milk buyers, inspectors and the organic trade. Environmental and public interest groups stated there were no adverse effects and it is an important material to treat animals. No alternative materials or methods, other than feed ration management around birthing, were mentioned.

On an organic dairy farm, glucose is an essential animal health tool. It is used typically to treat ketosis, and there was universal approval for keeping this material on the National List. Since glucose is an ingredient in calcium gluconate used to treat milk fever, retaining glucose on the National List of approved synthetics also maintains this important tool for treatment of this ailment as well.

Subcommittee vote:

Motion to remove glucose from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Sue Baird
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background from Subcommittee: 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 nonorganic dairy cows relax and "let down their milk". There are some concerns with overuse of oxytocin in nonorganic production systems. In the USDA organic 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 retained placenta. It has been recommended for use with USDA organic livestock since the inception of the USDA organic regulations, 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 for public comment

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?

Public comment:
The two largest milk buyers in the U.S., CROPP Cooperative/Organic Valley and White Wave/Horizon did not support renewal of this material. Numerous comments stated the current annotation "use in post parturition therapeutic applications" is unclear, leading to uses on organic milk animals that do not meet the intention of this annotation. Commenters asked for clarity detailing what time frame is considered "post parturition", and which therapeutic applications are allowed. Some certifiers would not allow its use for "milk let down", others would not allow its use for displaced abomasum, while other certifiers would. Two different certifiers, Pennsylvania Certified Organic (PCO) and California Certified Organic Farmers (CCOF), noted a total of 47 operations had used it, others noted it was not commonly used. Those in favor of relisting stated this is an important material in the dairy health toolkit, to assist animals after giving birth. Those not in favor stated there were preventative measures, as well as other activities that could be performed post birthing, that make oxytocin unnecessary in organic livestock production.

Commenters also noted the annotation was not clear, and the specific health incidents leading to the allowed use of this synthetic hormone were not consistent between certifiers.

Subcommittee Discussion:
Oxytocin has been on the National List of approved synthetics since the USDA organic regulations were implemented. However, over time, methods and materials have been developed that make oxytocin less essential for maintaining animal health and welfare. The expectations and awareness of dairy production tools by consumers has changed over time. They now expect organic milk be produced without the use of synthetic hormones. The Livestock Subcommittee realizes that some producers may need to learn new methods to address post parturition issues, but we believe the knowledge and materials are present, so that there will be no interruption in commerce, economic hardship, or lessening of animal welfare if this material is removed from the National List of approved synthetics. Veterinarians who work with organic dairy farmers, as well as educational organizations that provide information to organic dairy producers can provide this information on the methods and materials used that make oxytocin no longer essential in an organic dairy system.

Subcommittee vote:
Motion to remove oxytocin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (7 U.S.C. 6517) National List (b) (1) (A) (ii) and (iii), Section 2119 (7 U. S. C. 6518 (m) (6) and (7) and/or 7 CFR 205.600(b) (1): essentiality
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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. Tolazoline was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.

Discussion:
There were three written comments on tolazoline submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used.
- The second comment, also brief, stated that the substance should continue to be allowed, since its use lessens animal suffering; and
- The third comment, which was extensive, focused primarily on whether there is a reasonable basis for keeping xylazine—with which tolazoline works in conjunction—on the National List, since the scientific literature on xylazine indicates that there may be pharmacological side-effects and other problems associated with its use.

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of tolazoline.

The subcommittee noted, however, that were xylazine to be removed from the National List in the future, tolazoline would probably no longer be needed for organic production. Thus if xylazine is removed, the NOSB should consider removing tolazoline as well.

Subcommittee vote:
Motion to remove tolazoline from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Copper Sulfate is used in livestock management specifically as a walk-through footbath to help control and prevent hoof-related diseases in dairy cattle and sheep. Some of the specific problems that can affect skin adjacent to the claw horn of dairy cattle and sheep include 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 February 2015 technical evaluation report commissioned by the Livestock Subcommittee, there are no natural (non-synthetic) 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). TR lines 575-580.

The Livestock subcommittee feels that copper sulfate, used after appropriate management practices and disposed of properly, provides a valuable tool to livestock producers and recommends this material stay on the National List.

Subcommittee vote:
Motion to remove copper sulfate from §205.603(b) as topical treatment, external parasiticide or local anesthetic based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Jessie Buie
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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.

Lidocaine was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.
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.

A proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

To amend §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~~ <u>8 days</u> after administering to livestock intended for slaughter and ~~7 days~~ <u>6 days</u> after administering to dairy animals

Discussion:
For the spring 2017 NOSB meeting, there were five comments submitted in support of the continued listing of lidocaine (three from organizations and two from individuals), and there were no comments submitted in opposition. Therefore, it appears that there is still broad stakeholder support for continuing to list lidocaine. Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of lidocaine.

Subcommittee vote:
Motion to remove lidocaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Francis Thicke
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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.

Procaine was last reviewed in 2015, at which time the NOSB voted to renew it, with 3 "yes" votes to remove, 9 "no" votes, and 2 "abstentions."

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

A Proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC as follows:

To amend §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.

Additional information requested by NOSB

1. If procaine were removed from the National List and only lidocaine were available for use as a local anesthetic in organic livestock production, would lidocaine fully meet all potential veterinary needs?
2. Is procaine currently only available for use in combination with an antibiotic?

Discussion:
There were six written comments on procaine submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used, but did not express an opinion on renewal.
- 4 brief comments supported renewal, one of which noted that procaine is not very widely used; and
- One comment, which was more extensive, recommended removal for the following reasons:
    - Procaine is used as a local anesthetic, but is not as effective as lidocaine.
    - Procaine is not widely available, except in combination with the antibiotic penicillin, which is not allowed for use in organic livestock production.
    - There is no benefit to using procaine vs. lidocaine, so having it on the National List likely only creates confusion.

Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

Given the comments received so far, the Subcommittee is unclear whether procaine is currently being used in organic livestock production, and whether it is only available in combination with an antibiotic.

Subcommittee vote:
Motion to remove procaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: essentiality.
Motion by: Daniel Seitz
Seconded by: Sue Baird
Yes: 3 No: 2 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Sulfur-elemental
August 1, 2017

Summary of Petition [Petition for Sulfur (PDF)]:
The petition is for sulfur to be used in livestock production as a livestock parasiticide. Sulfur (elemental) is currently allowed for use in the production of organic crops as an insecticide, for plant disease control, and as a plant or soil amendment. Sulfur is used as a pesticide (repellent for mites, fleas & ticks) for domestic livestock (chickens, turkeys, ducks, geese, game birds, pigeons, equine, cattle, swine, sheep, and goats and for use on dogs). Sulfur is dusted liberally and rubbed into feathers or hair. Sulfur us also used for treatment of listed animals/livestock living quarters to prevent mites, fleas, and ticks.

Summary of Review:

Category 1: Classification

1. Substance is for: **Livestock**

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:

Sulfur is not being used as part of the finished product, but is a mineral used in an isolated form to be used as a pesticide.

   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:

Yes. Sulfur is an abundant element on the earth. Elemental sulfur is found in volcanic sites and salt domes. Sulfur was classically mined using the Frasch process in the U.S. as late as the 1920s. In the Frasch process superheated water is pumped into a sulfur deposit to melt the sulfur, which is then brought to the surface with compressed air. Sulfur produced by the Frasch process was 99.5% pure and required no further purification. In some locations sulfur is found near the earth's surface in sulfur craters. Here sulfur from the deposits is broken up and harvested with various kinds of mining equipment ranging from hand carried baskets to modern conveyor systems.

Sulfur is also found in petroleum, natural gas and fossil products from which it must be removed as a legal mandate to avoid the production of sulfur dioxide, a contaminant of the air. Hydrogen sulfide from petroleum refining and fossil fuels is converted to pure sulfur by the Claus process. The Claus process is used to produce the majority of sulfur available today. In a heating and cooling cycle, hydrogen sulfide recovered from fossil products is combusted to form water and elemental sulfur:

$$8\ H_2S + 5\ O_2 \rightarrow SO_2 + 7/2\ S_2 + 8\ H_2O$$

The addition of an aluminum or titanium catalyst permits the reaction of SO_2 formed during combustion with additional molecules of H_2S to yield sulfur and water:

$$2\ H_2S + SO_2 \rightarrow 3\ S + 2\ H_2O$$

In 2015, recovered elemental sulfur and its byproduct sulfuric acid were produced at 103 operations in 27 States. Total shipments were valued at about $933 million. Elemental sulfur production was 8.7 million tons; Louisiana and Texas accounted for about 52% of domestic production. Elemental sulfur was recovered, in descending order of tonnage, at petroleum refineries, natural-gas-processing plants, and coking plants by 39 companies at 96 plants in 26 States. Domestic elemental sulfur provided 64% of domestic consumption. About 11 million tons of sulfur were used in the US in 2015 (USGS, 2016).

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?

   Sulfur does contain active sulfur compounds §6517(c)(1)(B)(i). Elemental sulfur is a sulfur compound. Its use in this petition is a livestock parasiticide. Sulfur is exempt from a residual tolerance (40 CFR 180.1236) and listed as a stabilizer for food use in 40 CFR 180.930.

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)]

Diatomaceous earth, kaolin and lard are natural substances that may be used for organic production. They are used with sulfur for dustbathing poultry to prevent lice and mite infestations. For example, equal parts lard and sulfur can be used to treat birds for the scaly-leg mite. Another treatment for depluming mites uses a combination of ¾ oz. sodium fluoride (not on the National List), 2 oz. sulfur, ½ oz. of household soap and 1 gallon of water. For lice, a dust bath containing sulfur and lime is effective (Rumball, 1927). In the treatment of the hen house for mites, lice and fleas, it is recommended to not only clean and coat surfaces, but to dust with a 3:1 combination of powdered slacked lime and sulfur (Herrick, 1915). When sulfur is used to treat honeybee colonies for mites, no changes in the hedonic performance of the honey is observed in comparison to a water spray control (Hosamani et al., 2007). Sulfur is not toxic to the honey bee (Kuan and Chi, 2007).

Windblown elemental sulfur from storage piles can result in heavy local deposits: 1 to 100 metric tons/hectare or more. These soils become completely barren with pH 1 to 2. Reclamation is possible by adding large amounts lime, $CaCO_3$ (Nyborg, 1978).

Sulfur as an element is not particularly flammable. However, combining sulfur with potassium chlorate can produce a very unstable, even explosive mixture (Tanner, 1959). Strong oxidizers such as perchlorates, peroxides, permanganates, chlorates can react with sulfur spontaneously cause a fire or explosion (NJ Health, 2011).

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)]

Elemental sulfur is found naturally and combined with iron and base metals and sulfide minerals. In petroleum, sulfur occurs in a variety of complex molecules. In natural gas sulfur is present as hydrogen sulfide. Sulfur is present in plants, animals and humans in a number of biological molecules. Recovered sulfur is the primary source of sulfur used for industrial applications. It is recovered from sulfur ores, during the refining of oil, and through the purification of natural gas (Komarnisky et al., 2003). Table 2 provides the sources of sulfur in the environment.

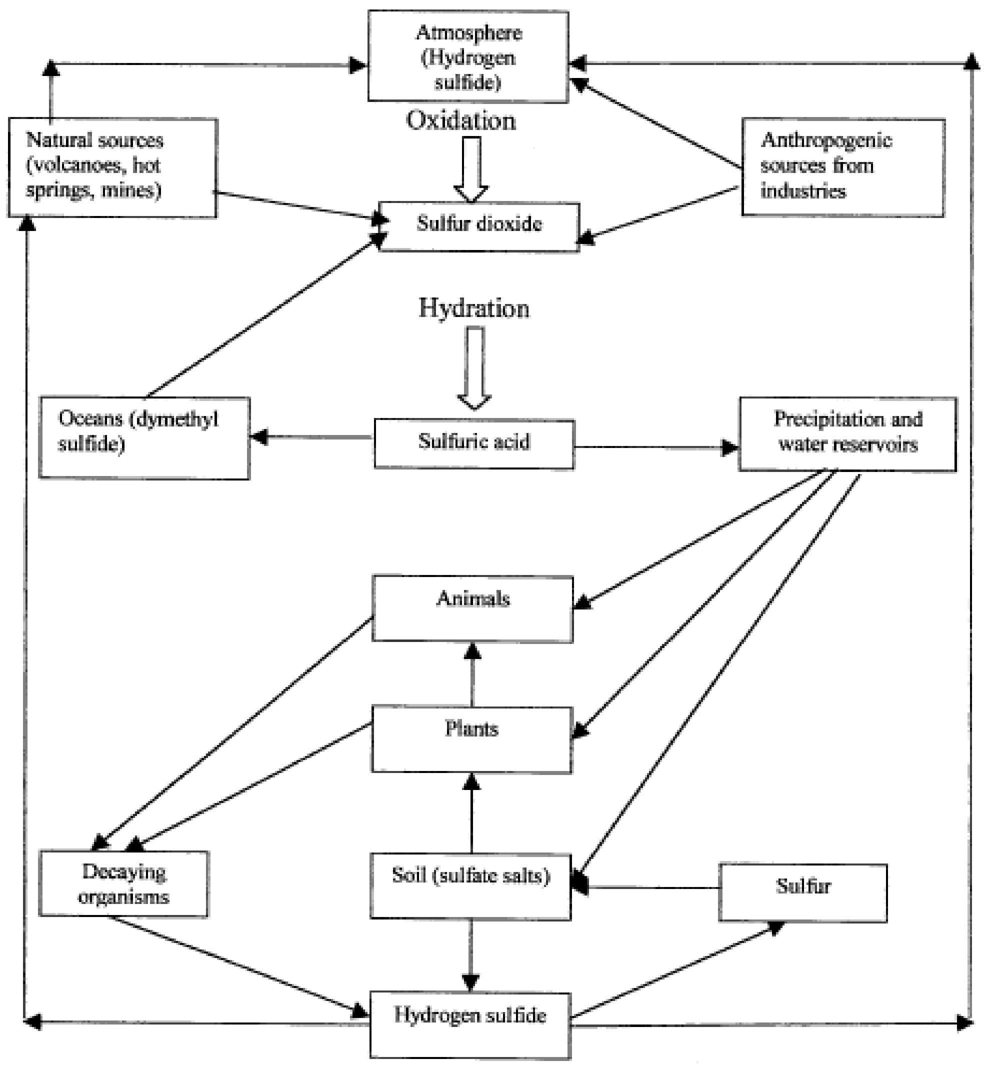

Fig 2. A simplified diagram of the natural sulfur cycle (Komarniskey et al., 2003)

Sulfur is essential for life in a range of concentrations as a part of or in combinations with other molecules. However, sulfur is known to cause polio encephalomalacia in ruminants and may inhibit arachidonic acid metabolism and platelet plasma membrane function in rabbits (Komarniskey et al., 2003). Consumption by ruminants of a high dietary percentage (>0.3%) of sulfur as elemental sulfur or sulfate can cause toxic effects. Sulfur bacteria in the rumen produce the poisonous gases, hydrogen sulfide and sulfur dioxide that eructate from the rumen and are absorbed through the lungs. Diets rich in sulfate can depress feeding. In spite of the liver's capability for detoxifying sulfide in the blood, extreme cases of sulfur toxicity can lead to death (Kandylis, 1984).

Elemental sulfur is insoluble in water. However, its solubility in organic solvents, such as methanol, is greater. Tests with zebrafish larvae showed sulfur toxicity at concentrations as low as 1%. A sulfur concentration that high may be achieved by dilution with methanol (Svenson et al., 1997).

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

Elemental sulfur is transported from mining, manufacturing and transshipping sites in pipelines and in tank cars in molten form. Molten sulfur has the potential to emit hydrogen sulfide gas, which 1) presents a safety hazard to those working in the vicinity and 2) an environmental hazard, since H_2S is very toxic (Sulphur Institute, 2013).

Pollution of the soils can take place where elemental sulfur is stored in the open. Wind eroding fine dust from sulfur blocks or grains stored in the open is deposited downwind of the manufacturing or storage facility. Over several years surrounding soils can become acidified with pH as low as 1. Acidification is the result of soil bacteria converting the sulfur to sulfuric acid. (Nyborg, 1978).

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

Current available U.S. Environmental Protection Agency toxicity studies and literature searches for elemental sulfur do not indicate any systemic toxicity associated with elemental sulfur exposure and no endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. Acute oral toxicity is a category IV hazard, i.e. fifty percent lethal dose (LD_{50}) is greater than 5000 milligrams (mg) per kilogram (kg) of body weight. Only the word caution or no signal word is required on the label for elemental sulfur for acute toxicity. Elemental sulfur is considered a category III hazard for dermal exposure and inhalation. For dermal exposure, LD_{50} > 2000 mg/kg ≤ 5000 mg/kg. Only the signal word caution is required. For inhalation, LC_{50} > 0.5 mg/L < 2.0 mg/L and the signal word caution must be on the label. Sulfur is an eye and skin irritant (category III, moderate irritation (erythema) at 72 hours), but is not a skin sensitizer. The EPA is satisfied that in most cases labels contain sufficient information about personal protective equipment and reentry and this information is generally followed by applicators (EPA, 2013a). The EPA's review of incident data indicates that both the relative number of reported incidents and the severity of reported health effects are low.

In livestock production, H_2S is a hazard to human health. This colorless toxic gas with a rotten egg odor is produced during the degradation of liquid manure stored in anaerobic conditions within agricultural livestock operations. In spite of regulatory limits for H_2S exposure of 1 ppm, levels as high as 9, 22 and 97 ppm have been reported for poultry, beef/dairy and swine production, respectively (Guarrasi et al., 2015). The contribution of elemental sulfur to the H_2S livestock production hazard for workers is negligible (EPA, 2013a).

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)]

Elemental sulfur is generally used for livestock insecticide applications in granular or finely powdered form. Liquids and mixtures are also in use. Small amounts of dusting sulfur or liquids find their way into soils or water, either as part of the manufacturing process, transport and storage or application to animals. None of these applications is recognized as an environmental problem (EPA, 1991b). In soils, sulfur is oxidized to sulfuric acid (H_2SO_4) by soil bacteria mostly of the genus *Thiobacillus*. Important factors for the rate of oxidation include 1) the fineness of the sulfur particles, 2) the resident population of *Thiobacillus* spp., 3) soil temperature and 4) soil moisture content. Powdered sulfur is quickly oxidized (Nyborg, 1978). In general there is very little effect on the vegetation, soil or the invertebrate population of the soil from small amounts of sulfur dust. Too much sulfur, e.g. from a sulfur storage or manufacturing facility will cause the pH of the soil to drop as low as pH 2.5 or lower. Although, H_2SO_4 in the soil can generally diffuse in the soil as a sulfate ion leachate, the introduction of high levels of sulfur can cause the loss of vegetative ground cover and affect a number of insect taxa (Carcamo et al., 1998). High sulfur contamination and subsequent acidification has a clear negative effect on earthworms, snails, and several ground beetle species. Among the beetles, ecological specialists are those most vulnerable to acidification, whereas ecological generalists are more resistant (Carcamo and Parkinson, 2001). Earthworms have an important influence on the sulfur turnover in the soil caused by their burrowing, feeding, digestion and egestion (Grethe et al., 1996).

Many species of sulfur reducing bacteria produce and metabolize elemental sulfur in a number of chemical transformations, both in soils and water. Quite a few of these have not yet been identified or characterized. In some cases, particularly in the absence of sufficient nitrate, hydrogen sulfide is produced in the metabolism of elemental sulfur. Hydrogen sulfide is responsible for a serious sulfur odor (Liang, 2016). Livestock operations frequently produce significant levels of hydrogen sulfide, notwithstanding from general practice rather than prevention or treatment for parasites using elemental sulfur (Guarrasi et al., 2015).

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

Sulfur has been used as a pesticide in the United States since the 1920s, and is currently registered for use as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Although sulfur has insecticidal and fungicidal properties when used as directed, it is also an abundant and ubiquitous element in the natural environment (Brown, 1982, EPA, 2013b).

Elemental sulfur is combusted at volcanic sites, and metabolized by sulfur bacteria to produce hydrogen sulfide that enters the atmosphere. Hydrogen sulfide in the atmosphere makes clouds more reflective producing a cooling effect on the earth. Sulfur in the atmosphere is involved in the prevention of global warming (Blake, 2007, Wingenter et al., 2007). Elemental sulfur is required for the existence of animal and plant life. Available evidence indicates that elemental sulfur is rapidly and extensively incorporated into the natural sulfur cycle via oxidation to sulfate and/or reduction to sulfide with subsequent volatilization (Lovelock, 1974; EPA, 2013b). The sulfur cycle can be simplified to four basic step: 1) mineralization of organic sulfur (e.g. methionine, cysteine) to an inorganic form (H_2S), 2) oxidation of sulfide, elemental sulfur and related compounds to sulfate, SO_4^{2-}, 3) reduction of sulfate to sulfide, 4) microbial immobilization of sulfur compounds and subsequent incorporation into an organic form of sulfur (Shaver, 2014; la Riviere, 1966). A simplified diagram of the natural sulfur cycle is shown in Fig 2.

Hydrogen sulfide entering the atmosphere reacts with oxygen to form sulfur dioxide. In water, sulfur dioxide forms hydrogen sulfite which in excess is responsible for generating acid rain, i.e. fossil fuels containing sulfur that are burned in the presence of air form sulfur dioxide that is subsequently absorbed into rain water. The pH range for acid rain is 4.2-4.4. Acidification of lakes, rivers and streams resulting from acid rain has led to the devastation of ecological communities and has put many on the brink of destruction. Industrial nations recognizing the environmental problems caused by acid rain have reacted by developing processes to remove sulfur from fossil fuels. Recovered sulfur is usually very pure (EPA, 2016).

Table 2 Occurrence of Sulfur in Nature			
Sources			
Natural			
	Volcanic deposits		Mixed with gypsum and pumice stone
			Realgar or ruby sulfur (arsenic sulfide)
	Subterranean deposits		
		Elemental	Sulfur Ore
		Metallic Sulfides	Acanthite, arsenopyrite, bismuthinite, chalcopyrite, cinnabar, cobaltite, copper pyrite, digenite, galena, iron, pyrite, molybdenite, pentlandite, sphalerite
		Non-metallic sulfides	Angelite, anglesite, barite or heavy spar, celestite, gypsum, thenardite
		Hot Springs	Sulfurous water
		Fossil Fuels	Coal, petroleum, natural gas
	Dietary		
		Food	Onion, cabbage, cauliflower, broccoli, oil of garlic, mustard, eggs
		Vitamins	Thiamine, pyridoxine (vitamin B6), biotin
		Amino Acids	Methionine, keto-methionine, cysteine, cystine, homocysteine, cystathionine, taurine, cysteic acid
		Preservatives	Sulfur dioxide
	Biological		
		Biochemicals	Proteins, lipoic acid, coenzyme A, glutathione, chondroitin sulfate, heparin, fibrinogen, ergothionine, estrogens, ferredoxin
		Microorganisms	Aerobic heterotrophic (most fungi and aerobic bacteria), *Desulfo vibrio* and *Desulfo tomaculum*, chemoautotrophic (e.g., thiobacillus), photoautotrophic (Chlorobium and Chromatium)
Industrial			
	Fertilizers		Phosphates and Ammonium sulfate
	Anthropogenic	Combustion of fossil fuels	SO_2, H_2S
from Komarnisky et al., 2003			

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)]

In livestock production, control of parasites living on the outside of animals (ectoparasites, e.g. mites) and in their housing should focus on excluding vectors such as wild animals and rodents from the production system. Pens and housing should be kept clean. In addition, caretakers should ensure that they do not transfer mites, ticks or lice from an infected population to a non-infected one. This can include placing baits and traps near the production facility for both the ectoparasites and their vectors, removing spilled feed, and monitoring rodent and wild bird activity. Buildings should be painted and sealed. Wood buildings must be treated to prevent infestation. In addition, livestock should be monitored regularly for infestations. Wild animal populations in fields, pastures, activity areas and forage should be monitored, and potentially infested animals should be sequestered from un-infested herds. Forage and pasture conditions should be monitored, since ectoparasite load is often affected by the extent of grass cutting. Livestock lines that are generally resistant to ectoparasite infestation should be chosen for breeding (Yakout and Wells, 2013).

Biological control of ectoparasites with pathogens such as nematodes, bacteria, fungi and viruses and predators that naturally prey on ectoparasites of livestock are potentially useful in ectoparasite management. For example, both parasitic wasps and the common bacterium, *Bacillus thuringensis* may be useful to protect sheep from various infesting flies, where the bacteria is also effective against lice. Some pathogenic fungi also selectively attack flies, lice and ticks (Wall, 2007).

2. **For Livestock substances, and Non-synthetic 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)]

Sulfur is currently used in crop production for pesticides on plants. During discussion, there was a question about the process of mining sulfur and whether that was detrimental to the environment. Much of the sulfur produced is a by-product of the petroleum, natural gas, and fossil industry. While there were few written resources discussing the human health effects of sulfur, current available U.S. Environmental Protection Agency toxicity studies and literature searches for elemental sulfur do not indicate any systemic toxicity associated with elemental sulfur exposure and no endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. In livestock production, H_2S is a hazard to human health. This colorless toxic gas with a rotten egg odor is produced during the degradation of liquid manure stored in anaerobic conditions within agricultural livestock operations. There are no alternatives except for the prevention of pests in the first place. Prevention methods include keeping livestock housing clean and using biological control (natural predators of pests). The information provided does not indicate a sulfur is incompatible with sustainable agriculture.

Subcommittee vote:
Motion to add sulfur as petitioned at §205.603
Motion by: A-dae Romero-Briones
Seconded by: Jessie Buie
Yes: 4 No: 0 Abstain: 2 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB August 29, 2017

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Hypochlorous Acid
August 15, 2017

Summary of Petition for Hypochlorous Acid:
Hypochlorous acid has been petitioned as a synthetic substance for addition to the National List at §205.603, as a topical treatment for pinkeye and wounds in livestock.

Hypochlorous acid was previously petitioned for use as a sanitizer in crop production, in livestock production, and in handling. In April 2016, the NOSB recommended adding hypochlorous acid to the National List at § 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems; at § 205.603(a)(7) Chlorine materials—disinfecting and sanitizing facilities and equipment; and at §205.605(b) Chlorine materials—disinfecting and sanitizing food contact surfaces.

The NOSB favored adding hypochlorous acid to the National List as a sanitizer because the technical review indicated that although hypochlorous acid is chlorine-based, it is used at a lower concentration and is safer for health and the environment than the other chlorine-based sanitizers already on the National List: namely, chlorine dioxide, sodium hypochlorite, and calcium hypochlorite.

Summary of Review:
The petition to add hypochlorous acid to the National List as a topical treatment for pinkeye and wounds in livestock entails different considerations than when hypochlorous acid was under review as a sanitizer. Livestock producers already have a number of natural (nonsynthetic) materials available for treatment of pinkeye and wounds.

The July 12, 2017, technical report (TR) of hypochlorous acid for use as a topical treatment for pinkeye and wounds in livestock mentions many nonsynthetic materials in use for pinkeye and wounds in livestock: calendula, chamomile, garlic, aloe vera, seabuckthorn, kiwi fruit, chickory, St. John's wort, olive, white poplar, rose, elder, navalwort, mullein, veronica, physic nut, bacterial predators, black kelp alginates, honey, sugar, pineapple fruit enzymes, omentum, chitosan, platelet gel, pink trumpet tree, Brazilian pepper tree, siam weed, echinacea, cochlearia, goldenseal, eyebright, essential oils, breast milk, and cod liver oil.

Personal communications with organic dairy farmers by the LS member leading the review of this material indicate that many use a commercially available formulation of the nonsynthetic materials aloe, garlic, calendula, and chamomile, and find that it works well on wounds and as an eyewash for pinkeye.

In light of the many nonsynthetic materials available and in use by organic livestock producers for wounds and pinkeye, the Livestock Subcommittee does not think it necessary to add a chlorine-based synthetic material to the National List for the same use.

Category 1: Classification

1. Substance is for: **Livestock**

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:

HOCl is produced by electrolyzing a brine solution made with purified water and sodium chloride

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?

Hypochlorous acid is petitioned as a livestock medicine.

Category 2: Adverse Impacts

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

The 2015 TR (lines 140-153) mentions that there can be a reaction with organic material (humic acid) which can lead to some potential concerns. It does go on to state though: It is generally accepted that carcinogenic and teratogenic trihalomethanes and haloacetic acids are not formed by the action of hypochlorous acid in neutral or near-neutral solutions (Satyawli et al., 2007). However, because only small amounts of hypochlorous acid would be used, sprayed directly onto wounds or eyes of animals, there would be little chance of interaction with other materials used in organic farming.

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)]

"In Huang's et al., 2008 review of the scientific literature, the authors suggested that hypochlorous acid penetrates cell membranes and produces hydroxyl radicals, which exert their antimicrobial activity through the oxidation of key metabolic systems" (2015 TR, lines 253-255).

"Diluted aqueous solution of hypochlorous acid decomposes very slowly in the dark but more rapidly in the presence of light, particularly rapidly in full sun light, by producing hydrogen chloride and oxygen. Some chlorine and chloric acid may also develop. Chlorine released into the environment is distributed into water and preferably air.
In water and in atmosphere chlorine/hypochlorite undergoes photolysis with an estimated half-life of 1-4 hours, depending on the time of the day. In natural water, in the presence of organic or inorganic compounds, the free available chlorine immediately reacts forming various chlorinated by-products e.g. chloramines and chloromethanes, which are mainly distributed to the hydrosphere, but are also able to

transfer to some extent to the atmosphere depending on their intrinsic properties. A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity (2015 TR lines 602-612).

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

This substance is formed by the electrolysis of a sodium chloride solution. Any environmental concerns would be from a spill during manufacturing or transport of a formulated end product.

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

Chlorine disinfectants have been shown to cause occupational dermatitis or skin irritation (2015 TR, line 662). However as a wound or pinkeye spray, only a small amount of hypochlorous acid would be sprayed directly onto an animal, so threats to human health would be minimal.

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)]

Because only small amounts of hypochlorous acid would be used, sprayed directly onto wounds or eyes of animals, there would be no chemical or biological effect on the agroecosystem, including soil organisms.

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

The TR, (lines 596-612) states that hypochlorous acid in aqueous solutions at pH< 7. Was of minimal toxicity to birds, but could be very toxic to fish and freshwater invertebrates. However as a wound or pinkeye spray, only a small amount of hypochlorous acid would be sprayed directly onto an animal, so it would not contaminate water resources.

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 noted in the 2017 TR (and above), there are many non-synthetic materials already available and currently being used by organic livestock producers as medical treatments for livestock wounds and pinkeye. There are also management practices that can be used to prevent pinkeye infections, including fly control; bolstering animals' immune system with vitamins, trace minerals, and kelp meal; and use of vaccines.

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)]

Given the many alternatives currently available, the Livestock Subcommittee does not think hypochlorous acid is a necessary material for livestock producers for treating wounds and pinkeye in livestock.

Subcommittee vote:

Motion to add hypochlorous acid at §205.603
Motion by: Francis Thicke
Seconded by: Harriet Behar
Yes: 1 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB August 29, 2017

National Organic Standards Board
Livestock Subcommittee Proposal
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production
August 29, 2017

I. INTRODUCTION

The use of parasiticides in organic production is strictly confined to emergencies under the current regulation. Parasiticides cannot be used routinely, but animals in need of medical attention cannot be ignored in favor of retaining organic status. Typically farmers perform preventative practices such as introducing clean animals into their herds or flocks, selecting breeds which have high resistance to parasites, and managing their land, especially pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, 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, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List.

A discussion document was circulated in Spring 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to § 205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if clarification of the term "emergency" was 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 by the USDA.

During the two years these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested the term emergency was not sufficiently well defined and use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an "emergency".

This proposal addresses the concerns of NOSB members and the organic stakeholder community to clarify when approved synthetic parasiticide use is performed as an emergency treatment. This proposal describes when the use of the synthetics to treat parasites would be seen as an emergency treatment. Included in the proposal is the monitoring of parasite threshold levels and examples of various organic production practices that would have been ineffective in controlling the parasite problems. Having this clarity on what circumstances constitute an emergency treatment provides operators and certifiers a consistent and clear standard. Organic stakeholders including livestock producers, certifiers consumers, handlers and others expect use of synthetics are overseen as part of a comprehensive organic system plan. The NOSB recommended change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics.

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. Public comment

The NOSB asked the following questions in our discussion document for the April 2017 meeting:

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?

Numerous certifiers and organic stakeholders stated they agreed with the necessity of providing further clarification for the term "emergency" when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk, Some stated that describing expectations of what constitutes an "emergency" provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Below is a sampling of responses to our questions:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis and visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained provided, that, such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

The proposal should include specific methods and practices as well as define "emergency" use to ensure consistency among producers and certifiers. "Emergency" should be defined as a situation that significantly jeopardizes the well-being of the animal treated and/or threatens to undermine the overall preventative practices protecting the rest of the herd or operation. An emergency should be demonstrated by a recommendation from a veterinarian, fecal tests, or other specific, measurable methods to ensure consistent enforcement.

"Emergency" with respect to the use of synthetic parasiticides is defined as a serious parasite load that effects the immediate welfare of an individual animal, where the use of parasiticides is the only way to protect that animal's welfare after other documented methods of treatment have failed.

The term "emergency" should mean the animal is infested and sick. If the health of the animal is compromised, the animal needs to be tested to validate the emergency. If validated, then it should be prescribed treatment. All of this should be done by a licensed veterinarian. Parasiticides shouldn't be used as a preventative method or as a regular routine to maintain a healthy animal. The veterinarian should approve any prescribed parasiticides before the farmer administers any medicine to the animal. There should also be specific preventative practices implemented to minimize the use of parasiticides. These include such things as not overgrazing the pastures; placing the feed in troughs instead of on the ground; and not overstocking the pastures with too many animals.

A definition of "emergency"- A sudden, irregular or unexpected situation that requires urgent attention."

Clarifying the hierarchy defined at §205.238(a-b), perhaps drawing from the structure of the Facility pest management standard at §205.271.

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis and visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained provided that such treatments are allowed under §205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a). For further clarification, the organic system plan's preventive measures should be defined through a hierarchy of management practices first, natural materials second, and approved synthetics third.

Further clarification will assist certifiers in enforcing these regulations consistently.
We support a definition of emergency that clarifies the following:

- *That the procedure is not routine.*
- *That preventative measures have failed.*
- *That identifies testing or procuring the recommendation of a veterinarian to determine infestation and whether the animal's life is at risk.*
- *Steps are taken to prevent a reoccurrence.*

This clarification will help certifiers with enforcement by having a specific area of the rule to cite that prevents routine use and requires a plan to prevent a similar issue from reoccurring.

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."

The Organic Livestock and Poultry Practices (OLPP) Final Rule (82 FR 7042, December 19, 2017) addresses in a general way how internal parasite problems should be addressed on an organic livestock operation. Public commenters asked the NOSB to consider the OLPP requirements and the NOSB livestock subcommittee believes this proposal further enhances the requirements of the OLPP.

Organic livestock operations must have comprehensive plans to minimize internal parasite problems in livestock. The plan will include preventive measures such as pasture management, fecal monitoring, and emergency measures in the event of a parasite outbreak. Parasite control plans shall be approved by the certifying agent."

V. Discussion

Public commenters and the NOSB agree that clarification is needed, both for what constitutes an emergency, and what should be required of an operator to lessen reliance on routine use of approved synthetic parasiticides. The Livestock Subcommittee recommends additional rulemaking at §205.238. Both the crops and handling sections of the final rule contain a pest management hierarchy requiring methods of control first, use of natural materials second and use of approved synthetics as a last resort. This proposal follows a similar hierarchy, offering a clear and verifiable system for both operators and certifiers.

Each age and type of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. These scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency. Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of the synthetic parasiticides is a last resort after other activities have been shown to be ineffective in parasite control. The short wait time proposed by the NOSB between use of these synthetic parasiticides and the sale of organic livestock products, should only be performed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as information that will result in consistency between certifiers when implementing this rule.

Examples of practices and monitoring are listed in the proposed rule below. Rather than providing a list that states the only methods of parasite monitoring and management, the proposal below provides examples which can allow producers and certifiers the flexibility to develop and approve other methods that perform the same function.

The proposal below would be sufficient in providing the needed clarification, and would not require a further definition of the term "emergency" in §205.200 Terms Defined. Since the word "emergency" is used in numerous places throughout the final rule, adding a definition that mostly relates to synthetic parasiticide use could result in unintended effects on other areas of the organic regulation.

This proposal strengthens the language within the Organic Livestock and Poultry Practices rule, and does not contradict it.

VI. PROPOSAL

Below is the current standard:

§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;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

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

(6) Administration of vaccines and other veterinary biologics.

(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 to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

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

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under §205.603, or any substance that contains a nonsynthetic substance prohibited in §205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis

This is the additional language to be added to §205.238(c)(4) [new text *in italics]:*

(4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*

i) Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.
ii) Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.

iii) Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.

iv) Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.

v) When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

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

Subcommittee vote:
Motion to approve the proposal on clarifying "emergency" for use of synthetic parasiticides in organic livestock production.
Motion by: Harriet Behar
Seconded by: Dan Seitz
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB August 29, 2017

Sunset 2019
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
November 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.

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

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: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/22

Subcommittee Review:

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 found in the Everything Added to Food in the United States (EAFUS) inventory, as it is referred to in 21 CFR Part 582—Substances Generally Recognized as Safe (GRAS)—at §582.99 when used as an adjuvant with pesticides (TR lines 63-65). The substance is also listed by EPA as an inert ingredient in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) pesticide products applied to food use sites (e.g., food crops, animals used for food) and nonfood use sites (e.g., ornamental plants, highway right-of-ways, rodent control). In addition, attapulgite can be used, under 40 CFR 180.910 Inert 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 (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). The substance meets OFPA criteria.

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

At the Spring 2017 NOSB meeting there was public support for re-listing due to active use of the material by certified operators. A couple comments were made that, overall, the material does not appear to be in widespread use and may not be necessary for the industry. The Handling Subcommittee supports continued listing of attapulgite on the National List.

Additional information requested by NOSB: None requested.

Subcommittee vote:
Motion to remove attapulgite from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Joelle Mosso
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/22

Subcommittee Review:
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.

At the Spring 2017 NOSB meeting public comment was received in strong support from the organic wine industry of relisting bentonite on the National List. A couple comments were made suggesting need to review the impact of mining activities in the production of this material; no new information was provided regarding that mining concern.

Bentonite satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports continued listing of attapulgite on the National List.

Additional information requested by NOSB

None requested.

Subcommittee vote:

Motion to remove bentonite from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Joelle Mosso
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/22

Subcommittee Review:

Background:

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

Diatomaceous earth (DE) 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 three 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. At the Spring 2017 NOSB meeting, public comment was received in strong support from numerous stakeholders for the relisting of DE on the National List. A couple comments were made suggesting need to review the impact of mining activities; no new information was provided regarding the mining concern.

Diatomaceous earth satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports continued listing of the substance on the National List.

Additional information requested by NOSB: None requested.

Subcommittee vote:

Motion to remove diatomaceous earth (DE) from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Joelle Mosso
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/22

Subcommittee Review:

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 is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.
Ancillary Substances: None

At the spring 2017 NOSB meeting there were a large number of public comments submitted in support of nitrogen remaining on the National List, and none in opposition.

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.

Subcommittee vote:

Motion to remove nitrogen from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Lisa de Lima
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/22

Subcommittee Review:

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

Public comment from the spring 2017 NOSB meeting stated sodium carbonate is essential for use as a leavening agent, neutralizer in baked goods, frozen desserts, and soy base extraction. It is also used as a pH adjuster in organic laundry detergents. One certifier commented that it is used to clean fruit and remove mold. Overall public comment was in support of sodium carbonate remaining on the National List. There was one commenter that requested a technical report to examine possible hazards during mining and manufacturing, need, and alternatives. One commenter requested clarification regarding which manufacturing processes are considered non-synthetic and permitted under the current listing.

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.

Sodium carbonate satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports its continued listing.

Additional information requested by NOSB: none

Subcommittee vote:

Motion to remove sodium carbonate from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Lisa de Lima
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

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: Sunset renewal notice 2017 (82 FR 14420)

Sunset Date: 03/15/22

Subcommittee Review:

Background:

Acidified sodium chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitations for using in direct food contact and as an indirect food additive:

- Direct Food Contact (Secondary Direct Food Additive, 21 CFR 173.325) – 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 Food Additive (Sanitizing solutions, 21 CFR 178.1010) – Food-processing equipment and utensils, and other food-contact articles

Manufacture:

ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with citric acid. Sodium chlorite and citric acid 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, 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 annotation on the National List specifies that only citric acid may be used to acidify sodium chlorite.

Discussion:
At the spring meeting we received comments both supporting and opposing relisting of ASC.
Comments in support of relisting stated:

- This is an essential tool in the fight against food borne pathogens
  Comments opposed to relisting stated:
- NOSB should do a comprehensive review of sanitizers.

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.

   This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of acidified sodium chlorite (ASC).

Subcommittee vote:
Motion to remove acidified sodium chlorite (ASC) from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Ashley Swaffar
Seconded by: Lisa de Lima
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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

All public comment received during the spring 2017 NOSB meeting was in favor of retaining carbon dioxide on the National List.

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.

Subcommittee vote:

Motion to remove carbon dioxide from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Background:

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: The NOSB has received several comments both supporting and opposing relisting. Several commenters opposed to the relisting stated: There needs to be a comprehensive review by NOSB of all sanitizers used. Several commenters in support of relisting stated: Essential materials required for food safety. To the best of our knowledge, our partners in dairy production as well as our member farms choose chlorine materials as the preferred sanitizer for food contact surfaces. Disallowing sodium hypochlorite, calcium hypochlorite and chlorine dioxide would have a profound effect. Please keep Chlorine Materials on the National List.

Chlorine materials are vital sanitizing agents that are used to sanitize food contact surfaces such as equipment and utensils. Chlorine is desirable because it is effective and because it evaporates and leaves little residue. The majority of our organic manufacturing facilities rely on chlorine to prevent the growth of pathogenic microorganisms. We request that chlorine materials remain on the list of substances that are allowed in organic handling.

While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation. There are also specific requirements to use chlorine above the 4ppm SDWA limit in several commodity specific industries. For example, as stated in 9 CFR 590.516 *Sanitizing and drying of shell eggs prior to breaking* "Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent.[1]"

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 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.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of chlorine materials.

Subcommittee vote:

Motion to remove chlorine materials from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Ashley Swaffar
Seconded by: Joelle Mosso
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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

[1] http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec590-516.pdf

Recent Regulatory Background: Sunset renewal notice 2017 [(82 FR 14420)]

Sunset Date: 03/15/22

Subcommittee Review:

Background:

Use: Magnesium chloride is used in organic food processing as a processing aid, as a coagulant/firming agent in tofu production, and used in certified organic dietary supplements. 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 USDA organic 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". Similar comments were submitted during the 2017 spring NOSB meeting in response to the material's 2019 sunset review.

During its previous sunset 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 organization 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. However, public comment received during the spring 2017 NOSB meeting pointed out that magnesium chloride is also used in certified organic dietary supplements.

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 for this 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 at the time supported 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 2016 TR 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)

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

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? If not, why?
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. If only non-synthetic magnesium chloride was allowed in organic processing and handling, would the supply be sufficient for all users?
4. Is there any difference in functionality or application between synthetic and non-synthetic magnesium chloride?
5. Besides a coagulant in making tofu, are there any other uses of magnesium chloride in organic processing/handling?

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of magnesium chloride.

Subcommittee vote:

Motion to remove magnesium chloride from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

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 commenters opposed continued listing of this material during the sunset review in 2015, nor during the Spring 2017 review (advanced sunset review).

Potassium acid tartrate is currently allowed under the National Organic Program (NOP) 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 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 technical report (TR), it recommended continued listing of potassium acid tartrate. A new TR, dated January 11, 2017, was received and is utilized for this 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).

FDA 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 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. Comments from the Spring 2017 NOSB review agreed that this material could be reclassified. The Handling Subcommittee supports continued listing of this material.

Additional information requested by NOSB: none

Subcommittee vote:

Motion to remove potassium acid tartrate from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Steve Ela
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Background:
The listing for sodium phosphates was recommended for addition to the National List in 1996 with the "dairy use only" annotation. The material is derived from phosphoric acid.

Uses: pH control agents and buffer, acidulant, sequestrant, texturizer, and nutrient. The NOP regulations restrict the use of sodium phosphates to organic dairy products only. In milk and cheese, they act as stabilizer, and as an emulsifier in cheese. Disodium phosphate can be used as a processing agent in heavy whipping cream, where it binds to milk minerals to prevent the milk from coating the equipment during processing. Sodium phosphates are used in some organic milk products, such as half and half and heavy whipping cream, to stabilize the milk protein and to ensure the products do not separate or lose protein prior to consumer use (Technical Report 2016).

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 (mono- 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). They also noted low calcium reported in susceptible individuals (p 6).

On the topic of the effect of phosphates on bone health, the 2016 technical report (TR) identified studies showing a range of conclusions. For example, one study found that phosphate additives were more harmful to bone health than other phosphorus sources (Kemi et al. 2009) (TR lines 615-622).

While another study showed that higher dietary phosphorus does not always lead to the associated negative health effects (Rue and Kestenbaum 2009) (TR lines 624-628) This is just one example of the contradictory studies presented in the TR.

The 2001 TAP suggests calcium citrate, potassium citrate, and sodium citrate as possible substitutes in certain applications such as dairy cheese processing, as well as calcium citrate as an alternative to trisodium phosphate in milk processing. The TAP also listed a number of alternatives such as lecithin, agar, alginic acid, pectins and gums, but these were only identified as appropriate for soy processing. (TAP lines 404-425)

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 (Japan).

Discussion: In 2015 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 an 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. Other public comment noted that while phosphorous is not listed on the nutritional panel, it would be listed on the ingredient panel when used as an ingredient. When used as an indirect food additive or processing aid, sodium phosphates may not appear on the ingredient panel as additives in these classes are not always required to be labeled. 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.

Public comment from the Spring 2017 NOSB meeting was varied, similar to the public comment received during the 2015 meetings. The spectrum included some commenters requesting sodium phosphate be removed from the National List due to human health concerns and lack of essentiality, with others suggesting an annotation limiting the material to those uses considered essential. One organization noted that research on sodium phosphates found negative impacts on bone, kidney, and heart health and that that phosphate foods additives are more readily absorbed during digestion resulting in a higher phosphorus load compared to naturally occurring phosphate. Alternatively, trade groups commented that health issues were linked to only a small segment of the population (individuals with chronic kidney disease) and that research into overconsumption and wider population impacts was currently insufficient to draw conclusions.

Public comment from handlers and processors stated that sodium phosphate is essential in organic cheese products, including liquid and powdered forms. Specifically, the material acts as an emulsifier and stabilizer for shelf stable cheese products. Handlers also reiterated sodium phosphates were essential for high protein dairy beverages for protein stability. An interest group questioned if additives for novel products like high protein dairy beverages should be considered essential.

The subcommittee requested information from public about alternatives used in Europe. A trade association noted that due to differences in cultures and consumer preference products found in America did not have the same demand in Europe therefore the need for sodium phosphates is different by region.

In Conclusion: There are 4 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

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

The Subcommittee would like to hear from manufactures about whether they have tried alternatives such as calcium citrate, potassium citrate, and sodium citrate, and what the results were.

Subcommittee vote:

Motion to remove sodium phosphates from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima
Seconded by: Tom Chapman
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Background:

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 nonorganic animals. Slaughterhouses do not separate certified organic and non-organic offal. Certified organic intestines from certified animals are not available commercially.

International Standards:

A review of international standards showed casings are allowed in the EU. Casings are not listed in the Japanese Agricultural Standard for Organic Processed Foods (JAS) standard, not do they appear on the indicative list of additives in the Codex guidelines. IFOAM does not allow it, unless by regional variation. Canada only allows it for collagen casings.

Discussion:

Since 2007, all casing sunset reviews have considered limitations on the availability of casings produced from organically raised livestock and agreed that 205.606 listing is appropriate. Echoing comments in 2015 and earlier, comments on casings submitted to the Spring 2017 meeting also raised concerns about the imitated availability of organically produced casing material. No new information as to the manufacture process or possible availability of certified organic intestines was presented. All comments were in favor of retaining use of non-organically produced casings as an option for production of organic sausage meat.

Concerns were raised about the need to incentivize production of organic casings but that was viewed as a long-term effort. Future NOSB meetings should consider whether a technical report reviewing barriers to the availability of organic casings is needed.

This material satisfies all OFPA criteria, and public comment confirmed its current use and need. The Handling Subcommittee supports continued listing of casings on the National List.

Subcommittee vote:

Motion to remove casings from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima
Seconded by: Tom Chapman
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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.

Prior to the Spring 2017 NOSB meeting, the Subcommittee put forth the questions below to determine if availability of organic konjac flour warrants its removal from 7 CFR 205.606. Very few public comments were received and none answered the questions posed. One food additives trade organization and one other public commenter supported relisting. No organic processors commented in favor of relisting this material. Three certifiers and one trade organization reported they did not receive a response from their clients or members, either in support of relisting or removal.

One commenter in favor of relisting acknowledged the availability of organic konjac flour as noted during the 2015 sunset review, however expressed “concerns about these suppliers and whether the konjac flour they offer is truly in compliance with organic standards.” The commenter continues, noting they have “…not been able to evaluate the specific suppliers noted” in the 2015 review. No data or evidence has been provided to show the validity of such statements.

Two commenters supported the removal of konjac flour, citing pesticide use in its conventional production. They further cited concern regarding the potential availability of a genetically modified variety of konjac flour and that measurers should be taken to avoid its use in organic production.

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?

The Subcommittee has not received evidence that the organic supply of konjac flour is insufficient to meet the demand of organic processors.

Subcommittee vote:
Motion to remove konjac flour from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (c)(1)(A)(ii): essentiality.
Motion by: Scott Rice
Seconded by: Ashley Swaffar
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

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 renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background:
Use: Pectin is extracted from citrus and pome fruits but so far there is no organic supply 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: Public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed extensively pectin's use and necessity in organic production. Once comment noted organic pectin was listed in the organic integrity database but also noted these products use it as a dietary supplement not as a gelling agent. Comments from a trade association representing the pectin industry spoke to constraints in commercializing organic pectin due to commingled raw material supplies and the current unavailability of organic pectin. A comment from an interest group stated pectin should be limited to high methoxyl pectin (HMP), extracted from citrus peel and apple pomace and wanted an evaluation to take into consideration the use of pesticides in the production of the non-organic raw materials. Board discussion noted the desire for the development of an organic pectin and discussed how this production could be incentivized but also noted the lack of commercial availability.
Pectin meets the OFPA criteria and is not available in sufficient organic supply, and no new substantive information was received during this review to contradict this listing.

Subcommittee vote:
Motion to remove pectin from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None
Motion by: Tom Chapman
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

National Organic Standards Board
Handling Subcommittee Proposal
Reclassification of Potassium Acid Tartrate
August 14, 2017

Summary of Proposed Action:
The Handling Subcommittee proposes to change the classification of potassium acid tartrate from a nonagricultural synthetic substance to an agricultural nonsynthetic substance and move the substance from § 205.605(b) to § 205.606 of the National List.

Subcommittee Review:
During its 2015 sunset review the NOSB noted a number of inconsistencies in the historical documents about potassium acid tartrate, confusion with specific names of similar sounding materials, and confusion in classification of this material. However, owing to lack of an up-to-date technical report (TR) the NOSB recommended continued listing of potassium acid tartrate until a new TR could be provided. A new TR, dated January 11, 2017, was received and is utilized for this reclassification recommendation.

During the winemaking process, sediments form that 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).

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 Guidance NOP 5033-1, this manufacturing process could be considered non-synthetic, 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 ($C_4H_5KO_6$, CAS Reg. 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 USDA organic regulations currently classify potassium acid tartrate as nonagricultural at 7 CFR 205.605.

Interestingly, potassium acid tartrate is a precursor to tartaric acid, which is another substance that is listed 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.

Potassium acid tartrate is derived from a crop (grapes) and there is no change in the chemical structure of the material when it is extracted. Using the decision tree for an agricultural vs. non-agricultural material in the Classification of Materials guidance (NOP 5033-2), potassium acid tartrate should be classified as agricultural. Using the decision tree for synthetic vs. non-synthetic (NOP 5033-1), potassium acid tartrate is extracted from a natural source, meets all the criteria described in Section 4.6 of NOP 5033, and has not gone through any chemical changes. That leads to a determination that it is non-synthetic.

The Handling Subcommittee proposes that potassium acid tartrate remain on the National List. However, the Handling Committee is bringing forward a proposal to change the listing from §205.605(b) to §205.606 due to the determination that potassium acid tartrate is agriculturally derived and non-synthetic under the guidelines of the Classification of Materials document.

Vote in Subcommittee:
Motion to reclassify potassium acid tartrate and change its listing from §205.605(b) to §205.606
Motion by: Steve Ela
Seconded by: Ashley Swaffar
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOSB August 15, 2017

National Organic Standards Board
Handling Subcommittee Proposal
Marine Algae Listings on the National List
August 31, 2017

Introduction

In 2016 and 2017, the Handling Subcommittee issued a discussion document and proposal on the topic of marine algae listings on the National List. These documents sought consistency in the nomenclature used to reference the various marine algae approved for and used in organic handling. These documents also sought public comment on the sustainability of marine algae sources. These documents are linked below.

April 2017

- Proposal: Marine Algae listings on the National List

November 2016

- Discussion Document: Marine Algae Listings on the National List

Request to Stakeholders for Additional Input

The Handling Subcommittee thanks the organic stakeholder community for the input it has provided in response to the previously issued discussion & proposal documents. Because of the shorter than usual written comment window in advance of the Spring 2017 meeting, a number of stakeholders expressed they did not have the time to substantively comment on the proposal put forward by the Subcommittee. Because of this, the Handling Subcommittee requests further stakeholder input on this topic via the NOSB open comment docket: https://www.regulations.gov/document?D=AMS_FRDOC_0001-1600.

Note that it is not necessary to resubmit comments and suggestions that were previously submitted in response to the prior discussion and proposal documents, as the NOSB has maintained a complete record of these. Please submit only **new** comments and suggestions. We look forward to receiving your input.

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOSB August 29, 2017

USDA National Organic Standards Board Research Priorities, 2017

Executive Summary

Overall: The National Organic Standards Board requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

1. Evaluation of methionine in the context of a systems approach in organic poultry production.
2. Prevention and management of parasites, examining breeds, geographical differences, alternative treatments, and pasture species.
3. Organic livestock breeding for animals adapted to outdoor life and living vegetation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable biobased mulch film.
2. Organic no-till practices for diverse climates, crops, and soil types.
3. Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control in apples and pears.
4. Alternatives to copper for plant disease and algae control: development of disease-resistant varieties, and particular research on algae control in rice.
5. Plant disease management through crop rotations, sanitation practices, plant spacing and disease-resistant varieties, and biopesticides.
6. Mitigation measures for pesticide residues in compost, including identification of problematic feedstock.
7. Management and control of spotted wing drosophila in fruits.

Coexistence

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.

Food Handling and Processing

1. Comparison of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.
3. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

National Organic Standards Board
Materials Subcommittee Proposal
2017 Research Priorities
August 8, 2017

INTRODUCTION

For the past six years, the National Organic Standards Board (NOSB), has presented a list of research priorities for organic food and agriculture. The priorities are proposed by the NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees at its annual fall board meeting, and reflect both written and oral public comments received by the Board. The topics listed below by Subcommittee are the 2017 priorities, including some from previous years that the NOSB thinks are still relevant. The older priorities and their dates of adoption can be found in a list at the end of this proposal.

BACKGROUND

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

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

PROPOSAL: 2017 RESEARCH PRIORITIES

The NOSB encourages integrated, whole farm research into the following areas:

<u>Livestock</u>

1. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production
Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 full board meeting. A systems approach that includes industry and

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

independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems, (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine, and (3) assessment of management practices for improving existing organic poultry welfare under different conditions. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary.

The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pastures, and pasture management.

2. Prevention and Management of Parasites

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

The research question on prevention and management of parasites must be systems based. What farm systems, animal breeds, herd or flock management systems have shown the best results with parasite control over the last 20 years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, or other alternative treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

3. Organic Livestock Breeding (*new in 2017*)

Organic rules require livestock products originate from animals that are not confined and are adapted to outdoor living as well as obtaining feed from living vegetation. A current FAO report states that globally one third of pigs, half of all egg layers, two thirds of milk animals, and three quarters of meat chickens are produced with breeds more suited to confinement or "industrial" production systems than a typical organic farm or ranch. Similar to plant breeding, the organic community sees a great need for regionally-adapted and publicly available livestock breeds that can thrive in organic systems.

Heritage, native regional breeds, and breeds used in the EU and other areas of the world that are typically more adapted to organic systems are still present but in small numbers. Increased research on the breeding, production needs, and improvement of these breeds is needed. Traits for good conversion rates from grazing to milk or meat, meeting consumer expectations for quality, as well as having the constitution and temperament to thrive outdoors would increase both the profitability and resiliency of organic livestock operations. Animal breeds that may have immunity to a variety of diseases and parasites would be useful traits to research and incorporate in a breeding program.

Crops

1. Biodegradable Biobased Mulch Film

This type of mulch film was recently approved by the NOSB but did not include a specific percentage of biobased components it must contain. In 2015, NOP issued a Policy Memo[2] that states that certifiers and material organizations should review biodegradable biobased mulch film products to verify that all of the polymer feedstocks are biobased. This requirement makes biobased mulches unavailable to organic producers, due to the petroleum-based polymers in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions would be useful to develop more clarity on mulch films and possibly develop an additional annotation to address any concerns:

- How rapidly do these mulches fully decompose, and does the percentage of the polymers in the mulch film affect the decomposition rate? Are there metabolites of these mulches that do not fully decompose?
- Are there different cropping systems, climate, soil types, or other factors that affect the decomposition rate?
- What type of effect does the breakdown of these polymers have on soil and plant life as well as livestock that would graze either crop residues or forages grown the subsequent year after this mulch film was used?
- Does the use of these synthetic polymers over time affect the balance of soil biology?
- Is there any cumulative effect if this mulch film is used 3-5 years or more in the same location?
- Are the testing regimens available adequate to meet the decomposition standards in our definition and to validate the non-GMO status of source materials?
- Even though petroleum-based polymers may be developed so they are consumed completely by the microbiological life in the soil, is the balance of various nutrients and/or biological life different from the decomposition of biologically-based materials? Is there any comparison between decomposing petroleum-based polymers and the effects that petroleum based fertilizers and other inputs have on soil biological life in nonorganic agricultural systems?

2. Organic No-Till

Organic no-till practices are quite different from herbicide-based no-till systems. Organic no-till, using a terminated cover crop for in-place mulching, can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. There can also be some challenges from organic no-till using a cover crop, such as occasional insect infestation associated with the cover crop.

Even though this killed-in-place mulch practice has been used for more than a decade, widespread adoption has not occurred. This type of production is also attractive to conservation minded nonorganic farmers, and more practical information could result in the growth of domestic organic production. There are some land grant universities and federal agencies doing research on this type of production, but more work needs to be done. Increased research is needed to develop organic no-till systems that

[2] Policy Memo 15-1

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

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- Which mulch crops, systems, and timing of practices provide specific weed management benefits to support crop growth and yield?
- Research on various techniques that would provide a variety of options for diverse cropping systems including but not limited to: strip tillage within a killed mulch, mowing or other organically approved techniques versus rolling to terminate the cover crop, and living mulches in standing crops.
- Development of systems that allow for either continuous no-till organic crops or for multiple years of organic no-till in the crop rotation.
- How does the lessened soil disturbance of this system contribute to pest, weed, and disease management?
- What specific insect problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest and disease management, as well as soil fertility?
- How can the use of this system be managed to improve water infiltration and retention in annual and perennial cropping systems?
- What are the biodiversity benefits to these living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Does this system affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?

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

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

4. Alternatives to Copper for Disease and Algae Control

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

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

Some avenues for research:

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

5. Plant Disease Management

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

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

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

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

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

7. Management and Control of Spotted Wing Drosophila in Fruits (*new in 2017*)
There is a large pool of research on the control of insects and diseases using organic methods. Many controls use a systems approach and are quite effective. The introduction of new invasive species into cropping systems threatens these systems approaches, and in several cases the organic control options are very limited or nonexistent. Spotted wing drosophila is a relatively recent invasive insect that infests soft fruits, such as berries, and many other fruits as well. Infestation renders fruit unusable since insect larvae feed inside the fruit and may reach critical levels before fruit is harvested. This insect is particularly problematic in that it has the ability to oviposit in green fruit and that it has multiple generations throughout the summer, creating an extensive control period. There is only one control material available, spinosad, and it is in danger of overuse. The control period may also extend so long that maximum label rates are used before the season ends. A second invasive insect is brown marmorated stink bug, and at this time there are no organic control measures beyond attempts at mass trapping. Research into organic control options for both these invasive pests is critical so that organic growers can integrate controls into their organic systems.

<u>Handling</u>

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

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

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?

- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
- Research on the absorption of chlorine by produce from its quantity and use in wash tanks, including information about amount of time of exposure. Would this be a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

2. Celery Powder

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

3. Alternatives to Bisphenol A (BPA)

The Handling Subcommittee is examining the issue of whether to prohibit BPA in packaging materials used for organic foods in light of direct evidence that these uses result in human exposures and mounting evidence that these exposures may be harmful. There is a need for increased research about alternatives for the linings of cans and jars used for organic products that do not result in human exposures and health risks.

Materials/GMO

In previous years, the Materials subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014). These issues are currently being addressed through a Genetic Integrity of Seeds Ad Hoc Working Group.

1. Fate of Genetically Engineered Plant Material in Compost

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

2. Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material

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

3. Prevention of GMO Crop Contamination: Evaluation of effectiveness

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

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

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

Previous Years' Research Priorities

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

Whole Farm Systems (2012, 2013)
Evaluation of Copper Sulfate for Rice (2012)
Evaluation of Genetically Modified Vaccines (GMO) (2012, 2013)
Organic Aquaculture (2012, 2013)
Carageenan (2012)
Aquatic Biodiversity (2013)
Pastured Poultry and Salmonella (2013)
Commercial Availability Assessments (2013)
Herd and Flock Health (2013, 2014, 2015)
Risk Reduction from Off-Target Exposure to Non-Permitted Materials (2014)
Seed Purity from GMO (2014)
Mastitis (2014)
Pneumonia (2014)
Plant Extracts (2014)
Soil Building Practices (2014)
Consumer Demand (2013, 2016)

Subcommittee Vote:
Motion to adopt the proposal on 2017 NOSB Research Priorities
Motion by: Emily Oakley
Seconded by: Dave Mortensen
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Approved by Harriet Behar, Subcommittee Chair, to transmit to NOSB August 22, 2017

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Additional Excluded Methods to be listed in the
National Organic Program Excluded Methods Guidance Document
August 22, 2017

Introduction and background

On November 18, 2016, the NOSB sent a recommendation to the National Organic Program (NOP), recommending the NOP develop a guidance document to improve the definition of excluded methods as applied to the use of genetically engineered materials used in agriculture. This recommendation provided improved definitions and attempts to address the increased diversity in types of genetic manipulations performed on seed, livestock and other inputs used in agriculture. It is understood that genetic engineering is a rapidly expanding field in science at this time, and that the NOSB and the NOP will need to continually review new technologies to determine if they would or would not be acceptable in organic agriculture. In addition to the recommendation passed by the NOSB in November 2016, providing a new framework of definitions for determining a genetic manipulation as an excluded method, there was also a discussion document that listed numerous technologies that needed further review to determine if they were within the definition of prohibited or excluded methods.

Goals of this proposal/document

This proposal for the October 2017 NOSB meeting addresses three of the "To Be Determined" methods listed in the discussion document voted upon in November 2016. Using the NOSB's proposed improved definitions of GE excluded methods, the NOSB Materials Subcommittee was able to determine if certain technologies should be considered an excluded method and therefore the products of these type of technologies would not be allowed in NOP organic agricultural production.

Public comment at numerous NOSB meetings over the years, continues to stress the desire that technologies used to manipulate the genetic code, in a manner that is outside traditional plant and animal breeding, should remain prohibited in organic production. Among all of the organic stakeholders, there is a strong belief that genetic engineering is a threat to the integrity of the organic label. Both organic producers and consumers reject the inclusion of genetic engineering in organic production.

Criteria

The NOSB previously recommended that biotechnology processes will be reviewed to the following criteria to determine if they are excluded methods:

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.

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

Definitions

The NOSB previously recommended the use of the following definitions to determine whether or not a method should be/is excluded.

A. Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.

B. Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources.

C. Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

D. Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity

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

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

It is this series of definitions and terminology was used to as the basis to determine the status of the many of the previously "To Be Determined" materials.

The NOSB voted on the methods listed below during its April 2016 meeting, and determined these to be excluded methods.

Terminology Chart				
Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via oligonucleotides CRISPR-Cas system* TALENs** Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are hard to test for.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid Transformation		YES	1, 3, 4	

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

** TALENs = Transcription activator-like effector nucleases.

The following genetic engineering methods were found to be NOT an excluded method, under the proposed new definitions.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Marker Assisted Selection		NO		
Transduction		*NO*		

Discussion
The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda, to determine if new technologies do or do not meet our current definitions. We may also need to incorporate additional criteria into our current definitions in order to evaluate new and unique technologies.

We also understand that many of the new technologies do not lend themselves to testing. . However, we still believe that the technology should be listed as an excluded method. The Materials Subcommittee may put forward another discussion document to aid the NOP in determining how to enforce this prohibition when there is no means to test and prove an excluded method was used in production.

Proposal

The items below have been determined to be considered an excluded method based upon the criteria listed above.

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Cisgenesis		YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene insertion can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.

Intragenesis		YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene rearrangement can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.
Agro-infiltration		YES	1, 3, 4	*In vitro* nucleic acids are introduced to plant leaves to be infiltrated into them. The resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.

The following methods will continue to be researched.

Terminology				
Method and synonyms	Types	Excluded	Criteria Used	Notes
Protoplast Fusion		*TBD*		There are many ways to achieve protoplast fusion and until the criteria about cell wall integrity is discussed, these technologies cannot yet be evaluated.
Transposons		*TBD*		Used in animal vaccines. May be excluded in some situations but not others.
Cell Fusion within Plant Family		*TBD*		Subject of an NOP memo in 2013, the issue of detection of these varieties needs to be addressed before further policies can be adopted.
Embryo rescue in plants		*TBD*		Many sources including FiBL[1] think this is not excluded but more study of the methods is
TILLING	Eco-TILLING	*TBD*		Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.

[1] Research Institute of Organic Agriculture (FiBL) http://www.fibl.org/en/switzerland/location-ch.html

Doubled Haploid Technology		*TBD*		There are several ways to make double haploids and some do not involve genetic engineering but some do. Difficult to impossible to find using tests.
Induced Mutagenesis		*TBD*		This is a very broad term and needs to be divided and classified based on what induces the mutations, chemicals, radiation, or other stresses.
Embryo transfer in animals	Embryo rescue in animals	*TBD*		FiBL distinguishes embryo rescue in plants from animals.

Subcommittee Vote:
Motion to accept the two sections of this proposal as stated above.
Motion by: Harriet Behar
Second: Dan Seitz
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair, to transmit to NOSB August 22, 2017

National Organic Standards Board
Materials/GMO Subcommittee
Discussion Document on Seed Purity
August 28, 2017

Introduction
In 2012, 2013 and 2016, the Materials/GMO Subcommittee issued discussion documents on the topic of “seed purity” (i.e., keeping seed stock used for organic production free from contamination by GMOs). In 2014, the subcommittee issued a report summarizing the public comments received in in response to the 2012 and 2013 discussion documents and the subcommittee’s analysis of the situation. The following are the links to these four documents:

April 2016
- Discussion Document: Next Steps for Improving Seed Purity (pdf)

April 2014
- Report: Seed Purity from GMOs (pdf)

April 2013
- Discussion document: GMOs and Seed Purity (pdf)

October 2012
- Discussion document: GMOs and seed purity (pdf)

The Materials/GMO Subcommittee thanks the organic stakeholder community for the extensive input it has provided in response to the previously issued discussion documents.

At its meeting on August 22, 2017, the Subcommittee agreed to develop a seed purity proposal for review at the spring 2018 NOSB meeting. In order to develop this proposal, the Subcommittee will draw upon previously submitted comments and suggestions, as well as any additional comments it receives in response to this discussion document.

Request of the Materials/GMO Subcommittee to Stakeholders for Additional Input

The Materials/GMO Subcommittee requests further stakeholder input on the topic of seed purity via the NOSB open comment docket: **https://www.regulations.gov/document?D=AMS_FRDOC_0001-1600**.

Note that it is not necessary to resubmit comments and suggestions that were previously submitted in response to the prior discussion documents, as the NOSB has maintained a complete record of these. Please submit only **new** comments and suggestions. We look forward to receiving your input.

Motion to accept the discussion document on non-GMO organic seed integrity.
Motion by: Dan Seitz
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Harriet Behar, Materials Subcommittee Chair, to transmit to NOSB August 29, 2017