



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

Comments to the National Organic Standards Board Fall 2020

National Organic Standards Board:

Thank you for this opportunity to provide comment on multiple topics. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others.

One of OTA's strongest assets as an organization is the diversity and breadth of its membership. Unlike many trade associations, OTA is uniquely structured to include the full value chain for the organic industry, ensuring that all segments, from farm to marketplace, have a strong voice within the organization. It also creates a platform for a diverse group of stakeholders to work together to catalyze solutions, form coalitions and collaborate on matters critical to the organic sector.

Addressing critical issues and growing the organic industry are all part of our work together. It all fits in with OTA's Mission, to **promote and protect organic** with a unifying voice that serves and engages its diverse members from farm to marketplace.

WHAT IS OTA'S COMMENT PROCESS?

OTA submits comments on behalf of its membership. Our positions and policies are primarily shaped through our member task forces. In all cases, OTA's regulatory and legislative staff carry out an extensive process of membership engagement to capture how current issues and activities such as proposed rules or NOSB recommendations will impact certified farmers and handlers. Prior to submission of final comments, draft comments are distributed to membership at least a week in advance. Members are provided an opportunity to weigh in and shape any changes that may be needed prior to final submission. To carry out a meaningful comment process under OTA's governance structure, a comment period needs to be at least 30 days.

The fall 2020 NOSB comment period was completely overlapped by the 60-day comment period on NOP's Strengthening Organic Enforcement Proposed Rule, the largest single piece of rulemaking since the organic regulations were first implemented. Unfortunately, this prevented OTA from being able to fully engage in the analysis, member engagement, and public comment process for all the items presented for this NOSB meeting. We realize that the timing and overlap with the Proposed Rule is outside of the Board's control. In any case where the Board feels it did not receive sufficient substantive comments to make an informed and judicious decision, we encourage the issue to be tabled and returned for public comment at the next spring 2021 meeting. We thank the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

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Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Crops Subcommittee – Wild, Native Fish for Fertilizer Production (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee's Proposal on Wild, Native Fish for Fertilizer Production.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

For the fall 2020 meeting, the NOSB Crops Subcommittee presents its [Proposal on Wild, Native Fish For Fertilizer Production \(starts on Page 11\)](#).

OTA was not able to fully analyze the substantive new information in the proposal due to the conflict of the comment period with the NOP Strengthening Organic Enforcement Rule comment period. In our initial assessment of the proposed annotation language and new definitions, we identified one notable concern – the proposed definition of *fish waste* excludes an important waste stream from fish processed for *animal* consumption. More time is needed to further analyze the proposal and to understand the impacts it would have on the availability of essential fertility inputs for organic farmers. OTA recommends that this proposal be returned to the Subcommittee for continued work so that NOSB has the opportunity to receive and integrate stakeholder feedback into the final proposal.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Crops Subcommittee – 2022 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2022 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each crop production material scheduled for review as part of the 2022 Sunset Review cycle. Materials placed on the National List for use in organic crop production should remain on the National List if: 1) they are consistent with organic farming; 2) they are still necessary to the production of the agricultural product because of the unavailability of wholly natural substitute products in organic production; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large. It's critical that NOSB hears from certified farmers on whether these inputs are consistent with and necessary for organic production, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2022 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked through its Farmers Advisory Council (ota.com/FAC) to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received 7 responses on our 2022 Crops Sunset Surveys (2 are new responses since the spring meeting). Below is a summary of the feedback received via OTA’s Sunset Surveys to date.

§205.601 – Synthetic substances allowed for use in organic crop production.

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 1 being “unnecessary” and 5 being “critical /would leave organic without it”)
Soap-based algicide/demossers	0		
Ammonium carbonate	0		
Insecticidal soaps	3	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used by long-time organic growers of bananas, citrus, lettuce, specialty greens, etc. - It is used to help control pests including meal bugs, scale insects, fungus gnats, etc. - Used as needed in a rotational spray program; at time of year when insect/fly numbers reach a threshold <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Natural oils have been used but they are not very effective and can cause phytotoxicity and leaf sunburn. Natural oils are used when seasonally appropriate. - There are limited tools available for organic production having options to use the most effective products with the least negative effect on the environment - Manual removal of the insects is not logistically possible at scale - No other alternative management practices available. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Insect populations can get out of control and damage the fruit. Insect damage can surpass 20-30 % making operation economically not viable. - Increase disease rates, lower yields - Potentially have to use products that may be more adverse to the environment - Food waste will increase representing a disposal problem at farms and packing plants 	4.5
Vitamin D3	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used for pest mitigation in dairy facilities. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - (no response) <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal health would suffer 	4

Aquatic plant extracts	3	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used by long-time organic growers to produce Fruits, Vegetables, Lettuce, Specialty Greens, Corn, Soy beans, Potatoes, Grains, Pastures, Orchards, and more - Controls pests, increases yield, improves soil, strengthens germination and root development, provides hundreds of macro- and micro-nutrients. - Used as fertilizer to support health and vigor of the crop - Used as a greening agent that provides vigor to baby leaf vegetables - Used every crop cycle / routinely in all spray and foliar applications, or as needed for stress relief <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No other substance are suitable substitute - No other tools are as environmentally friendly with the same effects. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Less healthy crops, Decreased nutrients and overall health of soil and plants - Lower yields - Increase use of nitrogen fertilizers, risk of leaching and/or violating nitrogen reporting needs 	4
Lignin sulfonate	0		
Sodium silicate	0		
EPA List 4 inerts	0	<p>Note: Please also see the separate comment submitted by the Organic Trade Association on this material.</p>	

§205.602 – Non-synthetic substances prohibited for use in organic crop production.

Substance	# of responses	Summary of responses
Arsenic	0	
Strychnine	0	

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Miranda
 Farm Policy Director
 Organic Trade Association

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Appendix A – Sample Survey for Crop and Livestock Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use the substance on/for? (e.g., lettuces, fruit trees, broiler chickens)
5. What function does the substance provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you tried using any *natural substances* as an alternative to the substance? (e.g., natural oils instead of synthetic pesticides) If so, please describe the availability and efficacy of the alternative substances.
8. Are there any other *management practices* that would eliminate the need for the substance? (e.g., hand weeding instead of using an herbicide; or using a particular harvesting practice to avoid a disease instead of using a fungicide). If so, please describe the efficacy of the alternative management practices:
9. Describe the effects to your operation if you were to no longer be allowed to use this substance in organic production:
 - Agronomic effects (effects to health of crops or livestock):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall necessity of this substance for your organic operation:

Unnecessary (don't need it at all)	Neutral (nice to have but could live without it)	Critical (would leave organic without it)
★	★	★



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Crops Subcommittee – Aquatic Plant Extracts (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee’s Sunset Review of Aquatic Plant Extracts.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- ✓ OTA supports the re-listing of Alkali-Extracted Aquatic Plant Extracts on the National List.
- ✓ Alkali-Extracted Aquatic Plant Extracts are necessary for organic crop production.
- ✓ OTA supports the continuous improvement in sustainable sourcing of inputs used in organic production, and encourages NOSB to engage in cross-subcommittee discussions to standardize decisions on environmental impacts of marine macroalgae materials across inputs and scopes.

We offer the following more detailed comments:

Background

Alkali-extracted aquatic plant extracts are currently listed on the National List at §205.601(j)(1) as allowed as plant or soil amendment for organic crop production: *Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount is limited to that amount necessary for extraction.* The use of phosphoric acid and other synthetic acids for pH adjustment of aquatic plant extracts is prohibited ([NOP Memo 14-1](#)).

The restricted allowance of alkali-extracted aquatic plant extracts has been in place since the NOP regulations were originally established in 2000, and continues to be renewed at all of the Sunset Reviews that have occurred for this listing over the past 20 years (2006, 2010, and 2015). Each review has demonstrated that the use of alkali-extracted aquatic plant extracts as listed at §205.601(j)(1) meets the criteria established in the Organic Foods Production Act (OFPA) for allowance of a synthetic substance: 1) The input must not be harmful to human health or the environment; 2) The input is necessary for production and processing of organic products because of the unavailability of natural or organic alternatives; and 3) The input is consistent with organic farming and a system of sustainable agriculture.

This year (2020), NOSB is conducting its fourth Sunset Review of this listing of aquatic plant extracts to determine its continued eligibility for inclusion on the National List as an allowed synthetic substance in accordance with criteria established in the Organic Foods Production Act. At the spring 2020 NOSB Meeting, the Crops Subcommittee collected public comments on this material and asked direct questions regarding the necessity of the material, availability of nonsynthetic alternatives, and suggestions for how NOSB should proceed with evaluating environmental impact.

OTA submitted [comments](#) in April 2020 in support of continued allowance of alkali-extracted aquatic plant extracts. Our comments included information demonstrating that alkali-extracted aquatic plant extracts are necessary for organic crop production. Alkali-extracted aquatic plant extracts are widely used by hundreds of organic farmers as a fundamental part of their system of maintaining and enhancing plant and soil health. The alkali extraction step is critical for releasing the bioactive compounds of seaweed and delivering benefits to crop production systems. Equivalent nonsynthetic alternatives are not known to be available. On the topic of environmental impact, we encouraged the Crops Subcommittee to engage in collaboration with other Subcommittees to standardize decisions across inputs and scopes where seaweed is used. The Materials & Handling Subcommittees had also been looking at some aspect of environment impact from sourcing seaweeds from marine environments for use as inputs in organic production and processing. We stressed the importance of NOSB to avoid making a decision on an individual Sunset Review [which only covers one form (synthetic) of one input (fertilizer) for one scope of materials (crops)] that could disrupt or conflict with the work of other subcommittees on other closely related forms, inputs, and scopes of marine materials. A coordinated approach across subcommittees and materials is essential for achieving meaningful progress towards NOSB's goal of ensuring that use of marine materials in organic production is not harmful to the environment.

Summary of Fall 2020 Proposal

For the fall 2020 NOSB Meeting, the Crops Subcommittee presents its [Sunset Proposal on Aquatic Plant Extracts \(starts on Page 32\)](#).

As stated in the Subcommittee's proposal, the Subcommittee is divided on this topic: *“Two members expressed a desire to gather more information, particularly with regard to the related work agenda item of marine macroalgae in plant fertility products in the Materials Subcommittee, before making a final determination on their position on this material. One member was concerned about the environmental impact of harvests.”*

There does not appear to be any concerns in the Subcommittee’s sunset review proposal regarding the other OFPA criteria regarding the necessary for production and processing of organic products because of the unavailability of natural or organic alternatives; the consistency with organic farming and a system of sustainable agriculture; and the input not being harmful to human health.

OTA supports the re-listing of alkali-extracted aquatic plant extracts

Alkali-extracted aquatic plant extracts are widely used by hundreds of organic farmers as a fundamental part of their system of maintaining and enhancing plant and soil health. The alkali extraction step is critical for releasing the bioactive compounds of seaweed and delivering benefits to crop production systems. Equivalent nonsynthetic alternatives are not known to be available. OTA finds that this substance meets the OFPA criteria for inputs that are necessary for production because of the unavailability of natural or organic alternatives.

OTA acknowledges and supports the ongoing interest of NOSB to evaluate and seek to minimize the possible negative environmental impact of sourcing seaweeds for use as inputs in organic production. However we strongly caution against NOSB de-listing this essential input. The concern about sustainable harvesting of seaweed is not exclusive to the §205.601(j) listing of alkali-extracted aquatic plant extracts. This listing only covers one form (synthetic) of one input (fertilizer) for one scope of materials (crops), whereas seaweed is also harvested for other form, uses, and scope throughout organic production and processing (nonsynthetic fertilizers, livestock feed and medical treatments, food ingredients). The decision from the Crops Subcommittee on the environmental impact of this single material will have far reaching impacts that could disrupt or conflict with the work other subcommittees are doing on evaluating the same subject matter – the Materials Subcommittee’s active work on evaluating environmental harm from harvesting marine macroalgae. It would be premature for the Crop Subcommittee to make a decision to de-list §205.601(j) based on questions of environmental harm when the Materials Subcommittee has not yet completed its work.

Alkali-Extracted Aquatic Plant Extracts are necessary for organic crop production

Alkali-extracted aquatic plant extracts are a widely and commonly used input in organic crop production. Certifiers report that hundreds of organic farm operations use alkali-extracted aquatic plant extracts, and Material Review Organizations list hundreds of brand-name products indicating a demand for their use. Removal of these products from the National List would negatively impact a significant number of organic farmers who are relying on alkali-extracted aquatic plant extracts as part of their organic crop production system. OTA’s Farmers Advisory Council¹ supports continued access of this critical crop fertility tools for farmers.

¹ The Organic Trade Association's Farmers Advisory Council (FAC) provides the Organic Trade Association Board of Directors and staff with input from small- and medium-sized organic farmers, ranchers, and growers on matters pertinent to the advancement of organic agriculture, with a specific focus on OTA’s policy agenda. More at ota.com/FAC

In the production of organic fruits and vegetables, alkali-extracted aquatic plant extracts are used as foliar fertilizers and soil conditioners. Organic producers state that these inputs are fundamental for maintaining and enhancing plant and soil health, while also reducing the need for other materials for disease and pest control. Application can help control pests, increase yield, improve soil, strengthen germination and root development, and provide hundreds of macro and micro nutrients to help increase health and vigor of the crop. As fertilizers, seaweeds can provide a natural form of soluble potassium. In production of organic baby leaf vegetables, alkali-extracted aquatic plant extracts are used as a greening agent without the addition of nitrogen products.

To manufacture these products, seaweed is treated with an extracting agent (only potassium hydroxide or sodium hydroxide are permitted) to break the cell walls of seaweed, thereby releasing the naturally occurring nutrients, minerals, vitamins, amino acids, hormones, and other beneficial biochemical compounds within the seaweed. Once released, the natural compounds are free to be absorbed by the crop plant and immediately used for physiological processes. The alkali extraction step is essential for release of the bioactive compounds from the seaweed. The extractant is small in terms of volume but significant in terms of delivering benefit and value to farmers through an effective product. Without alkali extraction, the beneficial compounds of the seaweed are not nearly as available or effective for providing benefits to crops. Manufacturers state that there is no alternative manufacturing processes to get the equivalent benefits from seaweed. Producers state that the variety of biostimulant compounds and multiple modes of action are unique in seaweed extracts, and there are not comparable alternatives.

Further collaboration is still needed to evaluate environmental impacts

In OTA's previous comments, we encouraged NOSB to engage in more collaboration across NOSB Subcommittees to standardize decisions on environmental impacts of sourcing seaweed across inputs and scopes where seaweed is used. We continue to support this request. Please see our comments to the Materials Subcommittee on Marine Macroalgae for Crop Fertility Inputs for more information.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Johanna Mirenda".

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Crops & Livestock Subcommittees – EPA List 4 Inerts of Minimal Concern (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop and Livestock Subcommittee's Sunset Review of EPA List 4 Inerts of Minimal Concern.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA supports renewal of the listings of EPA List 4 inert ingredients at §205.601 and §205.603 on the National List during this Sunset Review. Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed. As described in our previously submitted comments (Attachment A), EPA List 4 is an obsolete reference and a modernized system for reviewing inert ingredients is not yet in place, despite a 2015 NOSB Recommendation to update the National List with accurate references to EPA's current mechanism for approving the least-toxic inert ingredients. NOP has not taken any action to implement the recommendation, and there is no indication it would be able to complete the multi-year implementation process prior to the sunset date in 2022. The prohibition of List 4 inerts prior to establishment of a new system would cause significant disruption to the availability of essential pest control tools for organic production. Therefore, the continuation of the current listings of EPA List 4 inerts is critical for ensuring continued availability of effective and familiar pest control tools for organic producers.

OTA continues to support the 2015 NOSB Recommendation. We share NOSB's frustration that NOP has failed to implement the recommendation, and there is still no resolution to the longstanding discrepancy in the organic regulations with regard to inert ingredients. However, we strongly discourage voting to remove List 4 inerts from the National List without a viable alternative list of approved inerts (and regulatory references to such list) in place. Voting to prohibit this important class of substances is irresponsible and risky when farmers' access to critical tools for organic production is at stake. OTA's



Farmers Advisory Council¹ agrees and strongly urges caution to protect continued availability of critical pest control tools for farmers.

We call on NOP to commit to implementing the 205 NOSB Recommendation. Modernizing the system for review of inert ingredients is a priority of the organic industry. Pesticide product development and innovation are being stifled by the outdated regulatory references for inert ingredients. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products. A roadmap for implementing the 2015 NOSB Recommendation is already in place (See Appendix A, page 6) and now NOP must commit to action.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

¹ The Organic Trade Association's Farmers Advisory Council (FAC) provides the Organic Trade Association Board of Directors and staff with input from small- and medium-sized organic farmers, ranchers, and growers on matters pertinent to the advancement of organic agriculture, with a specific focus on OTA's policy agenda. More at ota.com/FAC

April 3, 2020

ATTACHMENT A

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-19-0095

RE: Crops & Livestock Subcommittees – EPA List 4 Inerts of Minimal Concern (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop and Livestock Subcommittee’s Sunset Review of EPA List 4 Inerts of Minimal Concern.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- ✓ Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed.
- ✓ To resolve longstanding outdated regulatory references, OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and modernize the system for review of inert ingredients in organic approved pesticide products.
- ✓ Pesticide product development and innovation is being stifled by the outdated regulatory references for inert ingredients.

We offer the following more detailed comments:

I. Background

Inert ingredients are defined in the National Organic Program (NOP) regulations as “**any substance** (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) **other than an active ingredient which is intentionally included in any pesticide product.**” The NOP regulations provide for certain synthetic inert ingredients to be used in organic approved pesticide products. EPA List 4 Inerts are permitted for use as inactive ingredients formulated with allowed active pesticide ingredients for both crop and livestock production. EPA List 3 Inerts have a more limited allowance only in passive pheromone dispensers in crop production.

The current listings on the NOP National List read,

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

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

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

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern

The listing for EPA List 4 Inerts has been included in the National List since the NOP Regulations were first published in 2000. The limited allowance for EPA List 3 Inerts was published in 2003. The references to EPA List 3 and 4 were based on EPA’s system of classification at the time, in which EPA organized individual substances in to List 1-4 according to toxicology (List 1 being most toxic to List 4 being least toxic). Shortly after listings for EPA List 3 and 4 were formalized in the NOP regulations, EPA began implementing a change to replace Lists 1-4 with a new system of tolerance assessments to be codified in 40 CFR Part 180. EPA completed its transition to the new system in 2006. As of then, EPA no longer uses or maintains Lists 1-4.

According to information contained in a [NOP Policy](#) for reviewing inert ingredients (emphasis added), **“EPA has informed USDA that the “Inerts List” system may no longer be effective or available for the NOP to reference in the Regulations.** Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations. As a result, **the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA.** NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations.”

The collaboration between NOP, NOSB and EPA was very active between 2011 and 2015. The **NOP-NOSB-EPA Inerts Working Group** was established in December 2010 with the goal of submitting a proposal to NOSB, through which NOSB would then develop a formal recommendation to NOP. The working group met frequently and reported regularly to the public at NOSB meetings. The Working Group evaluated several different options for resolving the outdated reference for inerts, and ultimately proposed that NOP work with the EPA’s new **Safer Choice Program** (Formerly the Design for the Environment Program). The Safer Choice Program is a voluntary program for verifying and labeling products that meet EPA Safer Choice Standards for human health and environmental safety. Ingredients must comply with the EPA’s **Safer Chemical Ingredient List (SCIL)**. The NOSB Crop and Livestock Subcommittees agreed with this approach and included a reference to the Safer Chemical Ingredient List (SCIL) in a proposal that was passed by NOSB in fall 2015.

The [2015 NOSB Recommendation](#) would revise the listing for inert ingredients at §205.601(m) and §205.603(e) to remove the outdated and obsolete references to EPA Lists 3 and 4, and replace with

EPA's current mechanisms for approving the least-toxic inert ingredients. The recommended annotation reads:

§205.601(m) and §205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use as inerts in minimal risk products exempt from pesticide registration under FIFRA section 25(b)
- (ii) Substances included on the EPA's Safer Chemical Ingredient List
- (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers
- (iv) [Reserved for any other inerts individually petitioned and reviewed]

The listing for EPA List 3 and List 4 inerts have been renewed at each of the three previous Sunset Reviews that have occurred over the past twenty years. The renewals of these listing have been critical to allow NOSB and NOP to continue their effort to resolve outdated reference for inerts with minimal disruptions. As cited by NOSB during the last Sunset Review of EPA List 4 Inerts in fall 2015, "To allow these materials to sunset at this point would be too disruptive to the industry." At that meeting, NOSB also presented a minority opinion that stressed the importance of resolving the inerts issue, citing concerns with the regulation's "current reliance on a now non-existent review process."

This year (2020), NOSB is conducting its fourth Sunset Review of the EPA List 4 Inerts to determine its continued eligibility for inclusion on the National List as an allowed synthetic substance in accordance with criteria established in the Organic Foods Production Act (OFPA): 1) The input must not be harmful to human health or the environment; 2) The input is necessary for production and processing of organic products because of the unavailability of natural or organic alternatives; and 3) The input is consistent with organic farming and a system of sustainable agriculture. At the spring 2020 NOSB Meeting, the Crops Subcommittee presents its [Sunset Summary and Request for Comments on EPA List 4 Inerts \(starts on Page 34 for crops and Page 99 for livestock\)](#). NOSB will collect public comments at the spring 2020 meeting to inform its proposal and vote at the fall 2020 meeting.

II. Necessity for Production

Inert ingredients are necessary for the manufacturing of many various forms of pesticide products. Inert ingredients are used in conjunction with active ingredients to facilitate functionality and efficacy of the active ingredient. (Note: Active ingredients are subject to individual review and approval in accordance with NOP regulations.)

Pest control products formulated with inert ingredients are widely used in organic crop and livestock production. Hundreds of organic-approved pest control products are formulated with synthetic inert ingredients. These products are part of a limited restricted toolbox that farmers can access only when their preventive pest, weed, and disease management practices have failed.

Continued availability of effective and familiar pest control products for both crop and livestock producers is necessary for organic farmers to reliably bring their organic products to market. It is critical that the availability of these products continue throughout NOSB and NOP's ongoing efforts to update the listings of inert ingredients on the National List.

III. Implementing the 2015 NOSB Recommendation

A plan for implementing the 2015 NOSB Recommendation was proposed by the Crop and Livestock Subcommittee at the fall 2015 meeting. After the NOSB's vote to proceed with the annotation change, the following items were expected to take place:

- NOP will publish a *Federal Register* Notice to notify stakeholders of the intended revision, and to outline the procedure and timeline for implementation. The notice would also call on stakeholders to submit applications for individual inert ingredients to EPA for inclusion on the Safer Chemical Ingredient List and/or to NOP for inclusion on the National List.
- NOP will proceed with the rulemaking process to amend the National List, which would include a reasonable implementation time (3-5 years) to accommodate manufacturers applying for SCIL consideration, petitioning NOSB, and/or reformulating their products.
- NOP will establish a Memorandum of Understanding with EPA to formalize their relationship and allow NOP to rely on EPA's Safer Chemical Ingredient List.
- NOSB will establish a procedure for addressing the elements of OFPA criteria that are not specifically addressed in EPA's review of materials on the Safer Chemical Ingredients List (such as compatibility with organic agriculture).

In NOP's response to the 2015 NOSB Recommendation, NOP stated "The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at §205.601(m) and §205.603(e)." For a short time after the 2015 NOSB Recommendation was passed, NOP made some effort to provide verbal updates at NOSB meetings to the organic community on its progress of implementing the recommendation, although this has not occurred since 2016. It has now been five years since NOP committed to implementing the NOSB recommendation; ten years since EPA directly requested NOP to remove the reference in its regulations; and about 15 years since EPA Lists became obsolete. Yet the NOP regulations still refer to EPA Lists that were last updated in August 2004.

OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and resolve the longstanding discrepancy in the organic regulations with regard to inert ingredients.

Modernizing the system for review of inert ingredients is a priority of the organic industry. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products. It is critical that NOP regulations have a valid system for identifying allowable ingredients that comply with OFPA criteria for the National List. OTA continues to support the 2015 NOSB Recommendation that utilizes EPA's current mechanisms for approving the least-toxic inert ingredients: FIFRA 25(b) pesticide program inerts, Safer Choice Program's Safer Chemical Ingredient List (SCIL), and inerts exempt from tolerance at 40 CFR Part 180 (for passive pheromone dispensers only). Incorporating these oversight and approval mechanisms aligns with USDA organic regulations,

which focus on human and environmental hazards, and provides product manufacturers clarity around how to reformulate their products as the organic standards become more current with the overall evaluation of pesticide products under EPA. We encourage NOP to continue working with EPA, NOSB, organic pest-control material manufacturers, and the organic sector at large to develop and implement a program that will both ensure continued safety of organic pest-control materials and minimize disruptions to the tools farmers rely upon when their preventive pest, weed, and disease management practices have failed.

IV. Questions from the Crops Subcommittee

1. *Can you provide examples of product development that have been stifled by the lack of clarity on the regulation and approval of inert ingredients in organically approved pesticide formulations?*

Pesticide product manufacturers have indicated to OTA that they will not invest research and development resources in new products when there is uncertainty about what ingredients will be allowed. The outdated regulatory reference for inert ingredients is stifling innovation in pesticide product development and organic agriculture.

2. *Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?*

We support NOP and NOSB efforts to implement a new system of review that would apply rigorous environmental and human health safety criteria to all inert ingredients. Under the 2015 NOSB Recommendation, inert ingredients would be approved under EPA's current mechanisms for approving the least-toxic inert ingredients. This new system of review would result in prohibition of some currently approved inert ingredients such as NPEs, a class of substances that has raised concerns at past NOSB meetings. We caution against using resources to pursue separate recommendations and rulemaking on individual inert ingredients when the broader solution would accomplish the same end goal and would cover more substances. Stakeholders always also have the option of submitting a petition to prohibit certain substances.

3. *Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?*

OTA supports implementation of the 2015 NOSB Recommendation. This recommendation is the result of years of collaborative work between NOP, NOSB, and EPA, and allows for multiple avenues of identifying allowed inert ingredients without the burden of NOSB having to individually review or list inert ingredients. See **Part III** for more information on implementing the 2015 NOSB Recommendation. If there are insurmountable obstacles to implementing the 2015 NOSB Recommendation, then we would support NOSB exploring alternative approaches. NOP should be transparent with NOSB and the organic community if such obstacles exist.

4. *What would be the consequences of an NOSB recommendation to delist List 4 Inerts?*

There would be significant disruption to organic production if EPA List 4 Inerts were delisted without a valid replacement system for reviewing and approving inert ingredients. Organic producers would lose critical tools for controlling pests when preventive practices fail. See **Part II** for more information.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Handling Subcommittee – Ion Exchange Filtration Proposal

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee’s Proposal on Ion Exchange Filtration. The Subcommittee, in response to a request from the National Organic Program (NOP), is making a recommendation on whether the substances associated with ion exchange filtration should be added to the National List.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA’s Board of Directors is democratically elected by its members. OTA’s mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- OTA supports the allowance of ion exchange filtration as an organic processing method.
- OTA supports the Handling Subcommittee’s recommendation that ion exchange recharge materials must be on the National List to be approved for use in organic processing.
- OTA agrees that the resins/membranes do not need to be on the National List to be approved for ion exchange filtration used in organic processing.
- OTA supports the allowance of ion exchange in organic processing, provided its use is described in detail in the certified operator’s Organic Handling Plan (including the resins and recharge materials), and it is reviewed and approved by the operation’s certifying agent. This includes verification that the resins are classified as food contact substances and the recharge materials are on the National List.

We offer the following more detailed comments:

Introduction

Prior to the spring 2020 NOSB meeting, the Handling Subcommittee asked four questions to help inform the proposal up for consideration at this fall 2020 meeting. OTA submitted extensive comments providing NOSB with an overview of ion exchange technology, followed by important background information that was not included in the Subcommittee’s Discussion Document. The topic of ion exchange is complex

both from a technical and a regulatory perspective. Excerpts of OTA’s spring 2020 comments are included again to help support a sound and informed proposal. OTA’s complete comments from the spring 2020 meeting are included as Appendix A.

Ion Exchange Filtration and its Use in Organic Processing

Ion exchange is a processing technology used for filtration and purification. It has been allowed in USDA-NOP certified organic processing since the organic regulations were first established. The intent of the technology is not to chemically change¹ a product, but to eliminate unwanted contaminants or impurities through removal of their associated ions.

There are several allowed NOP processing technologies that will chemically change a processed product. Examples range from cooking/baking and heating to the use of activated carbon for filtration, an allowed organic processing technology that relies on chemical absorption and separation. Similar to activated carbon filtration, ion exchange depends on a chemical process (exchange of ions of the same charge). In the context of organic processing, it can be identified as a processing technology or method that is allowed under filtration or “separating,” as described in § 205.270(a) - Organic Handling Requirements:

Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

The **ion exchange media**, on the other hand, are non-agricultural substances used “in or on” the organic product that either should or should not be subject to the National List review process depending on how they are regulated (secondary additive vs. processing aid vs. food contact substance). For any processed NOP certified product, ‘non-agricultural substances’ regulated as direct or secondary additives or as processing aids, must be on the National List, whether they are ‘synthetic’ or ‘non-synthetic.’ Accordingly, NOP is requesting a recommendation from NOSB on whether it is appropriate to include these non-agricultural substances on the National List.

Ion Exchange Filtration Media: Resins vs. Recharge Materials

Ion exchange filtration is a food processing (purification) technique that involves a column, like a large pipe, packed with **ion exchange resins** that selectively remove unwanted ions from the liquid. The **resin** is an insoluble matrix (or support structure) normally in the form of small microbeads, on which a fixed ion has been permanently attached. This ion cannot be removed or displaced; it is part of the resin structure. The ion exchange resin also holds charged molecules that are mobile and available for exchange with mobile molecules in a fluid that is passed through the column. The resin is charged with a chemical solution that is periodically regenerated with a **recharging material** when the resins become exhausted.

¹ It should be noted that it is neither the ion exchange resins nor the recharge materials that actually facilitate or bring about the chemical change. It is the water used in the process. This is a moot point, however, because the question of a “chemical change” is not relevant to the discussion of whether the media need to be on the National List; the materials under evaluation and not the processing technology itself.

The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. FDA currently regulates ion exchange resins as ‘food contact substances.’² The resins are not added to the organic product and they are not intended to have any technical effect. It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered.

Table 1

<i>Term</i>	<i>Definition</i>
Ion Exchange Resin: The ions are covalently bonded to the ion exchange resin and do not interact with the product. Considered food contact substances by FDA. Historically have not needed to be on the National List, per 2002 NOP policy. See ‘Background’ in Appendix A	An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. <i>Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins</i>
Recharging Material: Ions that interact with organic because they are mobile. Certifiers require these materials to be on the National List.	Chemical solution used for flushing or regenerating the ion-exchange resin. Returns the resin to its original ion-exchange capacity after it becomes saturated with unwanted ions from repeated use. <i>Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)</i>

As explained above, the recharge materials are compounds used to recharge the exchange resins, not the exchange resins themselves. It is the exchange resins that FDA considers food contact substances. There is an important distinction between the function of the resin and the function of the recharge material. The resins are plastic-type polymers coated with fixed ions that are permanently bound within the polymer matrix of the resin. They are not removed, and they do not become a part of the processed product.

Accordingly:

- ⇒ OTA agrees with the Handling Subcommittee recommendation that the **recharge materials must be on** the National List to be allowed in organic processing. This is consistent with current practice. **See Appendix A (OTA’s spring 2020 comments) under ‘Background.’**

- ⇒ OTA also agrees with the Handling Subcommittee that the ion exchange resins are food contact substances, and do not need to appear on the National List to be used in organic processing. This is consistent with the current practice.

² Section 409 of the FD&C Act defines a Food Contact Substance as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The Food Contact Substance Notifications (FCS), [FCS 45](#), [FCS 52](#) and [FCS 74](#), are examples of the specific ion exchange resins listed at 21 CFR 173.25.

Ion Exchange Filtration MUST be reviewed and Approved in the Organic System Plan!!

Consistent with the USDA-NOP policy information presented in 2002, 2008, and 2010 and with the Handling Subcommittee’s recommendation, OTA agrees that ion exchange filtration is allowed provided that **recharging materials** are on the National List. The **ion exchange resin** itself may be allowed provided it is FDA approved as a food contact substance *and* approved in the certified operation’s Organic System Plan. The review and approval via the Organic System Plan is a very important distinction that we want to place great emphasis on and draw NOSB’s attention to.

To the best of our knowledge, the use of ion exchange in organic processing must be documented and approved in the certified operator’s Organic System Plan, including a description of the materials used in the ion exchange process and a description of the sanitation and recharge procedures. Based on the 2010 NOP clarification, most certifiers are currently requiring the recharge materials to be on the National List, but not the resins. The approval process, however, does not start and stop with the National List. Certified operators must disclose the use of the technology and the associated ion exchange media so certifying agents can conduct a thorough review and ensure that the practices and materials are fully in compliance with the organic regulations. OTA requests this complete approval process be included in NOSB’s recommendation to help ensure that it will be included in subsequent NOP Guidance or Instruction and carried out consistently by all certifying agents.

Ion exchange used by public authorities and private water system users

Ion exchange filtration may be used by public water authorities and private water system users in the production of potable water. It is primarily used for softening, where calcium and magnesium ions are removed from water; however, it is being used more frequently for the removal of other dissolved ionic species such as arsenic, chromium, fluoride, mercury and nitrates. To the best of our knowledge, ion exchange resins used in the context of potable water treatment systems are outside the scope of certifier review so long as the treatments comply with the Safe Drinking Water Act (SDWA). As such, ion exchange can be used to purify or soften all the potable water used within certified organic products. This is a point of clarification that would also be extremely helpful if placed in NOP Guidance or Instruction.

Formal NOP Instruction is Critical for Transparency and Consistency

OTA welcomes clarification via a NOSB recommendation on the use and allowance of ion exchange filtration media. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as an organic processing technology. The moving target has been the status of the ion exchange media and whether all materials/inputs need to be on the National List. The uncertainty of the situation has gone on far too long, and undoubtedly has led to some inconsistencies in practice, both at the operator and certifier levels. OTA supports moving forward with this recommendation at this meeting and we look forward to NOP responding with Guidance and/or Instruction that is formalized in the NOP Handbook.

Conclusion

OTA appreciates the opportunity to share background, both technical and policy information, to support NOSB’s recommendation on whether the ion exchange resins and membranes need to appear on the National List. We support the Handling Subcommittee’s recommendation, we support the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency.



On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Gwendolyn V. Wyard".

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Attachment A: OTA's spring 2020 comments on the Ion Exchange Discussion Document

April 3, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – Ion Exchange Filtration (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee’s Discussion Document on Ion Exchange Filtration. The Subcommittee, in response to a request from the National Organic Program (NOP), is seeking information about the various ways ion exchange filtration is used by organic operations, the substances used to facilitate the process, potential alternatives to ion exchange technology, and recommendation(s) on whether it is appropriate to include the substances associated with ion exchange on the National List.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA’s Board of Directors is democratically elected by its members. OTA’s mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Introduction

NOSB is asking four questions to help inform its discussion and future proposal. Before answering the questions, OTA would like to provide NOSB with a simple overview of ion exchange technology, followed by very important background information not included in the Subcommittee’s Discussion Document. The topic of ion exchange is complex both from a technical and a regulatory perspective. OTA’s focus at this time is on the presentation of background information to help ensure that all considerations are on the table to inform future actions.

Ion Exchange Filtration

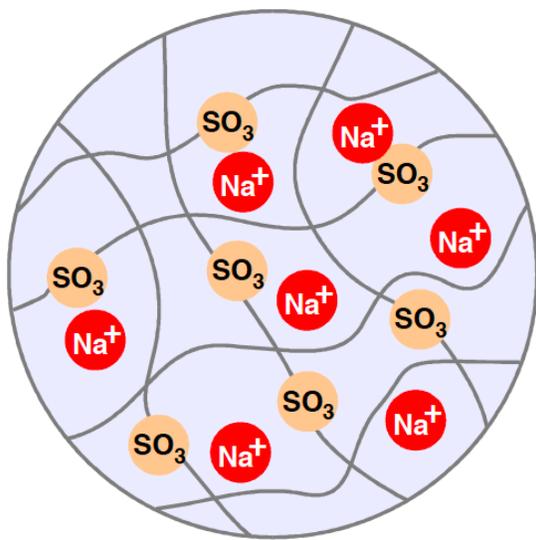
Ion exchange filtration is a food processing (purification) technique used to facilitate removal of unwanted salts, proteins, colors, flavors, odor compounds, acids, heavy metals, and other impurities using a chemical exchange process. The process involves a column, like a large pipe, packed with **ion exchange resins** that selectively remove unwanted ions from the liquid. The **resin** is an insoluble matrix (or support structure) normally in the form of small microbeads, on which a fixed ion has been permanently attached. This ion cannot be removed or displaced; it is part of the resin structure. The ion exchange resin also holds charged molecules that are mobile and available for exchange with mobile molecules in a fluid that is passed through the column. The resin is charged with a chemical solution that is periodically regenerated with a **recharging material** when the resins become exhausted.

The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. FDA currently regulates ion exchange resins as ‘food contact substances.’¹ The resins are not added to the organic product and they are not intended to have any technical effect. It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered. See also Figure 1.

Table 1

Term	Definition
Ion Exchange Resin: Considered food contact substances by FDA. Historically have not needed to be on the National List, per 2002 NOP policy.	An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. <i>Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins</i>
Recharging Material: Ions that interact with organic product and could become part of the finished processed product. Certifiers require these materials to be on the National List.	Chemical solution used for flushing or regenerating the ion-exchange resin. Returns the resin to its original ion-exchange capacity after it becomes saturated with unwanted ions from repeated use. <i>Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)</i>

Figure 1 – Schematic cation exchange resin bead



To preserve the electrical neutrality of the resin (SO₃⁻), each fixed ion must be neutralized with a counter ion (Na⁺). The counter ion is mobile and can get into and out of the resin bead. In this schematic on the left (cation exchange), the dark lines represent the polymeric skeleton of the resin bead: it is porous and contains water. The fixed ions of the cation exchange resins are sulphonates (SO₃⁻) that are attached to the skeleton. In this picture, the mobile ions are sodium cations (Na⁺) that come from the chemical solution or recharge material. Each ion going into the bead has to be replaced by an ion getting out of the bead to preserve electrical neutrality. This is what is called **ion exchange**.
NOTE: This is for illustrative purposes only. The functional group (sulfonates) would likely need to be recharged with a strong acid such as HCL or sulfuric acid, which are not on the National List. Therefore this resin would not be acceptable for use in organic.

¹ Section 409 of the FD&C Act defines a Food Contact Substance as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The Food Contact Substance Notifications (FCS), [FCS 45](#), [FCS 52](#) and [FCS 74](#), are examples of the specific ion exchange resins listed at 21 CFR 173.25.

Background: Ion Exchange Used in Organic Processing

Ion exchange filtration has been allowed in USDA-certified organic processing since the organic regulations were first established.

- ⇒ Based on USDA National Organic Program (NOP) policy information presented in 2002, 2008, and 2010, ion exchange filtration is allowed provided that **recharging materials** are on the National List.
- ⇒ The **ion exchange resin** itself is allowed provided it is FDA approved as a **food contact substance** (see FDA references below).

NOP Policy References and Timeline:

- **2002:** In a policy statement issued on December 12, 2002, after consultation with FDA, NOP clarified which substances are subject to review and recommendation by NOSB for inclusion on the National List. According to the policy, **substances that are listed in 21 CFR Part 173 as secondary direct food additives are subject to review, unless the substances are classified by the FDA as a food contact substance.** In 2002, FDA clarified that ion exchange resins were food contact substances, therefore ion exchange resins under the 2002 policy were not subject to the National List process. The 2002 food contact substance policy was archived when the NOP Handbook was created, however it has never been formally rescinded and remains in use by some certifiers. **See Attachment A**

FDA references are as follows:

- Ion exchange resins and membrane are listed in 21 CFR Part 173 as *secondary direct food additives*, which are substances that have a technical effect in food during processing but not in the finished food.
 - According to [FDA guidance](#), some secondary direct food additives also meet the definition of a *food contact substance*, which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.
 - Prior to 1997, FDA regulated ion exchange resins under 21 CFR 173.25. Once Congress established the term “food contact substance” in the Federal Food, Drug, and Cosmetic Act and initiated the Food Contact Notification Program (FCN) in 1999, all ion exchange petitions were converted to this approval method. There was no need to alter or change prior approvals under § 173.25, so they were left as is. Since that time, FDA has directed all new approvals of ion exchange resins through its FCN program. This clearly reflects FDA’s stance that they are food contact substances.
 - FDA maintains a [database](#) of approved Food Contact Substances, which include ion exchange resins that have been classified and approved by FDA as food contact substances. Any new ion exchange resin is subject to and directed through the Food Contact Notification Program.
- **2008:** The NOP Q&A dated May 14, 2008, included the question, “Is ion exchange allowed for processing organic products?” with the answer, “**Yes, ion exchange is allowed under the NOP regulations as a processing technology. Any synthetic associated with the use of such technology would still need to be on the National List as an allowed synthetic.**”

- **2010:** NOP addressed the topic of ion exchange in its annual training to certifiers in 2010. In the training slides (Dated August 8, 2010), NOP reiterated its existing policy that ion exchange technology is allowed, as long as materials used are on the National List. According to the training slides, **ion exchange technology is allowed, as long as materials used are on the National List.** NOP also gave examples of what materials may be used to charge the ion exchange columns based on this policy. Sodium hydroxide and sodium chlorite are examples of “National Listed” items that are allowed. Hydrochloric acid is an example of a “Not Listed” item. **See Attachment B**

(Note: As explained above, the recharge materials are compounds used to recharge the exchange resins, not the exchange resins themselves. It is the exchange resins that FDA considers food contact substances. There is an important distinction between the function of the resin and the function of the recharge material. The resins are plastic-type polymers coated with fixed ions that are permanently bound within the polymer matrix of the resin. They are not removed, and they do not become a part of the processed product.)

- **2012:** This topic was added to the NOSB work agenda at the beginning of 2012. From the NOSB Materials Subcommittee notes, they were waiting for more information on ion exchange resins from NOP before they could do any work on it. Eventually the topic was removed from the work plan by NOP.
- **2019:** Last year, the topic of ion exchange reappeared on NOP’s radar as a result of a conflicting materials review decision among certifiers. NOP published a policy notice to certifiers on May 7, 2019, to resolve the issue, but the notice was an abrupt departure from its long-standing policy. The notice stated that **“all non-agricultural substances used in the ion-exchange process must be on the National List. This includes but is not limited to resins, membranes, and recharging materials.”** In response to the policy notice, several stakeholders and certifiers submitted requests for NOP to clarify the rationale, extend the timeframe for implementation, and/or provide opportunities for input from stakeholders.

Concerns NOP received from certifiers regarding the 2019 NOP Policy Notice:

- The 2019 NOP Policy Notice states that FDA does *not* consider ion-exchange resins or ion-exchange membranes to be food contact substances, which is a departure from FDA references (see above) and the information NOP received in 2002.
 - The 2019 NOP Policy Notice states that ion-exchange resins must be on the National List, which is a departure from the 2002, 2008, and 2010 NOP policy statements (see above).
 - If ion-exchange resins were to be prohibited without suitable alternatives, many certified operations would not be able to produce certified organic product. This would have a significant impact on the industry at large. The prohibition could also affect the classification of many non-synthetic materials that are processed using ion exchange (e.g. citric acid, pullulan).
- **2019:** On August 19, NOP requested NOSB provide recommendations to address inconsistencies between certifiers and to ensure that organic stakeholders have an opportunity to provide input. NOP specifically asked for information “about the various ways ion exchange filtration is used by organic operations, the substances used in these processes, potential alternatives to ion exchange

technology, and recommendation(s) on whether it is appropriate to include these substances on the National List.”

NOSB Questions

1. **What organic products are currently produced through the ion exchange process?** First, the most common use of ion exchange is for water softening and water purification that is used in many organic processing facilities. The organic products we have identified that are currently produced using ion exchange include:

- Agave Syrup
- Beer
- Cane Sugar
- Juice Concentrates
- Infant formula
- Milk Powders, including Skim Milk Protein Concentrates
- Pullulan (research quantities scaling up to commercial production)
- Rice Syrup
- Starch sweeteners
- Stevia
- Vegetable Oils
- Wine

This list is not an exhaustive list and it only includes the primary ingredients that rely on ion exchange. It does not include all of the products that utilize these ingredients and would be impacted by a change of policy.

2. **Are there other processing methods used to produce these products?**

Not for all products listed and not to the purification level needed. We understand that activated carbon filtration is often used in combination with ion exchange, but activated carbon alone will not result in the desired purification to meet many specifications and desired outcomes. Any contaminant that is not ionized cannot be removed by ion exchange, therefore activated carbon can be ideal when used in combination. Ion exchange is a very powerful technology that can result in an extremely pure product. For example, we understand it is the only filtration technology that will remove heavy metals, such as arsenic, from organic rice products to meet both consumer expectation and FDA requirements.

Another similar technology is electrodialysis, a process for transporting ionic species across an ion exchange membrane. Ions and a solution in a desalting cell are transferred to a concentrating cell across a cation- and anion-exchange membrane under applied current. The process does not use recharge materials like the ion exchange process described thus far, but it still relies on ion exchange and use of ion exchange membranes.

Finally, another similar and effective filtration method is **Nanofiltration**. This process is a membrane filtration-based method that uses nanometer sized through-pores that pass through the membrane. Nanofiltration membranes have pore sizes from 1-10 nanometers, smaller than that used in microfiltration and ultrafiltration, but just larger than that in reverse osmosis. The

performance of this process however, while good and inexpensive, is much less effective than ion exchange and will not remove impurities to the levels desired if not required.

3. **What materials are being used in the ion exchange process for current organic products? Please include resins, recharge materials, membranes and any other substances.**

As explained earlier, ion exchange materials include resins and recharge materials. Ion-exchange resins are also produced as membranes. These [ion-exchange membranes](#), which are made of highly cross-linked ion-exchange resins that allow passage of ions, but not of water, are used for electro dialysis. The focus here will remain on resins and recharge materials used for ion exchange.

- **Resins:** The exchange **resins** can include polymeric resin beads, zeolite minerals, activated carbon, polystyrene resins and acrylic resins. Most typical ion-exchange resins are polymers that act as the medium for ion exchange. They are normally in the form of small porous beads providing a large surface area on and inside them. Most commercial resins are made of cross-linked polystyrene (polystyrene sulfonate). The structure of the resin is a polymer (like all plastics) on which a fixed ion has been permanently attached. This ion cannot be removed or displaced; it is part of the structure. There are two types of ion exchange resins. As the name suggests, cation exchange resins are used to remove positively charged contaminants, while anion exchange resins are used to remove negatively charged contaminants.
- **Recharge Materials:** When the resins are exhausted, you bring them back to the fresh state and start over again using recharge or regeneration materials. This happens when contaminant ions have bound to nearly all available active sites on the resin matrix. Examples of the common recharge materials include sodium chloride, potassium chloride, hydrochloric acid and hydrogen peroxide. Hydrochloric acid is not allowed. **See Table 1.**

4. **If you do not agree that there is chemical change to the products run through the ion exchange process, please provide rationale for this belief.**

OTA does not believe the question of “chemical change,” when applied to the organic product being processed, is relevant to the clarification NOP is seeking because it doesn’t impact the question of whether the ion exchange media (resins, membranes and recharge materials) need to appear on the National List. Under consideration is the ion exchange technology itself, which is not categorically prohibited under the NOP standards, and the regulatory status of the ion exchange media/materials. The question at hand is whether the ion exchange media (nonagricultural inputs) must appear on the National List.

The reference to a “chemical change” is found in the italicized section on page 2 of the Handling Subcommittee’s Ion Exchange Discussion Document (Page 44 of the NOSB packet). This is an excerpt from an unpublished background memo that the Organic Materials Review Institute (OMRI) sent to NOSB in October 2002. The excerpt includes the sentence, “The process chemically changes the resulting fluid.” The consideration of a chemical change *would be relevant* to a Materials Review Organization, such as OMRI, or to the National Organic Standards Board, when making a classification decision (synthetic vs. nonsynthetic) on an input such as citric acid

or pullulan. Both of these examples, as a point of interest, are produced using ion exchange and are classified as nonsynthetic.

As a processing technology, ion exchange is used for filtration and purification; the intent is not to chemically change a product, but to eliminate unwanted contaminants or impurities through removal of their associated ions. There are several allowed NOP processing technologies that will chemically change a processed product. Examples range from cooking/baking and heating to the use of activated carbon for filtration, an allowed processing technology that relies on a chemical absorption and separation. Ion exchange does in fact depend on a chemical process (exchange of ions of the same charge), but as a technology in the context of organic processing (under § 205.270 - Organic Handling Requirements), it can be identified as filtration or “separating.”

The ion exchange media on the other hand, are nonagricultural substances, that either should or should not be subject to the National List review process depending on how they are regulated (secondary additive vs. processing aid vs. food contact substance).

Conclusion

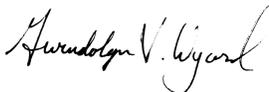
The topic of ion exchange filtration in organic processing is complex from both a technical and regulatory perspective, and there is a long history around its use and allowance. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as a processing technology. The moving target has been the status of the ion exchange media and whether all materials/inputs need to be on the National List.

To the best of our knowledge, the use of ion exchange in organic processing must be documented and approved in the certified operator’s Organic System Plan, including a description of the materials used in the ion exchange process and a description of the sanitation and recharge procedures. Based on the 2010 NOP clarification, most certifiers are currently requiring the recharge materials to be on the National List, but not the resins.

OTA appreciates the opportunity to share background technical and policy information to support NOSB’s effort to respond to NOP’s request to develop a recommendation on whether the ion exchange resins and membranes need to appear on the National List. We support the critical role of NOSB in this decision-making process and above all, we support transparency and consistency.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association



cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Attachment A: Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products

Attachment B: NOP Certifier Training 8-20-2010 (slides 25 & 26)

Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products

Accredited certifying agents, food processors, and food manufacturers have contacted the National Organic Program (NOP) regarding under what conditions synthetic substances used as ingredients in processed food products are subject to review and recommendation by the National Organic Standards Board (NOSB).

7 CFR 205.2 defines ingredient as “any substance used in the preparation of an agricultural product that is “still present” (quotations added) in the final commercial product as consumed.” This definition arose from an April 25, 1995, NOSB recommendation on good manufacturing practices in certified organic handling operations.

The NOP defines “still present” as those ingredients regulated by the Food and Drug Administration (FDA) as food additives permitted for direct addition to food for human consumption under:

1. 21 CFR Part 172, Food additives permitted for direct addition to food for human consumption.
2. 21 CFR Part 173, Secondary direct food additives permitted in food for human consumption: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. 21 CFR Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
4. 21 CFR Part 181, Prior-sanctioned food ingredients: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
5. 21 CFR Part 182, Substances generally recognized as safe.
6. 21 CFR Part 184, Direct food substances affirmed as generally recognized as safe.

The NOP also defines “still present” as those materials approved by the Bureau of Alcohol, Tobacco and Firearms (ATF) as being acceptable for use by proprietors in the production of alcohol beverages under:

1. 27 CFR Part 24, Section 24.246, Materials authorized for the treatment of wine and juice: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
2. 27 CFR Part 24, Section 24.247, Materials authorized for the treatment of distilling material: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. The Brewers Adjunct Reference Manual: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.

Attachment A

Accordingly, substances listed in 21 CFR Parts 172, 173, 180, 181, 182, and 184; 27 CFR Part 24; and the Brewers Adjunct Reference Manual, except those substances classified by the FDA as food contact substances, must be on the National List of Allowed and Prohibited Substances to be used in the production of an “organic” or “made with organic (specified ingredients or food group(s))” processed product.

Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim.

December 12, 2002



Ion Exchange

Situation: Certifiers are asking if ion exchange is allowed in organic handling. Specific questions are what materials may be used to charge the ion exchange columns.



Ion Exchange

NOP Guidance:

- NOP has posted policy that ion exchange technology is allowed, as long as materials used are on the National List.
- For example-
 - Listed items:
 - Sodium hydroxide
 - Sodium chloride
 - Not listed:
 - Hydrochloric acid



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Handling Subcommittee – 2022 Sunset Reviews for §205.605

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2022 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each handling input scheduled for review as part of the 2022 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if: 1) they are still essential to and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2022 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review.

Results of OTA Sunset Surveys

OTA has received 105 total (605 and 606) responses on our 2022 Handling Sunset Surveys. Below is a summary of the feedback received via OTA’s Sunset Surveys to date on the § 205.605 materials only. Please see our separate comments on the § 205.606 ingredients.

- **§ 205.605 Responses:** 24 responses

§205.605(a) – Non-synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

Substance	# of responses	Summary of responses	Average rating of Essentiality <small>(from 1 to 5, with 5 being “critical – would leave organic without it”)</small>
Kaolin	0		
Sodium bicarbonate	9	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Routinely used as a leavener to make cookies, crackers, cereal, baking mixes, refrigerated baking doughs, granola bars, tortillas, and baked goods. - Leavening agents are essential for non-yeast baked goods like cookies, crackers, and bread. - Also used as processing aid for soy extraction to make plant-based beverages and coffee creamers <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other leaveners are available, but this is the most functional and widely used in both consumer, commercial and industrial baking. Although it only performs in acidic foods, so often requires an acidic baking powder. - No organic alternatives or practices identified. - Have searched annually and confirmed lack of commercially available alternatives. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Without it, baked products would be dense and unpalatable. - Several of the products we sell would have to reformulate, if possible, or convert to conventional. - We would not be able to produce the products to the same level as quality as currently offered to consumers. 	4.3
Wood rosin	0	Note: Wood rosin is erroneous listed as “wood resin” on the National List.	

§205.605(b) – Synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

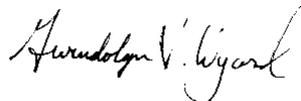
Substance	# of responses	Summary of responses	Average rating of Essentiality <small>(from 1 to 5, with 5 being “critical – would leave organic without it”)</small>
Ammonium bicarbonate	3	The material is essential because:	4

		<ul style="list-style-type: none"> - Used as leavening agent to make cookies, crackers, baked goods - Frozen breakfast foods, frozen entrees - Used as a stabilizer <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Non-synthetic alternatives have not been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - would have to reformulate many products, if possible, or convert to conventional - Reduce the availability of ingredient for breakthrough innovation 	
Ammonium carbonate	0		
Calcium phosphates	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a leavener, nutrient, anti-caking agent - Used in making crackers, cereal, baking mixes, cookies, tortillas, baked goods, plant-based beverages, seasoning blends. - Calcium Phosphate is the acidic ingredient often used in aluminum-free baking powders - Leavening agents are essential for non-yeast baked goods like cookies, crackers, and bread. - Used for fortification in making yogurt and baby foods <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other leaveners are available, but this is often the most functional when used in combination with Baking Soda (Sodium Bicarbonate) in foods that require the addition of acid to release the carbon dioxide needed to leaven baked goods. - No organic alternatives identified. - Rice Concentrate does not work on vegetable products with a high sugar content. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Without it, baked products would be dense and unpalatable. - Devastating to not have anti-caking agents. - Would have to reformulate, if possible, or convert to conventional 	5
Ozone	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a sanitizer - Disinfectant for the cleaning process of production lines <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Non-synthetic alternatives have not been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Limiting the number of available sanitizers is not in the best interest of food safety. 	4
Sodium hydroxide	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a processing aids in making soaps, body care, plant-based beverages, baby food - Used as an alkalizing agent in making black cocoa powder 	4.5

		<ul style="list-style-type: none"> - Balances pH in infant formula powder - Used in cereals, baked goods/snacks. Frozen breakfast foods, frozen entrees for pH adjustment of rice bran extract. It allows for the use of water to extract the necessary nutrients and functional ingredients. - Used in human and pet food, dietary supplement ingredients <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Potassium carbonate has been tested as an alternative, but it does not get the same black cocoa color as the addition of the Sodium Hydroxide - There is a search done annually to confirm lack of commercial availability - There is not another alternative performing in the same manner. Trials have been completed and have not proved adequate performance - There are no alternatives that will raise the pH above 10. A weaker material would require us to use more which would nullify our organic certification. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - We wouldn't be able to make a USDA organic claim on our personal care products - Would have to reformulate, if possible, or convert to conventional. - You'd be hard pressed to make Oreo/Hydrox type products without the black cocoa - It would change the production of the product - The loss of this ingredient would cause a stop in the production of this ingredient. Our ingredient has been in the market for almost 28 years and in thousands of organic formulations globally. We are the only maker of this ingredient; it was patented and there are no other producers. Additionally, there are no other organic alternatives. 	
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard
 Vice President of Regulatory and Technical Affairs
 Organic Trade Association

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Appendix A – Sample Survey for Handling Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use this substance on/in? (e.g., yogurt, fruit juices, baked goods, etc.)
5. What function does the substance provide in your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you conducted a search for the availability of natural (if the substance in question is synthetic) or organic (if the substance in question is natural) alternatives? (e.g. using yeast instead of chemical leavening agents)
 - If so, please describe what your search entailed:
 - Based on your search, describe the availability of allowed alternatives (organic or natural) in terms of quality, quantity and form:
 - If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives in your organic product(s)? Briefly describe the results. Did they meet your specification requirements?
8. Are there any other management practices that would eliminate the need for the substance? (e.g., delayed harvesting instead of using a chemical growth hormone for ripening). If so, please describe the efficacy of the alternative management practices:
9. Describe the impact to your operation should you no longer be allowed to use the substance:
 - Organic product effects (effects to the quality of the organic product(s) you are marketing):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall essentiality of this substance for your organic operation:

Unnecessary (don't need it at all)		Neutral (nice to have but could live without it)		Critical (would leave organic without it)
★	★	★	★	★
11. NOSB collects information about the "ancillary substances" (e.g. carriers, preservatives, stabilizers) that may be used to formulate commercial forms of the substance. Please list any ancillary substances that are identified on the ingredient statement on the specification sheet that accompanies the substance you purchase.



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Handling Subcommittee – 2022 Sunset Reviews for §205.606

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2022 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each handling input scheduled for review as part of the 2022 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if:

- 1) They are still essential to and compatible with organic production and handling practices;
- 2) There are no commercially available alternative materials (natural, organic) or practices; and
- 3) No new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List).

Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2022 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review.

Organic Ingredients and Commercial Availability

Agricultural ingredients listed on § 205.606 of the National List must be used in organic form when they are commercially available (quality, quantity, form). The process of determining whether an ingredient is available in organic form is an interactive process that takes place between a certifying agent and a certified operation, and it occurs on at least an annual basis. Certified operators must document and demonstrate their efforts to source organic ingredients, and certifying agents must carefully assess and document their approval. For the certified operator, this process includes a description of the frequency that the search is performed and research efforts to evaluate the quantity, quality and form of known organic sources. For the certifier, this process includes evaluating the applicant or certified operator's Organic System Plan and the operator's documented claims that the organic ingredient is commercially available/unavailable in the form, quality, or quantity needed to fulfill the required function of the organic product.

The inclusion of an ingredient on § 205.606 of the National List does not mean wholesale allowance to use a non-organic form. It means an organic alternative does not exist or there is a fragile supply, and therefore certifying agents must make determinations on a case-by-case basis. It also means that there is an opportunity for the development of an organic alternative that is available in the quality, quantity and form that will meet the industry's needs (aka *commercially available*). The organic industry and NOSB must work together to determine when the supply of a particular § 205.606 ingredient is no longer fragile. It is important to recognize that while the Sunset process continues, so does the relationship between the certified operation and certifying agent and the **requirement** to use organic when it is commercially available. Further, the option to petition a material OFF the National List is always open, and we commend the example that has been set with the petition to remove Whey Protein Concentrate.

OTA acknowledges that for some there is frustration with the number of agricultural ingredients that remain on the National List, and there is growing discontent with "commercial availability" and the role it plays in the organic standard. Does it serve its purpose or is it actually an impediment? The challenges we are grappling with mirror the discussions and NOSB recommendations that have occurred with organic seed, and the option to use non-organic seed when an equivalent variety is not commercially available. One notable difference, however, is that NOP issued Guidance on Commercial Availability of Organic Seed and Planting Stock (NOP 5029), whereas the 2006 NOSB recommendation on Commercial Availability for § 205.606 ingredients continues to be unaddressed by NOP. Another notable difference is that NOSB recently passed a recommendation for a rule change that requires organic producers to demonstrate improvement in use of organic seed/planting stock every year. NOSB also more recently passed a recommendation to update the existing Guidance on organic seed/planting stock. Aside from the unaddressed NOSB recommendation on §205.606, the only Guidance we know of that is publicly available on commercial availability for handling materials has been developed by the Organic Trade Association¹ and the Accredited Certifying Association². Both documents describe the process and criteria that is followed by most certifiers in the course of reviewing commercial availability for any § 205.605 or § 205.606 ingredient.

¹ [USDA organic flavors Required When Commercially Available](#) – A practical guide to complying with the new requirements for natural flavors

² [ACA Best Practices for Commercial Availability of Natural Flavors, June 2020](#)

OTA shares concerns about how well the commercial availability provision actually drives market incentive. We recognize the role that industry can take, and we are constantly working on initiatives to advance efforts and resources to support the development of natural and organic alternatives. We have long considered § 205.606 to be the “entrepreneurial list of opportunity,” and we have a record of advocating for the removal of items when there is industry consensus that the organic supply of an ingredient is available and stable. We have also championed petitions and efforts to assign commercial availability to ingredients on § 205.605 (natural flavors, yeast and silicon dioxide), and of course we are leading efforts to develop an organic alternative to celery powder.

OTA is sensitive to the frustrations of the organic community and the ongoing role of commercial availability almost 20 years into the National Organic Program. We are interested in the best approach to drive innovation and incentive within the boundaries of OFPA and NOSB’s authority. The question that we continue to hear is, “What is my role as an NOSB member and how do we know when the time is right to vote an ingredient off the National List?” As one member of NOSB summarized the dilemma in 2008, “I feel like I am stuck in a chicken-and-an-egg thing ... until it is off the list, industry won’t be incented to use it.”

OTA does not support voting a material off the National List to make a point, or to scare or drive incentive. We can appreciate the temptation and even the sentiment, but a decision to vote a material off the National List without sufficient evidence to prove that the ingredient is commercially available in an organic form is not consistent with OFPA criteria or the role of NOSB. We understand that it is often difficult to know when there is sufficient evidence, but at the same time, we *know when there is* sufficient evidence because there is consensus and the industry voice will come through. We also recognize that the Sunset process--as well as the petition process--is a two-stage rulemaking process. Therefore, if NOSB is *uncertain* and votes to remove an ingredient from the National List, there is the NOP rulemaking process to further confirm that decision via another comment period that tends to catch the attention of stakeholders that were not aware of the NOSB process. With this second comment period in mind, if a NOSB member prematurely votes a material off the National List to send a message, unfortunately, this may end up reflecting poorly on USDA and the organic community as a whole, if USDA is not able to accept that recommendation because it doesn’t meet the criteria of OFPA.

OTA is committed to further discussion about the sunset and petition process and the best approach to support the development of organic alternatives. We have invested heavily in this area but clearly there is much more work to be done. We believe there are untapped solutions for incentivizing the development of organic ingredients, supporting organic manufacturers and certifying agents, and setting clear guidelines for improvement that can incentivize the creation of new organic ingredients and enforce the highest standard of “organic preference.” OTA welcomes a discussion document on this topic.

For this round of Sunset on § 205.606, based on the survey results we collected and direct outreach to our members, it appears that there is a stable supply of **Turkish Bay Leaves** and the listing should sunset. It also appears that there is a stable supply of **Whey Protein Concentrate**. Again, we commend the petition that was submitted because it reflects a proactive approach and will allow for a much deeper analysis with more time for consideration if needed. We did not receive any comments on sweet potato starch, but again, we also didn’t receive any information to prove that the organic form is available. For all other § 205.606 ingredients, the organic supply appears to be fragile, meaning that the quality, quantity and/or

form is not available as needed at this time. We look forward to seeing the comments submitted by others that will hopefully fill in some gaps and shed further light.

Finally, please continue to keep in mind that for all of the ingredients listed on § 205.606, the use of an organic form *is required* when it is commercially available despite its listing on § 205.606. We frequently see organic products that contain organic colors, organic corn starch, organic gums, organic carnauba wax and others. The presence of these organic ingredients on the statement of organic products in the marketplace demonstrate success, and it shows that the process is working. It is critical that we recognize the certifier end of the review process and the efforts that are in fact being made by the organic industry. Organic consumers want to see an ingredient statement list all organic ingredients and that demand drives the most powerful form of incentive.

Results of OTA Sunset Surveys

OTA has received 105 total responses (605 and 606 combined) on our 2022 Handling Sunset Surveys. Below is a summary of the feedback received via OTA’s Sunset Surveys to date on § 205.606 only. Please see our separate comments on the § 205.605 substances.

- **§ 205.606 Responses:** 81 responses

§205.606 – Non-organically produced agricultural products allowed as an ingredient in or on processed products labeled as “organic” only when the product is not commercially available in organic form.

Substance	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Carnauba wax	5	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for texture and appearance in gummy bears and fruit snacks; it creates a shiny appearance on gummy snacks and provides an anti-stick coating to keep the products from clumping - Used for gummy dietary supplements - Cereals, snacks, frozen entrees and breakfast foods – functions as a component of an anti-sticking agent. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Organic carnauba wax is available consistently according to one respondent, but others report that a reliable and stable organic supply has not yet been established. - Encourage that Carnauba Wax remain on 606 until a stable organic supply has been established. - We contact 3 or more suppliers annually to source organic alternatives. There is limited availability and it does not function as intended as determined through research trials. - Limited availability in the organic version; does not function as intended <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic supply may not be available if non-organic forms are prohibited. - Without this material, we would need to reformulate and sell non-organic instead of organic products. 	2.5

		- Would require reformulation	
Colors Several new comments were submitted	48 (total)	<p>Survey responses were received for the following:</p> <ul style="list-style-type: none"> • Beet Juice Extract Color (2 responses) • Beta-carotene Extract Color (3 responses) • Black Current Juice Color (2) • Black/Purple Carrot Juice Color (6) • Blueberry Juice Color (3) • Carrot Juice Color (3) • Cherry Juice Color (2) • Chokeberry, Aronia Juice Color (2) • Elderberry Juice Color (3) • Grape Juice Color (2) • Grape Skin Extract Color (1) • Paprika Color (2) • Pumpkin Juice Color (2) • Purple Sweet Potato Juice Color (2) • Red Cabbage Extract (5) • Red Radish Extract Color (3) • Saffron Extract Color (2) • Turmeric Extract Color (3) <p>Colors are essential because:</p> <ul style="list-style-type: none"> - Coloring agents are used in fruit snacks, candy, juices, cereal, plant-based ice cream and yogurt, baby teether crackers, crackers, baked goods, gummy dietary supplements - Used in certified organic flavors - Used in juices containing mango which browns readily (comment for beta carotene). Also a natural source of vitamin A. - Used in cereals and snacks <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Organic forms are beginning to be available and suitable for some products, although it takes considerable amount of resources and time to validate the organic options, and some products need to be reformulated to meet manufacturing processing capabilities. - Annual search done and has been determined there is not an organic source available - Support that Fruit/Veg Colors remain on 606 while the work continues to validate organic options. - They are not commercially available, but we continue to work with our certifier on an annual basis and must demonstrate that we cannot find an organic alternative. We must document a search as well as report R & D efforts. - At least annually we ask approved suppliers for organic sources of beta carotene. We have been unable to find a supplier that could provide sufficient quantities and still meet our own internal food safety, quality and 3rd party audit requirements. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would have to reformulate, if possible, or convert to conventional - Would have to discontinue products 	4

		<ul style="list-style-type: none"> - Would need to discontinue products and therefore stop sourcing and using rest of the 95% of the organic ingredients - Would not be competitive with conventional products - Organoleptic change to both flavor and CPG product - Loss of sales due to inability to provide expected product - We would lose the ability to keep trying to source and develop organic colors while the market grows because we would need to discontinue organic. - It may not result in the development of organic colors and instead the loss of organic products. 	
Glycerin	8	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a solvent, carrier in manufacturer of organic flavors and plant-based ice cream, yogurt, baby food - Use as humectant and moisture stability in making granola bars. It helps lower water activity to prevent mold growth. It helps with moisture control to allow for a chewy texture. - Stabilizes enzyme preparations, protecting them in the event of extreme temperature changes. Enzymes are used in the process of standardizing the amount of pectin in certain fruits, such as grapes, as they are prepared for use as juice and in fruit spreads. Depectinization ensures that the fruit is consistent in these products from batch to batch. Enzymes are essential to processing certain fruits, but are used at extremely low levels and do not have a function in the finished products. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some manufacturers are currently using organic glycerin. However, others report that high quality organic forms are not available for some manufacturers. Others have identified suitable organic alternatives, but reliable stable supplies are not established. - The supply of organic glycerin will not support our current annual demand to manufacture and sell organic compliant flavors - Support glycerin to remain on 606 until a stable organic supply has been established. - Organic flavors and organic compliant flavors use organic glycerin, but there is not enough organic glycerin to supply the entire market. It is a developing minor organic ingredient and supply of organic products in general is not high enough to bring up a consistent supply of organic glycerin. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - The supply of organic glycerin will not support our current annual demand to manufacture and sell organic compliant flavors. The cost of using organic glycerin in lieu of natural glycerin would not align with our client's cost-in-use. Loss of business is expected. - The entire line of organic compliant flavors would not be available and that would have a devastating impact on the organic industry. 	5
Inulin-oligofructose – enriched (IOE)	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in making plant-based ice cream and yogurts, fluid milk, dairy yogurt, and infant formula 	5

		<ul style="list-style-type: none"> - Provides fiber - Provides mouthfeel/bulking to help with sweetness perception - Pre-biotic <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - IOE from chicory is not available in organic form - organic inulin + conventional FOS does not provide same functionality - Have searched and not found any alternatives. - Search the USDA database regularly <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Unable to produce organic products without it - Would leave the organic market; stop making organic products 	
<p>Kelp</p> <p>No new comments since spring 2020</p>	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for flavor in organic seasoning blends - Use as thickener and supplement in plant-based protein supplements <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Not identified. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Loss of flavor profile 	4
<p>Orange shellac – unbleached</p> <p>No new comment since spring 2020</p>	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Prevents jelly beans from sticking together <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other alternatives have not provided functional equivalence <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Products would be discontinued 	5
<p>Cornstarch</p>	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Thickener in macaroni and cheese, tortillas, baking mixes, and baked goods - Used in cereals, snacks, frozen entrees and breakfasts - Build viscosity to maintain fruit distribution in fruit preparations - Used as a moulding medium for gummy bears and fruit snacks. It is a processing aid in manufacture of confections. - Critical for our production process. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some manufacturers are able to find organic forms, although consistency of supply is not reliable (two shortages in past ten years). Other manufactures have not found any organic form that meets their specifications for functionality and quality - We have other types of starch but they are not functional equivalents. - We have not found alternatives that work. 	4.5

		<ul style="list-style-type: none"> - Support cornstarch to remain on 606 until a reliable, stable organic supply has been established. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic supply may not be available if non-organic forms are prohibited. - Would have to reformulate, if possible, or convert to conventional - We would no longer be able to manufacture organic products 	
Sweet potato starch	0	No comments were provided	
Turkish bay leaves No new comments since spring 2020	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for flavor in a wide range of canned soups <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - N/A - Respondent states there is full availability of organic forms. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - No impact because organic forms can be used and are available. 	1
Whey protein concentrate (WPC) One new commenter since spring 2020	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for nutrition in baby food - Used in cereals, baked goods/snacks, frozen breakfasts and frozen meats as a protein source, flavor and thickener <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some organic processors are not able to find enough organic supply, while others do not have a problem finding this ingredient in organic form. - There is a search done annually and regularly as there is not always organic supply available and/or supply is not consistent. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - At least one processor reports that they would have to continually change formulas of products to deal with inconsistent supply or organic form. <p>One manufacture said that organic alternatives are available and will meet the requirements needed. However, leaving it on the list would support any interruption in supply continuity.</p> <p>According to another manufacturer of WPC that completed our survey: We produce Whey Protein Concentrate. It is made from cheese whey which yields lactose and whey protein concentrate. Lactose is a very popular offering. Whey protein concentrate is in less demand. We believe this is due to use of non-organic whey protein concentrate. If we utilized all our whey stream (which we are working on) we do not feel organic availability will be an issue.</p>	3



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink, which appears to read "Gwendolyn Wyard".

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A – Sample Survey for Handling Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use this substance on/in? (e.g., yogurt, fruit juices, baked goods, etc.)
5. What function does the substance provide in your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you conducted a search for the availability of natural (if the substance in question is synthetic) or organic (if the substance in question is natural) alternatives? (e.g. using yeast instead of chemical leavening agents)
 - If so, please describe what your search entailed:
 - Based on your search, describe the availability of allowed alternatives (organic or natural) in terms of quality, quantity and form:
 - If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives in your organic product(s)? Briefly describe the results. Did they meet your specification requirements?
8. Are there any other management practices that would eliminate the need for the substance? (e.g., delayed harvesting instead of using a chemical growth hormone for ripening). If so, please describe the efficacy of the alternative management practices:
9. Describe the impact to your operation should you no longer be allowed to use the substance:
 - Organic product effects (effects to the quality of the organic product(s) you are marketing):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall essentiality of this substance for your organic operation:

Unnecessary (don't need it at all)

Neutral (nice to have but could live without it)

Critical (would leave organic without it)



11. NOSB collects information about the "ancillary substances" (e.g. carriers, preservatives, stabilizers) that may be used to formulate commercial forms of the substance. Please list any ancillary substances that are identified on the ingredient statement on the specification sheet that accompanies the substance you purchase.



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Livestock Subcommittee – 2022 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2022 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each livestock production material scheduled for review as part of the 2022 Sunset Review cycle. Materials placed on the National List for use in organic livestock production should remain on the National List if: 1) they are consistent with organic farming; 2) they are still necessary to the production of the agricultural product because of the unavailability of wholly natural substitute products in organic production; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large. It's critical that NOSB hear from certified farmers on whether these inputs are consistent with and necessary for organic production, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2022 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked through its Farmers Advisory Council (ota.com/FAC) to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received 9 responses on our 2022 Livestock Sunset Surveys (1 is new responses since the spring meeting). Below is a summary of the feedback received via OTA’s Sunset Surveys to date.

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

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 1 being “unnecessary” and 5 being “critical /would leave organic without it”)
Butorphanol	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used as pain relief for a dairy cow when prescribed by a vet. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - (no response) <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal health would suffer - Fewer options for animal health care 	4
Flunixin	3	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used for inflammation, fever reduction and pain management in dairy cattle. - Prescription, non-steroidal - Used as needed when an animal is sick or injured - Strong enough for severe cases. - This is a very important tool in the toolbox for managing animal pain and comfort. Having this available for use is an animal welfare issue. It should be left on with the current restriction. - Pain management in calves & cattle and treatment for respiratory disease (before resorting to antibiotic treatment - Flunixin is an extremely important tool to us in providing pain management during painful procedures (dehorning) and during times of illness (respiratory, and other conditions where pain and inflammation are an issue ie. dystocia, severe metritis, pneumonia, severe scours in calves..) - On as needed basis other than dehorning where it is a vet recommended pain management tool during this process. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Alternatives are not as strong for use in more severe cases - Our operation uses aspirin in mild cases, but efficacy is questionable in cases and has to be given at higher frequency to gain any efficacy. - There is not any alternative to this product that would provide the same efficacy. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal comfort and wellbeing will be greatly diminished if this is removed. - Negative economic impact if animals have to be sold because they have a curable illness or injury that requires stronger pain management 	5

		<ul style="list-style-type: none"> - I see this having major animal welfare implications for livestock producers if flunixin is removed as an approved substance. We currently are unable to use so many pain management substances because of being organic and at the same time are always getting pressure from our organic welfare certifying agency on this topic. We use flunixin as our primary source of pain management where aspirin is not sufficient. If this was not an option I could see us reaching a point of not being able to obtain welfare certification. 	
Magnesium hydroxide	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used as an antacid and laxative in dairy cow management. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - (no response) <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal health would suffer 	4
Poloxalene	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Relieves bloat in dairy animals. - It is needed because bloat is life-threatening and if left untreated, can quickly cause death. - It is used very rarely, only in emergency cases. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Sometimes plant oils can work but not always. Also, sometimes you find an animal beyond help from plant oils and the only quick remedy is Poloxalene. - There are management tactics to help prevent bloat. But even though you try to prevent, it can still occur despite your best efforts in some cases. This is an emergency-only treatment. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Livestock wellbeing would be jeopardized - Unnecessary loss of livestock would be a high cost 	4
Formic Acid	0		
Excipients	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used as inactive ingredients formulated with allowed medical active ingredients for dairy cow management <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - (no response) <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal health would suffer 	
EPA List 4 inerts	1	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is necessary because:</p>	4

		<ul style="list-style-type: none"> - Used as inactive ingredients formulated with allowed pesticide active ingredients for dairy cow management <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - (no response) <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Animal health would suffer 	
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§205.604 – Non-synthetic substances prohibited for use in organic livestock production.

Substance	# of responses	Summary of responses
Strychnine	0	

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda
 Farm Policy Director
 Organic Trade Association

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Appendix A – Sample Survey for Crop and Livestock Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use the substance on/for? (e.g., lettuces, fruit trees, broiler chickens)
5. What function does the substance provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you tried using any *natural substances* as an alternative to the substance? (e.g., natural oils instead of synthetic pesticides) If so, please describe the availability and efficacy of the alternative substances:
8. Are there any other *management practices* that would eliminate the need for the substance? (e.g., hand weeding instead of using an herbicide; or using a particular harvesting practice to avoid a disease instead of using a fungicide). If so, please describe the efficacy of the alternative management practices:
9. Describe the effects to your operation if you were to no longer be allowed to use this substance in organic production:
 - Agronomic effects (effects to health of crops or livestock):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall necessity of this substance for your organic operation:

Unnecessary (don't need it at all)	Neutral (nice to have but could live without it)	Critical (would leave organic without it)
★	★	★



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Crops & Livestock Subcommittees – EPA List 4 Inerts of Minimal Concern (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop and Livestock Subcommittee's Sunset Review of EPA List 4 Inerts of Minimal Concern.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA supports renewal of the listings of EPA List 4 inert ingredients at §205.601 and §205.603 on the National List during this Sunset Review. Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed. As described in our previously submitted comments (Attachment A), EPA List 4 is an obsolete reference and a modernized system for reviewing inert ingredients is not yet in place, despite a 2015 NOSB Recommendation to update the National List with accurate references to EPA's current mechanism for approving the least-toxic inert ingredients. NOP has not taken any action to implement the recommendation, and there is no indication it would be able to complete the multi-year implementation process prior to the sunset date in 2022. The prohibition of List 4 inerts prior to establishment of a new system would cause significant disruption to the availability of essential pest control tools for organic production. Therefore, the continuation of the current listings of EPA List 4 inerts is critical for ensuring continued availability of effective and familiar pest control tools for organic producers.

OTA continues to support the 2015 NOSB Recommendation. We share NOSB's frustration that NOP has failed to implement the recommendation, and there is still no resolution to the longstanding discrepancy in the organic regulations with regard to inert ingredients. However, we strongly discourage voting to remove List 4 inerts from the National List without a viable alternative list of approved inerts (and regulatory references to such list) in place. Voting to prohibit this important class of substances is irresponsible and risky when farmers' access to critical tools for organic production is at stake. OTA's



Farmers Advisory Council¹ agrees and strongly urges caution to protect continued availability of critical pest control tools for farmers.

We call on NOP to commit to implementing the 205 NOSB Recommendation. Modernizing the system for review of inert ingredients is a priority of the organic industry. Pesticide product development and innovation are being stifled by the outdated regulatory references for inert ingredients. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products. A roadmap for implementing the 2015 NOSB Recommendation is already in place (See Appendix A, page 6) and now NOP must commit to action.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

¹ The Organic Trade Association's Farmers Advisory Council (FAC) provides the Organic Trade Association Board of Directors and staff with input from small- and medium-sized organic farmers, ranchers, and growers on matters pertinent to the advancement of organic agriculture, with a specific focus on OTA's policy agenda. More at ota.com/FAC

April 3, 2020

ATTACHMENT A

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-19-0095

RE: Crops & Livestock Subcommittees – EPA List 4 Inerts of Minimal Concern (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop and Livestock Subcommittee’s Sunset Review of EPA List 4 Inerts of Minimal Concern.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- ✓ Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed.
- ✓ To resolve longstanding outdated regulatory references, OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and modernize the system for review of inert ingredients in organic approved pesticide products.
- ✓ Pesticide product development and innovation is being stifled by the outdated regulatory references for inert ingredients.

We offer the following more detailed comments:

I. Background

Inert ingredients are defined in the National Organic Program (NOP) regulations as “**any substance** (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) **other than an active ingredient which is intentionally included in any pesticide product.**” The NOP regulations provide for certain synthetic inert ingredients to be used in organic approved pesticide products. EPA List 4 Inerts are permitted for use as inactive ingredients formulated with allowed active pesticide ingredients for both crop and livestock production. EPA List 3 Inerts have a more limited allowance only in passive pheromone dispensers in crop production.

The current listings on the NOP National List read,

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

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

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

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern

The listing for EPA List 4 Inerts has been included in the National List since the NOP Regulations were first published in 2000. The limited allowance for EPA List 3 Inerts was published in 2003. The references to EPA List 3 and 4 were based on EPA’s system of classification at the time, in which EPA organized individual substances in to List 1-4 according to toxicology (List 1 being most toxic to List 4 being least toxic). Shortly after listings for EPA List 3 and 4 were formalized in the NOP regulations, EPA began implementing a change to replace Lists 1-4 with a new system of tolerance assessments to be codified in 40 CFR Part 180. EPA completed its transition to the new system in 2006. As of then, EPA no longer uses or maintains Lists 1-4.

According to information contained in a [NOP Policy](#) for reviewing inert ingredients (emphasis added), **“EPA has informed USDA that the “Inerts List” system may no longer be effective or available for the NOP to reference in the Regulations.** Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations. As a result, **the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA.** NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations.”

The collaboration between NOP, NOSB and EPA was very active between 2011 and 2015. The **NOP-NOSB-EPA Inerts Working Group** was established in December 2010 with the goal of submitting a proposal to NOSB, through which NOSB would then develop a formal recommendation to NOP. The working group met frequently and reported regularly to the public at NOSB meetings. The Working Group evaluated several different options for resolving the outdated reference for inerts, and ultimately proposed that NOP work with the EPA’s new **Safer Choice Program** (Formerly the Design for the Environment Program). The Safer Choice Program is a voluntary program for verifying and labeling products that meet EPA Safer Choice Standards for human health and environmental safety. Ingredients must comply with the EPA’s **Safer Chemical Ingredient List (SCIL)**. The NOSB Crop and Livestock Subcommittees agreed with this approach and included a reference to the Safer Chemical Ingredient List (SCIL) in a proposal that was passed by NOSB in fall 2015.

The [2015 NOSB Recommendation](#) would revise the listing for inert ingredients at §205.601(m) and §205.603(e) to remove the outdated and obsolete references to EPA Lists 3 and 4, and replace with

EPA's current mechanisms for approving the least-toxic inert ingredients. The recommended annotation reads:

§205.601(m) and §205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use as inerts in minimal risk products exempt from pesticide registration under FIFRA section 25(b)
- (ii) Substances included on the EPA's Safer Chemical Ingredient List
- (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers
- (iv) [Reserved for any other inerts individually petitioned and reviewed]

The listing for EPA List 3 and List 4 inerts have been renewed at each of the three previous Sunset Reviews that have occurred over the past twenty years. The renewals of these listing have been critical to allow NOSB and NOP to continue their effort to resolve outdated reference for inerts with minimal disruptions. As cited by NOSB during the last Sunset Review of EPA List 4 Inerts in fall 2015, "To allow these materials to sunset at this point would be too disruptive to the industry." At that meeting, NOSB also presented a minority opinion that stressed the importance of resolving the inerts issue, citing concerns with the regulation's "current reliance on a now non-existent review process."

This year (2020), NOSB is conducting its fourth Sunset Review of the EPA List 4 Inerts to determine its continued eligibility for inclusion on the National List as an allowed synthetic substance in accordance with criteria established in the Organic Foods Production Act (OFPA): 1) The input must not be harmful to human health or the environment; 2) The input is necessary for production and processing of organic products because of the unavailability of natural or organic alternatives; and 3) The input is consistent with organic farming and a system of sustainable agriculture. At the spring 2020 NOSB Meeting, the Crops Subcommittee presents its [Sunset Summary and Request for Comments on EPA List 4 Inerts \(starts on Page 34 for crops and Page 99 for livestock\)](#). NOSB will collect public comments at the spring 2020 meeting to inform its proposal and vote at the fall 2020 meeting.

II. Necessity for Production

Inert ingredients are necessary for the manufacturing of many various forms of pesticide products. Inert ingredients are used in conjunction with active ingredients to facilitate functionality and efficacy of the active ingredient. (Note: Active ingredients are subject to individual review and approval in accordance with NOP regulations.)

Pest control products formulated with inert ingredients are widely used in organic crop and livestock production. Hundreds of organic-approved pest control products are formulated with synthetic inert ingredients. These products are part of a limited restricted toolbox that farmers can access only when their preventive pest, weed, and disease management practices have failed.

Continued availability of effective and familiar pest control products for both crop and livestock producers is necessary for organic farmers to reliably bring their organic products to market. It is critical that the availability of these products continue throughout NOSB and NOP's ongoing efforts to update the listings of inert ingredients on the National List.

III. Implementing the 2015 NOSB Recommendation

A plan for implementing the 2015 NOSB Recommendation was proposed by the Crop and Livestock Subcommittee at the fall 2015 meeting. After the NOSB's vote to proceed with the annotation change, the following items were expected to take place:

- NOP will publish a *Federal Register* Notice to notify stakeholders of the intended revision, and to outline the procedure and timeline for implementation. The notice would also call on stakeholders to submit applications for individual inert ingredients to EPA for inclusion on the Safer Chemical Ingredient List and/or to NOP for inclusion on the National List.
- NOP will proceed with the rulemaking process to amend the National List, which would include a reasonable implementation time (3-5 years) to accommodate manufacturers applying for SCIL consideration, petitioning NOSB, and/or reformulating their products.
- NOP will establish a Memorandum of Understanding with EPA to formalize their relationship and allow NOP to rely on EPA's Safer Chemical Ingredient List.
- NOSB will establish a procedure for addressing the elements of OFPA criteria that are not specifically addressed in EPA's review of materials on the Safer Chemical Ingredients List (such as compatibility with organic agriculture).

In NOP's response to the 2015 NOSB Recommendation, NOP stated "The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at §205.601(m) and §205.603(e)." For a short time after the 2015 NOSB Recommendation was passed, NOP made some effort to provide verbal updates at NOSB meetings to the organic community on its progress of implementing the recommendation, although this has not occurred since 2016. It has now been five years since NOP committed to implementing the NOSB recommendation; ten years since EPA directly requested NOP to remove the reference in its regulations; and about 15 years since EPA Lists became obsolete. Yet the NOP regulations still refer to EPA Lists that were last updated in August 2004.

OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and resolve the longstanding discrepancy in the organic regulations with regard to inert ingredients.

Modernizing the system for review of inert ingredients is a priority of the organic industry. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products. It is critical that NOP regulations have a valid system for identifying allowable ingredients that comply with OFPA criteria for the National List. OTA continues to support the 2015 NOSB Recommendation that utilizes EPA's current mechanisms for approving the least-toxic inert ingredients: FIFRA 25(b) pesticide program inerts, Safer Choice Program's Safer Chemical Ingredient List (SCIL), and inerts exempt from tolerance at 40 CFR Part 180 (for passive pheromone dispensers only). Incorporating these oversight and approval mechanisms aligns with USDA organic regulations,

which focus on human and environmental hazards, and provides product manufacturers clarity around how to reformulate their products as the organic standards become more current with the overall evaluation of pesticide products under EPA. We encourage NOP to continue working with EPA, NOSB, organic pest-control material manufacturers, and the organic sector at large to develop and implement a program that will both ensure continued safety of organic pest-control materials and minimize disruptions to the tools farmers rely upon when their preventive pest, weed, and disease management practices have failed.

IV. Questions from the Crops Subcommittee

1. *Can you provide examples of product development that have been stifled by the lack of clarity on the regulation and approval of inert ingredients in organically approved pesticide formulations?*

Pesticide product manufacturers have indicated to OTA that they will not invest research and development resources in new products when there is uncertainty about what ingredients will be allowed. The outdated regulatory reference for inert ingredients is stifling innovation in pesticide product development and organic agriculture.

2. *Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?*

We support NOP and NOSB efforts to implement a new system of review that would apply rigorous environmental and human health safety criteria to all inert ingredients. Under the 2015 NOSB Recommendation, inert ingredients would be approved under EPA's current mechanisms for approving the least-toxic inert ingredients. This new system of review would result in prohibition of some currently approved inert ingredients such as NPEs, a class of substances that has raised concerns at past NOSB meetings. We caution against using resources to pursue separate recommendations and rulemaking on individual inert ingredients when the broader solution would accomplish the same end goal and would cover more substances. Stakeholders always also have the option of submitting a petition to prohibit certain substances.

3. *Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?*

OTA supports implementation of the 2015 NOSB Recommendation. This recommendation is the result of years of collaborative work between NOP, NOSB, and EPA, and allows for multiple avenues of identifying allowed inert ingredients without the burden of NOSB having to individually review or list inert ingredients. See **Part III** for more information on implementing the 2015 NOSB Recommendation. If there are insurmountable obstacles to implementing the 2015 NOSB Recommendation, then we would support NOSB exploring alternative approaches. NOP should be transparent with NOSB and the organic community if such obstacles exist.

4. *What would be the consequences of an NOSB recommendation to delist List 4 Inerts?*

There would be significant disruption to organic production if EPA List 4 Inerts were delisted without a valid replacement system for reviewing and approving inert ingredients. Organic producers would lose critical tools for controlling pests when preventive practices fail. See **Part II** for more information.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 1, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0041

RE: Materials Subcommittee – Marine Macroalgae in Crop Fertility Inputs (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials Subcommittee's Proposal on Marine Macroalgae in Crop Fertility.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- ✓ **OTA compliments the diligence in the work to prepare this proposal but recommends that it be returned to the Subcommittee for continued work.** This meeting is the first time that the proposed annotation language and new addition to the National List are being presented to the public for comment, and it will impact one of the most important and widely used inputs on organic farms – seaweed fertilizers. OTA was not able to fully analyze the proposal due to the substantive length of the proposal, technical complexity of the annotation, and the conflict of the comment period with the NOP Strengthening Organic Enforcement Rule comment period. Stakeholders need more time to analyze the proposal, understand the impacts, and provide constructive feedback to NOSB.
- ✓ **OTA support continuous improvement in sustainable sourcing of seaweed used in organic production, and recommends the following actions to support development of an actionable and effective proposal.**
 1. NOP should confirm the legal options available to NOSB for establishing harvest parameters for seaweed used as crop input materials.
 2. NOSB should commission third-party technical reports to address remaining gaps in technical information.
 3. NOSB should continue working with stakeholders to address initial concerns with the proposed annotation language.

We offer the following more detailed comments:

Background

The Organic Foods Production Act authorizes NOSB to recommend prohibition of natural substances if technical information demonstrates that use of the substance is harmful to the environment or human health, or is inconsistent with organic farming and handling principles.

The evaluation of whether the use of marine macroalgae materials such as alkali-extracted aquatic plant extracts as crop production inputs is “not harmful to the environment” received increased scrutiny by NOSB in recent years. The Crops Subcommittee began questioning the issue during the last Sunset Review of alkali-extracted aquatic plant extracts in fall 2015. Since then, the Materials Subcommittee has carried the issue forward through its work agenda topic for Marine Materials used in Crop Production. Despite the generic “marine materials” title, this NOSB topic is focused only on seaweed materials, both synthetic and nonsynthetic forms, and does not include fish.

To more fully examine the sources, species, harvest methods, and specific usage of marine plants and algae in organic production and processing, NOSB commissioned a Technical Report. The [Technical Report](#) was completed and published in 2016. A [discussion document](#) posted for the fall 2016 NOSB meeting addressed the nine separate listings for marine materials on the National List (Crops and Handling), and posed questions about the nomenclature of marine plant/algae on the National List, the need to specify uses or harvesting guidelines of certain species, and whether further NOP guidance is needed.

In 2018, the Materials Subcommittee began its work in earnest to evaluate environmental impacts and consider whether restrictions on harvesting seaweed for use in fertilizers are warranted. The NOSB Materials Subcommittee posted a [discussion document](#) for the fall 2018 meeting that explored a potential requirement for marine plants to be certified organic when used in crop inputs, and a number of alternative approaches such as: limiting or prohibiting harvest of certain marine algae; exploring other existing third-party standards for sustainable harvesting; or adding annotations to material listings on the National List to require sustainable harvesting.

In spring 2019, the Materials Subcommittee presented another [discussion document](#) on the approach of requiring organic certification of marine algae ingredients in crop inputs, attempting to address the concerns raised at the previous meeting. The discussion document also puts forth additional discussion questions for stakeholder feedback. In fall 2019, the Materials Subcommittee presented the same [discussion document](#) from spring 2019 with one additional discussion question.

There was also an [Expert Panel](#) on Marine Materials at the fall 2019 NOSB meeting, composed of two scientists (Dr. Allison Schmidt, *Dalhousie University*, and Dr. Nichole Price, *Bigelow Laboratory for Ocean Sciences*), one harvester (Dr. Rahul Ugarte, *Acadian Seaplants Ltd.*), and one certifier (Chis Grigsby, *Maine Organic Farmers and Gardeners Association [MOFGA] Certification Services*) who each presented technical information to the Board.

A wealth of technical information about seaweed harvesting has been submitted from scientists and industry through public comments, technical reports, and an expert panel. Still, many questions remain unanswered about globally representative data, extent of existing legal oversight, and feasibility of various solutions.

In its closing remarks at the fall 2019 meeting, the Materials Subcommittee continued to express interest in a requirement for organic certification of marine materials used in crop inputs, but only if: 1) NOP can commit to establishing a task force to develop more specific guidelines for organic production and certification of marine materials; and 2) the requirement is paired with an ample implementation time period. The subcommittee will also consider the option of narrowing its focus only on the species that are more highly used. There was agreement across the board with general sentiments about the importance of protecting the environment, but conflicting opinions about how to move forward with this particular issue. Some board members identified a need for information that is more globally representative, as much of the discussion thus far is focused on Maine and Nova Scotia. There are outstanding questions about the logistics and practicality of organic certification of marine production systems.

Overall, NOSB has expressed an interest in taking a slow and careful approach to this complex issue. A clear path forward was not yet apparent. The spring 2020 NOSB Meeting agenda did not include this topic.

The Organic Trade Association has been engaging on this topic for the duration of its existence on the NOSB’s work agenda, and we formalized a member task force in 2019. The OTA Marine Materials Task Force, comprised of OTA member companies across the seaweed value chain from harvesters, fertilizer manufacturers, certifiers, consultants, and end-users, has been meeting regularly to inform OTA’s substantive comments.

- [Spring 2020 – OTA Comments on Crop Subcommittee’s Sunset Review of Aquatic Plant Extracts](#)
- [Spring 2020 – OTA Supplementary Background Information on Seaweed and Fish-Based Inputs](#)
- [Fall 2019 – OTA Comments on Materials Subcommittee’s Discussion Document on Marine Materials in Organic Crop Production](#)
- [Spring 2019 - OTA Comments on Materials Subcommittee’s Discussion Document on Marine Materials in Organic Crop Production](#)
- [Fall 2018 – OTA Comments on Materials Subcommittee’s Discussion Document on Marine Materials in Organic Crop Production](#)
- [Spring 2017 – OTA Comments on Crops and Handling Crops Subcommittee proposal addressing the marine algae listings on the National List](#)

NOSB has been accepting public comments on marine materials for the past three meetings without any new information being presented until now. Public comments have been building up since the last new information was presented in an NOSB Meeting packet in spring 2019. The spring 2019 Discussion Document was reissued in fall 2019, and there was not any proposal or discussion document in the meeting packet for spring 2020, although stakeholders still voluntarily submitted comments on this topic.

As of spring 2020, there were still many questions and concerns identified by stakeholders in public comment that had not been addressed.

- OTA raised questions about the extent of the problem that needs to be solved (*so that appropriate solutions can be identified*).
- OTA identified specific gaps in the record where technical information is needed regarding the effect seaweed harvesting has on the environment as documented by scientific evidence (*to justify listing as prohibited on §205.602*), and the existing legal framework for oversight of seaweed harvesting in countries where most seaweed is sourced (*to understand the extent to which environmental goals are already being addressed outside of organic regulations*).
- OTA raised questions about the impact of new restrictions on the availability of essential seaweed-based inputs to organic producers, and suggested that a supply chain assessment is needed to understand impacts and evaluate whether industry can build up sufficient supply of compliantly harvested seaweed to meet needs of organic producers.
- OTA raised concerns regarding the inconsistency that would be created if seaweeds for fertilizer were subjected to different requirements than other uses, such as un-annotated seaweeds on §205.606 as food ingredients, and suggested that better harmonization is needed.
- Organic farmers submitted comments emphasizing the essentiality of seaweed fertilizers as inputs on their organic farms, and raised concerns about lack of availability under new restrictions.
- Seaweed harvesters and scientists submitted technical information that runs counter to claims of environmental harm.
- Certification agencies identified concerns about enforceability of annotations, and a fundamental need for clearer standards on organic certification of aquatic plants.

Summary of Fall 2020 Proposal

For the fall 2020 NOSB Meeting, the Crops Subcommittee presents its [Proposal on Marine Macroalgae in Crop Fertility Inputs \(starts on Page 145\)](#).

This is the first time in three meetings that new information is included in a NOSB Meeting Packet from the Materials Subcommittee on Marine Macroalgae Materials. As described in the *Background section* above, there was nothing in the spring 2020 meeting packet from the Materials Subcommittee on this work agenda item. And the fall 2019 meeting packet included the same discussion document that was previously released in spring 2019.

The Materials Subcommittee is proposing **two amendments** to the National List that would specify harvest parameters for aquatic plants and other marine macroalgae (seaweed, kelp, etc.) that are harvested for use in crop fertility inputs. Both annotations contain the same harvest parameters. The first amendment would add an annotation to the current listing for alkali-extracted aquatic plant extracts on §205.601(j)(1). The second amendment would create a new listing for marine macroalgae on §205.602 with an annotation that would prohibit all marine macroalgae unless these harvest parameters are met.

Amendment #1: The proposal would add a restrictive annotation to current listing of aquatic plant extracts at §205.601(j)(1) as follows (underlined text is new):

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

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction. Harvest Parameters - Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

Amendment #2: The proposal would add create a new listing at §205.602 (Prohibited Nonsynthetics) to prohibit marine macroalgae unless produced in accordance with the annotation as follows (underlined text is new):

§205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

Marine macroalgae (seaweed) – unless harvested in accordance to the following parameters: Noncommercial harvests for whole and unprocessed seaweed are exempt from these parameters. Harvest Parameters - Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

OTA recommends that the proposal be returned to Subcommittee for continued work.

The Subcommittee explains that a select group of scientists have been directly involved in developing the annotation language over the past year. However, the entire rest of the organic community is seeing this proposed annotation language and addition to the National List for the first time at this meeting. A broader spectrum of organic stakeholders needs to be given the opportunity to weigh in on the proposed requirements, especially given that the proposal is so significant. The proposal is lengthy and substantive. The requirements in the proposed annotation are complex and highly detailed, containing multiple requirements for harvest locations, methods and timing. Attempting to capture an entire standard of production and harvest of an agricultural crop, it is the largest annotation ever proposed for the National List. An annotation of this magnitude has never been presented before. As this proposal will impact one of the most important and widely used inputs on organic farms (seaweed fertilizers), stakeholders need more time to analyze the proposal, understand the impacts, and provide constructive feedback to NOSB.

Unfortunately, this NOSB comment period is completely overlapped by the 60-day comment period on NOP's Strengthening Organic Enforcement Proposed Rule, the largest single piece of rulemaking since the organic regulations were first implemented. This prevented OTA and other stakeholders from being able to fully engage in the analysis and public comment process for the items presented for this NOSB meeting. OTA has not been able to fully evaluate the details of the proposal to understand whether the harvest parameters can be met by harvesters, or resulting impacts that the annotation would have on the availability of compliant seaweed fertilizers for organic farmers.

Upon seeing the full annotation language for the first time, it is not unreasonable to expect public stakeholders will need more time and may not be ready to immediately support the annotation as is. Returning proposals to subcommittee so that proposals can be refined following public comment is common practice for building stakeholder consensus through the NOSB process. If NOSB has any intention of integrating stakeholder feedback into its annotation, this item would need to go back to the subcommittee to make substantive changes to the proposal. Without sending this proposal back to subcommittee, NOSB will remove the opportunity to receive and integrate stakeholder feedback into the final proposal. As this proposed annotation will impact one of the most important and widely used inputs on organic farms, it is very important that the exact language is fully analyzed and impacts are understood. If NOSB members feel that they didn't get enough substantive feedback to make a judicious and informed decision, we encourage returning the proposal to Subcommittee for further work.

OTA recommends that additional actions are needed to support development of an actionable and effective proposal.

OTA support continuous improvement in sustainable sourcing of seaweed used in organic production. Upon returning the proposal to Subcommittee to allow more time for stakeholders to weigh in on this complex and important issue, we recommend the following additional actions that can be taken to continue advancing efforts towards a better understanding of the problems needing to be solved, and ensuring appropriate solutions are actionable and effective.

1. NOP should confirm the legal options available to NOSB for establishing harvest parameters for seaweed used as crop input materials.

The two proposed amendments to the National List contained in the Materials Subcommittee’s proposal are substantive and are based on many years of hard work on behalf of NOSB and stakeholders. To make sure the outcomes of this work can be actionable through rulemaking, NOP needs to be proactive in communicating the legal options for being able to actually implement and enforce NOSB’s recommendations on this subject matter. Confidence in legal standing of these large and detailed annotations – early in the policy development process – is essential to making efficient and responsible use of NOSB and stakeholder efforts.

In the proposal, we see that NOP determined that language requiring verification within the annotation itself is not feasible. NOP should communicate the feasibility of remaining portions of the annotation language. NOP should also communicate the feasibility of adding a new listing to §205.602 without a new petition (noting that p. 27 of the [NOSB Policy and Procedures Manual](#) describes NOSB’s authority to propose changes to annotations, classification of materials, or remove existing listings without a new petition but does not address authority to *add* new listings without a new petition), and how this action is or is not consistent with how §205.602 is established (noting that other natural substances listed as prohibited on §205.602 have been demonstrated to pose direct toxicity to the environment or human health and/or are in direct conflict with organic soil fertility building practices.) We also ask NOP to communicate the role of Guidance documents in this process, and whether substantial undertakings that involve harvest parameters could be incorporated into the NOP Handbook if National List annotations and new listings are not a viable option.

2. NOSB should commission third-party technical reports to address remaining gaps in technical information.

We appreciate the Subcommittee’s diligence in compiling the review of literature within this meeting’s proposal to work towards a better understanding of the environmental impacts of seaweed harvesting. Due to the length of the proposal, complexity of the annotation, and the conflict of the comment period with the NOP Strengthening Organic Enforcement Rule comment period, OTA has not been able to fully study the body of the proposal and the extent to which it addresses our outstanding questions and concerns as of spring 2020. However in our initial review of the proposal, we identify several areas of technical information identified in stakeholder comments throughout the past two years that remain unaddressed,

such as comprehensive review of existing legal frameworks, and a supply chain analysis to understand impacts of harvest restrictions on availability of seaweed fertilizers to organic farmers. Additionally, the Crops Subcommittee in its Sunset Review of Aquatic Plant Extracts expressed a desire to gather more information on environmental impacts of harvesting seaweeds for use in crop fertility inputs.

We encourage NOSB to take a critical look at the areas of technical information that are most needed to ensure an informed and judicious decision on seaweed harvest parameters and pursue Technical Reports as needed to fill those information gaps. This exercise is important to support a robust technical evaluation of the environmental impacts of seaweed harvesting and an informed policy-making process for both the Materials and Crops Subcommittees. Technical Reports are the formal mechanism for NOSB to request comprehensive technical information prepared by qualified subject matter experts in compliance with best practice for reviewing and citing current peer-reviewed literature. Comprehensive technical information is a foundation to effective policy development especially when setting policy that will impact numerous macroalgae species across different environments around the globe, and will ultimately impact farmers' access to important seaweed fertilizers for use in organic crop production.

Conclusions about the environmental harm from seaweed harvesting should be informed by comprehensive technical information and data representative of the areas where those materials are harvested around the globe, as well as being relevant to materials harvested specifically for use in organic production and processing. Significant amounts of technical information have been submitted to NOSB through public comments over the course of many meetings, some references are included in the proposal presented at this meeting, and some references were presented at the Expert Panel. A Technical Report on the environmental impacts of harvesting seaweed for use in fertilizer is needed to compile and validate the current and peer-reviewed technical information relevant to the environment impact of seaweed harvesting, to ensure a full spectrum of information is presented along with the cited references from the proposal. A Technical Report can also identify items to add to NOSB Research Priorities as needed to address areas where information is not currently available.

Furthermore, a comprehensive overview of existing legal frameworks for harvesting seaweed in countries where most seaweed is harvested is still needed. An accurate understanding of the status quo should be informed by the oversight and enforcement mechanisms outside of the NOP regulatory framework throughout the countries where seaweeds are harvested that may influence environmental impact. A Technical Report can compile information about legal oversight of seaweed harvesting around the globe and the extent to which environmental impacts are evaluated by the legal systems. This information is essential to understanding the current situation and potential net positive outcome of an NOSB recommendation specific only to crop inputs on organic farms.

Lastly, a Technical Report can be used to gain a better understanding of the impact of certain harvest restrictions on the availability of essential seaweed-based inputs to organic producers, and whether industry can build up sufficient supply of compliantly harvested seaweed to meet needs of organic producers. A supply chain assessment is needed to understand whether harvest parameters could support NOSB's dual goals of environmental protection and protecting organic farmers' access to seaweed fertilizers.

3. NOSB should continue working with stakeholders to address initial concerns with the proposed annotation language.

OTA was not able to fully analyze the language used in the two proposed National List amendments due to the length of the proposal, complexity of the annotations, and the conflict of the comment period with the NOP Strengthening Organic Enforcement Rule comment period. However in the short time available, we were able to conduct an initial assessment of the proposed annotation language and identified some concerns about the ability for seaweed harvesters to implement the annotation as it is currently worded (listed below).

- The requirements for harvest areas, as stated, would prohibit harvesting in conservation areas, which are considered some the *most* sustainable and under the *most* scrutiny from third parties. Conservation areas have oversight from a third party whereas other areas do not have the same level of increased oversight. In some examples such as in Iceland, managed seaweed harvesting is considered a conservation benefit. Commercial harvesting of kelp forests in the Monterey Bay National Marine Sanctuary is permitted under regulated management¹.
- The requirements for monitoring bycatch, as stated, could prohibit harvesting entirely depending on how one defines if bycatch is “prevented” or “eliminated.” In some practical harvesting scenarios, it is not possible to completely prevent or eliminate bycatch such as mollusks naturally attached to seaweed. Compare this example to harvesting hay and expecting that no other insects or species are captured in the harvest.
- The requirements for harvest timing, as stated, could prohibit harvesting entirely depending on how one measures if biomass and architecture “approaches” that of undisturbed stands. For some common species, it is not possible for biomass or architecture of harvested stands to return, or approach return to the original state because biomass and architecture will change. For example in the case of *Ascophyllum*, repeat harvesting will usually *increase* biomass and the architecture will get *bushier*. Such changes may or may not be harmful to the environment, but may be impossible for harvesters to accurately quantify.
- Implementation and enforcement of the annotation will be difficult because of the subjective wording, which makes it difficult to understand which current practices will be allowed or prohibited.
- The motion for adopting the proposal does not include the provisions that the Subcommittee previously reported would be mandatory. At the fall 2019 meeting, the Subcommittee assured the public that any proposal for a new annotation would be contingent on an NOP Task Force, Guidance, and lengthy implementation timeframes.

These initial concerns, along with the lack of time to fully analyze the proposal, prevent us from being able to support the proposed annotation as written. We encourage the Materials Subcommittee to continue working with stakeholders to address these initial concerns to ensure that and proposed regulatory requirements can be readily understood, possible to implement, and would retain availability of seaweed fertilizers for use by organic farmers.

¹ <https://montereybay.noaa.gov/resourcepro/resmanissues/kelp.html>

As the Materials Subcommittee explores how to address these initial concerns, we also encourage more collaboration across NOSB Subcommittees to standardize decisions on environmental impacts of sourcing seaweed across inputs and scopes where seaweed is used. The Materials Subcommittee explains in the proposal that it disagrees with this sort of collaboration, stating that each marine material on the National List represents a discreet use and warrants individual attention. However, in this proposal the Subcommittee is not evaluating the end-use, it is evaluating the question of environmental impact from sourcing. The Subcommittee itself states that the same seaweed can be harvested for multiple end-uses.

The question addressed in this proposal is essentially, *Under what conditions does harvesting seaweed cause harm to the environment?* This same question could be asked (and in some cases is already being asked) of the Crops Subcommittee regarding synthetic-extracted aquatic plant extracts, of the Livestock Subcommittee about kelp used in livestock feed and medical supplements, and of the Handling Subcommittee about seaweeds listed on §205.606 for use as food ingredients. Collaboration will help each NOSB Subcommittees define parameters of harmful seaweed harvesting in a common manner, instead of each subcommittee coming up with its own definition. Collaboration will support consistent and balanced decision-making on common questions around the environmental impact of harvesting seaweeds for use in organic production and processing. Subcommittees can agree to work from a common base-line understanding of how certain harvested seaweeds comply with OFPA criteria for being harmful to the environment. The base-line will provide a common starting point when making end-use -specific decisions about how the environmental criteria are balanced against other OFPA criteria such as necessity for production or processing due to absence of natural or organic alternatives. Additionally, these discussions can support a consistent approach for developing annotations, restrictions, and verification requirements in cases when sourcing of a marine materials is determined to cause harm such that a regulatory amendment is warranted.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Johanna Mirenda".

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



September 10, 2020

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-20-0041

RE: Materials Subcommittee - Research Priorities Fall 2020 (Proposal)

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comments on the Materials Subcommittee proposal on the Fall 2020 Research Priorities.

The Organic Center is a non-profit organization with the mission of convening credible, evidence-based science on the environmental and health benefits of organic food and farming and communicating findings to the public. We are a leading voice in the area of scientific research about organic food and farming, and cover up-to-date studies on sustainable agriculture and health while collaborating with academic and governmental institutions to fill knowledge gaps.

The Organic Center thanks the Materials Subcommittee for its recommendation on Research Priorities. We appreciate the creation of the Research Priority Framework and the efforts made by each Subcommittee to bring forth its research priorities for the fall of 2020.

Summary:

- ✓ The Organic Center supports the subcommittee's proposed Fall 2020 Research Priorities. The proposed priorities are in line with the needs of the organic community, and will serve as an important resource to guide The Organic Center's research priority focus and project development.
- ✓ Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of **benefits and risks of livestock integration into crop rotations, nutritional value of organic animal products (such as dairy, meat, and eggs), protection of organic farmers from chemical contaminants, comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products, and alternatives to conventional celery powder for curing organic meat** be considered for inclusion in the Fall 2020 Research Priorities.



We offer the following more detailed comments:

Current Research Needs

We have reviewed the list of topics included for Fall 2020 Priorities, and we're particularly pleased to see the inclusion of "whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices," "organic no-till practices for diverse climates, crops, and soil types," "development of systems-based plant disease management," "strategies for the prevention, management, and control of invasive insects," "the relationship between on-farm biodiversity and pathogen presence and abundance," and "reducing greenhouse gas emissions." The Organic Center is actively involved in conducting and communicating research on these issues, and we expect the prioritization of these topics by NOSB may help us secure further funding.

Economic, Social, and Environmental Impact of Farming Systems Choices

The Organic Center has been interested in the economic and social impacts of organic farming for a number of years, as there is extremely limited research on these issues. Understanding the economic impact of best practices is especially important because it can dictate adoption rates of new techniques. One of our current research projects addresses this by quantifying yield impacts of soil health practices, because different soil building practices do not necessarily have an equitable effect on yields. When considering the adoption of new practices, it is important for farmers to be able to evaluate which practices are most likely to promote environmental sustainability while simultaneously maintaining (or increasing) their bottom line. One goal of this project is to act as an immediate incentive for encouraging the adoption of best soil building practices in organic, because it will connect all the dots between the most important organic strategies for building soil health and sequestering carbon that also translate into higher, more consistent yields.

Unfortunately, while yield data is available to conduct this analysis, most studies do not track the full suite of variables that would be needed for a full profitability comparison, such as input costs. We are pleased to see the NOSB highlight the need for additional economic analyses of organic systems, as it will allow for a more holistic understanding of the economic opportunities and pitfalls for organic growers, and more accurately pair environmental practices with economic incentives for organic growers.

Organic No-Till Practices

The Organic Center is collaborating with Dr. Kate Tully's lab at the University of Maryland to examine practices improving soil health on organic farms. We [published a scientific article](#) from research on this topic, and one of the areas that we included was the comparison of no- and low-till in organic production versus standard tillage in organic production. Overall, our results suggest that surface-level soil organic carbon levels are higher in low/no-till organic plots compared to standard organic tillage plots. However, we also found that no/low-tillage in organic was associated with significant reductions in yield. These findings suggest that while organic farmers could improve carbon sequestration through no/low-tillage, there needs to be further research to support farmers wishing to make this conversion to ensure that it is a viable and economically feasible option for a wider variety of crops. We are thankful that NOSB included this priority in its Fall 2020 Research Priorities, as it will help encourage research on this critical issue, and provide much-needed tools to help organic farmers realize the benefits of reduced tillage without the threat of reduced yields.

Plant Disease Management

The Organic Center has been working on several aspects of plant disease management. For example, we have an active project on citrus greening, caused by the bacterium *Candidatus liberibacter*. Our research to find organic solutions to control citrus greening disease is an ongoing project in collaboration with the University of Florida, the University of California, Davis, USDA-ARS, citrus growers, and other non-profits. We published a scientific paper and accompanying farmer guide consolidating existing literature on allowable methods for combating citrus greening in organic groves. It details science-based best practices for organic citrus growers. We leveraged this paper to apply for additional funding, and were awarded an OREI planning grant to develop a proposal that takes a



systems-based approach to combat both the bacterium that causes citrus greening disease and its insect vector, the Asian citrus psyllid, in organic systems.

Invasive Insects

In addition to our work on the Asian citrus psyllid, The Organic Center is also completing research to develop Integrated Pest Management strategies for organic rice production in the Southern United States. This project is being conducted in collaboration with Texas A&M University's AgriLife Research & Extension Center, Texas A&M Department of Soil and Crop Sciences, USDA's ARS Dale Bumpers National Rice Research Center, University of Arkansas Rice Research and Extension Center, and University of Arkansas at Pine Bluff Department of Agriculture. Flooded rice production systems used by organic farmers result in increased pressure from the diseases, weeds, and insect pests not commonly found in dryland cropping systems. This is especially problematic in the South because of the region's warm, humid environments and long growing season. This project focuses on developing cover crop-based production systems in combination with cultivar choice and seed treatment to enhance disease, weed, insect pest, and nutrient management, allowing producers to grow organic rice more sustainably and profitably in the South.

Pathogen Prevention

Unfortunately, there are often disparities between third-party food safety regulations and biodiversity-maintenance strategies employed by organic farmers due to the fallacy that increased on-field faunal biodiversity may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this myth, more research, extension, and education are needed to fully understand the impact these discrepancies are having on organic farmers, and the true relationship between on-farm biodiversity and food safety. Additionally, extension must take place to both organic growers third-party food safety auditors alike so that evidence-based strategies can be incorporated into their audits. Therefore, we thank the committee for including a pathogen prevention research focus in 2020.

The Organic Center is deeply involved in research examining pathogen presence in organic soil amendments. For example, we are collaborating with the University of California, Davis, among other organizations, to address the need for additional information on raw manure intervals to provide critical information for guidelines on risk mitigation of foodborne pathogens for organic and sustainable agriculture. We have [published multiple articles and abstracts on the subject](#), and are currently developing an education module in collaboration with Cornell University to communicate our findings to a broad audience.

Reducing Greenhouse Gas Emissions

Climate change is having serious consequences on our environment and public health, and we appreciate the inclusion of the "Climate Change" focus in the Fall 2020 priorities. The Organic Center has been engaged with climate change issues for several years now on multiple levels. For example, last year co-hosted our annual Organic Confluences Conference with USDA, FiBL, The Climate Collaborative, and ISO FAR to focus on mitigating and adapting to climate change. The conference brought together scientific experts, farmers, policymakers, and organic stakeholders to address the current impacts of climate change and best practices within the organic sector for mitigation and adaptation, while examining methods for encouraging the adoption of strategies for fighting climate change. We are currently working on a white paper detailing the outcomes of the event, but it is clear that additional research is needed to address this issue; the long-term security of our food system depends on it.

We also have active research projects on the subject of climate change mitigation, and are specifically conducting analyses to "pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security." For example, we are working on a project in collaboration with researchers at the University of Maryland to pinpoint specific strategies organic farmers can take to increase carbon sequestration in the soil. We are also working with Harvard University's Department of Public Health examining the specific aspects of organic agriculture that can contribute the greatest benefits to



climate stability. These net benefits include carbon sequestration in the soil and reduced energy usage by avoiding synthetic nitrogen fertilizer.

Additional Research Needs

The Organic Center is continually collecting information on research needs from multiple sectors of the organic community. We conduct industry roundtables, work with the Organic Trade Association's Farmers Advisory Council, meet with professors on our Science Advisory Board and hold one-on-one meetings with individual companies, farmers, professors, and consumers. We feel that the NOSB Materials Subcommittee's proposed Fall 2020 Research Priorities are in line with the needs of the organic industry, and appreciate the release of this report as an important resource to guide The Center's own research priorities and project development. Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of livestock integration into crop rotations, nutritional value of organic milk and meat, protection of organic farmers from chemical contaminants, comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products be considered for inclusion in the Fall 2020 Research Priorities. We also feel that the focus on alternatives to conventional celery powder for curing organic meat that was included in the 2019 Research Priorities be included in this year's priorities, because, while research is underway, the importance of this topic should not be forgotten.

Livestock Integration into Cropping Systems

Livestock grazing of cover crops could be beneficial for organic systems, because it maximizes the strengths of cover cropping, including enhanced soil fertility, structure, water infiltration and storage, and reduced nitrate leaching, while addressing challenges that have limited the expansion of cover crop use such as concerns over cover crop water use and nutrient immobilization, which could increase deficiencies and increase input costs of the crops that follow.

Unfortunately, despite the well-known benefits of animal-crop integration, concerns over microbial food safety are limiting the expansion of animal integration into cropping systems. Recent research has shown that integrated crop-animal systems [perform well in keeping pathogens out of meat](#), but additional research is needed to examine the synergistic impacts of the use of livestock for cover crop grazing on ecosystem health and food safety.

The Organic Center is working on this project in collaboration with the University of California, Davis by examining food pathogen persistence and survival in soil and transfer to vegetable crops, and the relationship between soil health properties, environmental factors and pathogen survival in grazed cover crop-vegetable production in three states. Researchers will measure changes in soil health indicators over two years of grazed cover crop-vegetable production, and assess benefits and potential tradeoffs of vegetable cash crop productivity.

Nutritional Value of Organic Milk and Meat

We were pleased to see the inclusion of "Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons" in the Fall 2020 Research Priorities, as we agree with the committee analyses that a better understanding of how pre- and post-farmgate practices impact crop nutrition is needed. However, the committee discussion focuses around fruit and vegetables. We encourage the committee to include animal products such as meat, dairy, and eggs in their priorities, because while

This year the Organic Center conducted a review of recently published studies on the impacts of organic meat production, and while we found that while research suggests that organic practices result in animal products with higher nutritional value most of that research has been conducted in Europe and are based on European livestock standards. Additional studies based on U.S. standards will be critical for fully understanding the impacts of production methods on meat nutrition.

Protection of organic farmers from chemical contaminants

Unintentional pesticide contamination in organic crops has been flagged as a major challenge by the organic sector,



across the supply chain. For example, the Organic Trade Association's Farmers Advisory Council has highlighted it as a top priority in their 2019 work plan, and the Organic Trade Association is currently assembling a task force to engage the industry in protecting organic integrity from pesticide contamination. Contamination can have a disproportionate impact on organic farmers, because organic stakeholders along the entire supply chain are burdened with the cost of testing and experience losses when tests are positive. While the organic community has identified this as a critical topic for investigation, little data has been collected synthesizing the current experiences and specific research needs of the organic community.

The Organic Center was recently awarded an OREI planning grant to address this issue by bringing together organic stakeholders across the supply chain with scientists to determine the crops that are most heavily impacted by contamination, pesticides that the organic industry has detected on its crops, losses that organic farmers and industry members have experienced, strategies that organic farmers have undertaken to reduce pesticide drift, and research needs for identifying vectors and preventing contamination to inform the development of a large-scale and multi-disciplinary research project that will provide farmers with strategies for combating current contamination.

While we laud the NOSB for including the focus "Prevention of GMO Crop Contamination: Evaluation of effectiveness," the issue of contamination is not unique to genetically modified material, and we request that chemical contamination be included in the research priorities as well.

Comparisons of synthetic residues in organic and conventional products

Understanding the benefits of organic when it comes to avoiding synthetic toxins is critical, because it is the basis behind hypotheses for recent research finding health benefits to consuming an organic diet such as a 25% reduction in overall cancer risk.

The Organic Center completed a study in collaboration with Emory University showing that organic is an easy way to avoid pesticides, antibiotics, and synthetic growth hormones in dairy. Specifically, the study found no detectable levels of any antibiotics in organic milk in comparison with 60% of conventional samples having detectable levels of antibiotics. We also found that over 30% of conventional samples had residues of antibiotics that are banned for use in lactating cows. Conventional levels of growth hormones were twenty times higher than the organic levels. For pesticides, we found that organic milk didn't have any residues of currently used pesticides, but pesticides over 60% of conventional milk, including chlorpyrifos, atrazine, and diazinon.

Additional research on the impacts of organic on exposure to residues, and connections between these exposures and health outcomes are critical for understanding emerging research on the long-term health effects of an organic diet.

Celery Powder

In collaboration with the Organic Trade Association's National List Innovation Working Group and the University of Wisconsin, Madison, we are investigating the potential for developing organically grown celery or other vegetables used in the curing of organic meat products. This OREI-funded research will help identify potential varieties of organic crops that would meet the chemical specification needed for curing, while being easily incorporated into current crop rotation systems. It will also identify potential management protocols to achieve target nitrate levels in the curing crop to produce the required shelf life and prevent bacteria in the cured meat, and to produce the desired flavor, color and texture in food. This research will take 4 years to complete. During this time period, or until final results are collected to meet this need, we request that alternatives to conventional celery powder for curing organic meat be included in the NOSB Research Priorities.

Please do not hesitate to contact us for information on the data that we have been collecting or with questions you would like us to pose the research community.

Again, on behalf of The Organic Center, I would like to extend my thanks to the Materials Subcommittee for your commitment to furthering organic agriculture.



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Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center