



April 3, 2020

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

Docket: AMS-NOP-19-0095

Comments to the National Organic Standards Board Spring 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.

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

Docket: AMS-NOP-19-0095

RE: Crops Subcommittee – Paper-based Crop Planting Aids (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee's Proposal on Paper-based Crop Planting Aids.

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 continues to support the allowance of paper to be planted in the soil when used as a planting aid because paper is already allowed for equivalent uses (e.g., as mulch).
- ✓ We support the decision by NOSB to define the scope of review to be inclusive of generic products that are paper-based and used as planting or seeding aids left to degrade in the soil (e.g. pots, chains, seed tape).
- ✓ We have questions about whether particular aspects of the proposed definition will be effective in achieving the NOSB's goal of allowing a range of paper-based crop planting aids. Our questions address the inclusivity of the 85% biobased restriction and alternatives to ASTM D6866 testing.

We offer the following more detailed comments:

I. Background

NOSB received a petition in August 2018 for the addition of paper planting pots to the National List: “§205.601(o) production aids - Plant pot or growing container-hemp or other paper, without glossy or colored inks.” Paper pots are used as a vessel for growing transplants intended to be planted directly in the soil along with the plant material. Nitten paper chain systems, which are the subject of the petition, are used to efficiently transplant closely spaced crops as part of a non-motorized machine transplanting system. The petitioned material is planted into the soil along with the plant material.

At the fall 2018 meeting, the NOSB Crops Subcommittee presented a discussion document to solicit public comments on the necessity and environmental impact of the material and the availability of alternatives. At the spring 2019 meeting, the Subcommittee presented a second discussion document that continued to explore the petitioned material, and expanded the scope of its review to include a variety of paper-based production aids including pots, seed tape, collars, and hot caps. Out of concern for the use of synthetic fibers in paper-based planting aids, the Subcommittee requested a technical report to evaluate the types of synthetic fibers and the biodegradability of the synthetic fibers used in these types of products. The [Technical Report](#) clarified that synthetic fibers in paper pots and containers are also found in other paper materials currently allowed in organic production as mulches and compost feedstocks. At the fall 2019 meeting, the Subcommittee presented a third discussion document to request comments on a proposed listing and annotation that specified limits on biobased content, synthetic polymer content, and biodegradability. Commenters provided feedback on these items as well as considerations regarding the scope of review for other paper-based planting aids that are left to decompose in the field.

At this meeting (spring 2020), the Subcommittee is presenting a [Proposal](#) to add a new definition to the NOP regulations and a new listing to the National List to allow the use of paper-based crop planting aids under certain conditions.

II. Proposed Definition and Listing

The Subcommittee proposes to add the following definition and listing to the NOP regulations:

Add to §205.2 (Terms Defined):

***Paper-based crop planting aid.* A material that is comprised primarily of cellulose-based paper, including pots, seed tape, and collars that are placed in or on the soil and are intended to degrade into the soil. Contains no less than 85% biobased content with biobased content determined using ASTM D6866 (incorporated by reference; see §205.3).**

Add to §205.601 (National List):

***§205.601(o) Production Aids:* Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without colored or glossy inks. If these paper-based crop planting aids are commercially available with 100% biobased fiber content, these must be used.”**

Consistent with our previous comments, we continue to support the allowance of paper to be planted in the soil when used as a planting aid because paper is already allowed for equivalent uses (mulch, compost feedstock) that have been determined by NOSB to meet OFPA criteria for synthetics on the National List.

The necessity of paper-based planting aids for production has also been communicated in our previous comments and directly from other stakeholders. The use of paper chain pots and other paper-based planting aids has been highlighted by OTA members as a necessary part of their operation, from small to commercial scales of production, due to the absence of natural alternative products and management practices that would achieve the equivalent level of efficiency (of time and labor), quality (of crops produced), and waste reduction (of plastic trays, for example).

We agree with the scope of review in the Subcommittee’s proposed definition that is inclusive of generic products that are paper-based and used as planting or seeding aids left to degrade in the soil (e.g. pots,

chains, seed tape). This is an appropriate balance of scope and is consistent with OTA's previous comments that encouraged a scope of review that would make efficient use of NOSB's efforts to review the existing variety of paper-based planting aids that share these key common characteristics of being paper-based, used as planting or seeding aids, and were left to degrade in the soil.

We have questions about whether particular aspects of the proposed definition will be effective in achieving NOSB's goal of allowing a range of paper-based crop planting aids.

- **Is the prohibition on products containing less than 85% biobased content inclusive of the spectrum of commercially available forms of generic paper-based crop planting aids that are intended to be allowed under this listing?** We recognize that NOSB has evaluated a wealth of technical information on paper-based pots and containers, including a Technical Report as well as information submitted by the petitioner and through public comments from other paper-based pot and container manufacturers. We also recognize that it is not feasible or appropriate for NOSB to review brand-name products for compliance with a proposed listing. Rather, the question we raise is whether the spectrum of generic planting aids *other than pots* such as seed tapes and collars have been evaluated against this criteria, seeing as the NOSB's technical review has focused on pots and containers. Confirming the spectrum of allowable commercially-available products under the definition would avoid unintended consequences, such as inadvertently setting a restriction that excluded any certain class of crop planting aids.
- **Is the definition intended to *only* include pots, seed tape, and collars, or is the definition not limited to only these examples?** We question if the Subcommittee should consider clarifying that the definition includes "but is not limited to" these examples, to avoid unintended interpretations that these examples serve as a closed list.
- **Could alternative methods besides ASTM D6866 testing achieve the intended outcomes of determining the percent biobased fiber content?** Material Review Organizations have identified their ability to determine percent biobased content of previously reviewed paper-based planting aids by using the formulation list provided by manufacturers. We question if the Subcommittee should consider alternative verification methods that align with current review procedures.

The Subcommittee highlights the importance of ensuring biodegradability of non-biobased content (e.g., non-paper synthetic fibers, adhesives, and other additives that provide strength and functionality), and justifies its approach based on several factors identified throughout the proposal, including: the same materials are also found in other allowed uses of paper; these materials have not shown negative environmental impacts when used in in other allowed uses of paper, the Technical Report confirms that many of these materials biodegrade without harming the environment; limiting these materials to no more than 15% of the product will ensure minimal environmental risks.

The proposed annotation requires the use of 100% biobased materials if they are commercially available. We are supportive of efforts for continuous improvement in sourcing input materials. Although this would be the first instance of a commercial availability restriction on the National List for synthetic crop inputs, it is a common restriction already in use for the original crop input – seeds (§205.204(a)). We support certifiers' efforts to work together to develop common requirements for verifying and enforcing such a restriction should this listing be added to the National List.



In closing, we'd like to acknowledge and appreciate the Subcommittee for its thoughtful and science-based consideration of this range of products over the past two years. The Subcommittee actively pursued technical information through a third-party technical report and has worked constructively with stakeholders across the organic community and input manufacturing industry. The proposal presented at this meeting is the result of a sound process for evaluation of materials in accordance with OFPA. We also appreciate NOP for permitting the use of previously approved paper pots while the NOSB continues its deliberation on the petition, allowing NOSB to take its time to complete a thorough review and also avoiding disruptions to organic producers who have been using these materials in good faith.

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



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Ms. Michelle Arsenault
National Organic Standards Board
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RE: Crops Subcommittee – Wild, Native Fish for Liquid Fish Products (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee's Discussion Document on Wild, Native Fish for Liquid Fish Products.

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 spring 2020 meeting, the NOSB Crops Subcommittee presents a [discussion document](#) that summarizes the results of a new [Technical Report](#), and presents questions for stakeholder feedback about how the Subcommittee should proceed to ensure that harvesting fish for use in crop fertilizers is not harmful to the environment. Notably, the Handling Subcommittee is concurrently evaluating a restriction on fish harvested for use as fish oil in organic processing, and has presented a discussion document for public stakeholder consideration. There does not appear to be cross-referencing of technical information or attempts to align decisions on environmental impact between the Subcommittees.

In its discussion document, the Crop Subcommittee asks, *“Given the results of the Technical Report indicating that there are no species of wild, native fish harvested exclusively for use in [Liquid Fish Products], please provide feedback on any next steps the subcommittee should take on this issue.*

Additional actions by the Subcommittee appear to not be warranted based on the finding of the technical report. **However, if the Subcommittee intends to continue to evaluate environmental impacts, NOSB should engage in cross-subcommittee discussions to calibrate decisions on environmental impacts of marine-sourced raw materials across inputs and scopes.** More information about our suggested approach to cross-subcommittee evaluation of environmental impacts is provided below.

Cross-Subcommittee Evaluation of Environmental Impact of Marine Materials

Across the history of NOSB since 2016, there have been at least *16 topics* across *three subcommittees* when a marine-sourced material was evaluated against OFPA criteria for environmental impact. As NOSB has evaluated materials sourced from marine environments, the question of environmental

impact has been scrutinized to varying degrees. Seaweed and fish have both received increased scrutiny for similar concerns about the impact that harvesting these material has on marine ecosystems. Third-party Technical Reports were commissioned for some topics but not others. Harvesting methods and frequencies were elevated as an issue of concern for some topics but not others. For more information on the history of NOSB topics related to marine materials, please see the attached document: **NOSB TACKLES SEAWEED & FISH-BASED INPUTS.**

It is clear that NOSB, across subcommittees, is interested in protecting marine environments and ensuring that use of marine materials in organic production is not harmful to the environment. OTA agrees with the goal of continuously improving the sustainable sourcing of inputs. It is also clear that it is a complex topic with many intersecting issues at play. NOSB must approach the issue carefully, using science-based information and thoughtful consideration of the global industry impacts of any new regulatory requirements, so that organic operations continue to have reliable access to essential tools for production and processing.

To achieve NOSB's goal of ensuring that the use of marine materials in organic production is not harmful to the environment, NOSB must change its evaluation approach to be more inclusive of materials sourced from marine environments for use in organic production and processing. Meaningful outcomes can't be achieved by just looking at individual inputs in isolation.

OTA encourages NOSB to engage in cross-subcommittee discussions to calibrate (standardize, harmonize) **decisions on environmental impacts of marine-sourced raw materials across inputs and scopes.** A collaborative approach across subcommittees will support consistent and balanced decision-making on common questions around the environmental impact of harvesting marine materials. A common process for collecting and sharing technical information should be established for subcommittees to be working from a common base-line understanding of evidence about environmental impacts of various materials and sourcing methods across regions. Collaborative discussions could also serve to establish a common base-line for evaluating the extent to which sourcing of a marine materials is "harmful," so that subcommittees have a common starting point when making use/scope-specific decisions about how the environmental criteria are balanced against other OFPA criteria. 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.

As the vehicle for such cross-subcommittee discussions, perhaps the Materials Subcommittee could expand the Marine Materials work agenda item to look at all uses of marine materials across scopes instead of focusing just on seaweed in fertilizers. Or, establish a Joint Subcommittee, Task Force, or Working Group to support this effort and bring in outside experts. In any case, a centralized group should be responsible for leading the discussions and calibrating decisions on environmental impacts of harvesting inputs from marine environments. This centralized group can take actions to more broadly address environmental impacts of marine materials across scopes/uses, such as:

- Collect **technical information** about environmental impacts to support informed policy-development processes.
 - Establish the scope of information needed to make informed decisions about the environmental impact of marine materials (e.g., Conclusions about the environmental harm

from seaweed or fish harvesting should be informed by 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.)

- Compile available technical information on environment impact of seaweed and fish harvesting. (e.g., Significant amounts of technical information have already been submitted to NOSB through public comments over the course of many meetings, and this information could be summarized and reflected back to NOSB and the public in a synthesized and thorough manner)
 - Commission Technical Reports as needed to fill information gaps.
 - Identify items to add to NOSB Research Priorities as needed to address areas where information is not currently available.
-
- Develop recommendations to clarify the **taxonomic nomenclature** of marine materials on the National List across crops, livestock, and handling scopes. NOSB began this work in 2016 and it has not yet been completed. A Discussion Document was posted in fall 2016, and proposals were presented by each the Crops and Handling Subcommittees in spring 2017 although both were sent back to subcommittee for further work. Inconsistencies still persist, and there is still a need for clear and accurate terms and definitions for marine materials in the NOP regulations.
 - Explore options to address in a consistent manner the environmental impact of inputs sourced from natural substances such as mineral, plant, or animal matter. What does it look like to ensure “not harmful to environment” of non-synthetic inputs not on the National List? Could there be a uniform approach to all non-synthetic inputs, such as a preference for less harmful or certified organic substances based on commercial availability? Could there be special annotations carved out for high risk substances, such as those sourced directly from native wild ecosystems?
 - Explore opportunities for NOP certification to be better positioned as a tool for ensuring sustainable agriculture in marine environments. Continuous improvement of the regulations and guidance are needed to accommodate the unique conditions of marine agriculture. Additional guidance on the certification of marine plants under crop and wild crop standards would assist the organic community in ensuring that NOP certification can provide certain outcomes for sustainability.
 - Work with NOP to explore the legal authority under OFPA to require organic certification of an ingredient in a product that is not intended for livestock or human consumption, such as crop fertilizers. This information is essential for informing future discussions and whether organic certification is a viable solution for verifying environmental impacts of materials used in crop fertilizers.

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

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



April 3, 2020

Ms. Michelle Arsenault
National Organic Standards Board
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RE: Crops Subcommittee – Biodegradable Biobased Mulch Film (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee's Discussion Document on Biodegradable Biobased Mulch Film.

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 is supportive of the efforts being made to seek out biodegradable alternatives to plastic mulch. Consistent with our position in 2012, we view this as an opportunity to encourage the development of technologies that are compatible with organic principles. Across the organic industry, organic businesses are exploring options for reducing plastic throughout their value chains, from on-farm uses to retail packaging.

Current NOP regulations are not effective to allow biodegradable biobased mulch film as alternative to plastic mulch. The listing of biobased mulch film on the National List at §205.601(b)(iii) reads, "*Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.*" The definition at §205.2 reads, "*A synthetic mulch film that meets the following criteria: (1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3); (2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and (3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).*"

The final rule to add biodegradable biobased mulch film (BBMF) to the National List was published September 30, 2014, in response to an NOSB Recommendation in fall 2012. Following the final rule, NOP published a Policy Memo in January 2015 to specify that BBMFs must not contain any non-biobased content. NOP rescinded the Policy Memo in October 2019, but the requirement for 100% biobased content remains in effect because it is articulated in the preamble to the final regulations adding BBMF to the National List.

What has resulted is a conflict between the NOP's regulatory allowance and the industry's commercially available products. Commercially available BBMFs contain around 20% biobased content. Therefore, there are no products on the market that meet the terms of the NOP's regulatory allowance. The topic of BBMF has returned to the NOSB work plan to seek resolution. A [Technical Report](#) was commissioned in 2016 to evaluate long-term biodegradability of BBMF, and was inclusive due to limited research available at the time. NOSB has continued to track new research by commissioning an expert panel at the spring 2016 NOSB Meeting. NOP also commissioned a [new report](#) from Michigan State University, which was made available in October 2019.

We encourage NOSB to continue working on a solution to resolve this conflict, and to meet its original goal of allowing Biodegradable Biobased Mulch Film as an alternative to plastic mulch. When NOSB passed its formal recommendation in fall 2012, it stated that "NOSB sees the approval of these materials as an opportunity to reduce pollution substantially without sacrificing organic farming principles." Unfortunately, the regulatory implementation of the intended approval has not resulted in any actual outcomes for approved materials, nor reduction in pollution. Organic producers are still without allowable biobased alternatives to plastic mulch. NOSB should continue to advance efforts to effectively implement a regulatory allowance of biodegradable biobased mulch films.

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, reading "Johanna Mirenda".

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



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

Docket: AMS-NOP-19-0095

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 5 responses on our 2022 Crops Sunset Surveys. 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	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used by long-time organic growers of bananas, citrus, etc. - It is used to help control pests including meal bugs and scale insects. - Used as needed in a rotational spray program; at time of year when insects abound. <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 - 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. - 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. 	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	2	Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.	5

		<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used by long-time organic growers to produce Fruits, Vegetables, 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. - Supports health and vigor of the crop - Used as a greening agent that provides vigor to baby leaf vegetables - Used 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 tools are as environmentally friendly with the same effects. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decreased nutrients and overall health of soil and plants - Increase use of nitrogen fertilizers, risk of leaching and/or violating nitrogen reporting needs 	
Lignin sulfonate	0		
Sodium silicate	0		
EPA List 4 inerts	0	Note: Please also see the separate comment submitted by the Organic Trade Association on this material.	

§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 Mirinda
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)





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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

- ✓ Alkali-Extracted Aquatic Plant Extracts are necessary for organic crop production.
- ✓ To evaluate environmental impacts, NOSB should engage in cross-subcommittee discussions to calibrate decisions on environmental impacts of marine-sourced raw materials across inputs and scopes.

We offer the following more detailed comments:

I. 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. The listing has been renewed at each of the three Sunset Reviews (2006, 2010, and 2015) that have occurred for this listing over the past 20 years. Each review has demonstrated that the use of alkali-extracted aquatic plant extracts as listed at §205.601(j)(1) meet the

criteria established in the Organic Foods Production Act for allowance of a synthetic substance: 1) The input must not be harmful to not 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 presents its [Sunset Summary and Request for Comments on Aquatic Plant Extracts \(starts on Page 27\)](#). 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

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. As indicated in our Sunset Surveys, respondents rate the necessity of products as a 5 out of 5, meaning that products are critical and they would leave organic without it.

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 biostimulants compounds and multiple modes of action are unique in seaweed extracts, and there are not comparable alternatives.

III. Impact on Environment

The evaluation of whether the use of marine 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 (broader evaluation of seaweed used in crop production, including non-synthetic forms). When the Materials Subcommittee last discussed this topic in fall 2019, there was still no consensus from the public about the extent of environmental harm caused by seaweed harvesting, and if/how NOSB intervention would be appropriate to ensure environmental protection. 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 across regions where seaweed is harvested across the globe, and the extent to which environmental impacts are already addressed by existing legal oversight in these regulated industries. NOSB has expressed an interest in taking a slow and careful approach to this complex issue. A clear path forward on this particular work agenda item is not yet apparent.

Questions about the environmental impact from harvesting resources from marine environments have persisted throughout other subcommittees and input materials. The Handling Subcommittee has raised similar questions in its Sunset Review of seaweed-based ingredients and derivatives used in processing and handling. The Handling Subcommittee has also begun evaluating similar questions for harvesting fish, and the Crops Subcommittee is looking at environmental impacts of fish harvested for use in fish-based fertilizers. On the spring 2020 agenda alone, there are *four topics across two subcommittees* looking at some aspect of marine environmental impact from sourcing of input materials. Across the history of NOSB since 2016, there have been at least *16 topics across three subcommittees* when a marine-sourced material was evaluated against OFPA criteria for environmental impact.

As NOSB has evaluated materials sourced from marine environments, the question of environmental impact has been scrutinized to varying degrees. Seaweed and fish have both received increased scrutiny for similar concerns about the impact that harvesting these material has on marine ecosystems. Third-party Technical Reports were commissioned for some topics but not others. Harvesting methods and frequencies were elevated as an issue of concern for some topics but not others. For more information on the history of NOSB topics related to marine materials, please see the attached document: **NOSB TACKLES SEAWEED & FISH-BASED INPUTS**.

It is clear that NOSB, across subcommittees, is interested in protecting marine environments and ensuring that use of marine materials in organic production is not harmful to the environment. OTA agrees with the goal of continuously improving the sustainable sourcing of inputs. It is also clear that it is a complex topic with many intersecting issues at play. NOSB must approach the issue carefully, using science-based information and thoughtful consideration of the global industry impacts of any new regulatory requirements, so that organic operations continue to have reliable access to essential tools for production and processing.

To achieve NOSB’s goal of ensuring that the use of marine materials in organic production is not harmful to the environment, NOSB must change its evaluation approach to be more inclusive of materials sourced

from marine environments for use in organic production and processing. Meaningful outcomes can't be achieved by just looking at individual inputs in isolation.

OTA encourages NOSB to engage in cross-subcommittee discussions to calibrate (standardize, harmonize) **decisions on environmental impacts of marine-sourced raw materials across inputs and scopes.** A collaborative approach across subcommittees will support consistent and balanced decision-making on common questions around the environmental impact of harvesting marine materials. A common process for collecting and sharing technical information should be established for subcommittees to be working from a common base-line understanding of evidence about environmental impacts of various materials and sourcing methods across regions. Collaborative discussions could also serve to establish a common base-line for evaluating the extent to which sourcing of a marine materials is “harmful,” so that subcommittees have a common starting point when making use/scope-specific decisions about how the environmental criteria are balanced against other OFPA criteria. 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.

As the vehicle for such cross-subcommittee discussions, perhaps the Materials Subcommittee could expand the Marine Materials work agenda item to look at all uses of marine materials across scopes instead of focusing just on seaweed in fertilizers. Or, establish a Joint Subcommittee, Task Force, or Working Group to support this effort and bring in outside experts. In any case, a centralized group should be responsible for leading the discussions and calibrating decisions on environmental impacts of harvesting inputs from marine environments. This centralized group can take actions to more broadly address environmental impacts of marine materials across scopes/uses, such as:

- Collect **technical information** about environmental impacts to support informed policy-development processes.
 - Establish the scope of information needed to make informed decisions about the environmental impact of marine materials (e.g., Conclusions about the environmental harm from seaweed or fish harvesting should be informed by 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.)
 - Compile available technical information on environment impact of seaweed and fish harvesting. (e.g., Significant amounts of technical information have already been submitted to NOSB through public comments over the course of many meetings, and this information could be summarized and reflected back to NOSB and the public in a synthesized and thorough manner)
 - Commission Technical Reports as needed to fill information gaps.
 - Identify items to add to NOSB Research Priorities as needed to address areas where information is not currently available.
- Develop recommendations to clarify the **taxonomic nomenclature** of marine materials on the National List across crops, livestock, and handling scopes. NOSB began this work in 2016 and it has not yet been completed. A Discussion Document was posted in fall 2016, and proposals were

presented by each the Crops and Handling Subcommittee in spring 2017 although both were sent back to subcommittee for further work. Inconsistencies still persist, and there is still a need for clear and accurate terms and definitions for marine materials in the NOP regulations.

- Explore options to address in a consistent manner the environmental impact of inputs sourced from natural substances such as mineral, plant, or animal matter. What does it look like to ensure “not harmful to environment” of non-synthetic inputs not on the National List? Could there be a uniform approach to all non-synthetic inputs, such as a preference for less harmful or certified organic substances based on commercial availability? Could there be special annotations carved out for high risk substances, such as those sourced directly from native wild ecosystems?
- Explore opportunities for NOP certification to be better positioned as a tool for ensuring sustainable agriculture in marine environments. Continuous improvement of the regulations and guidance are needed to accommodate the unique conditions of marine agriculture. Additional guidance on the certification of marine plants under crop and wild crop standards would assist the organic community in ensuring that NOP certification can provide certain outcomes for sustainability.
- Work with NOP to explore the legal authority under OFPA to require organic certification of an ingredient in a product that is not intended for livestock or human consumption, such as crop fertilizers. This information is essential for informing future discussions and whether organic certification is a viable solution for verifying environmental impacts of materials used in crop fertilizers.

IV. Questions from Crops Subcommittee (Spring 2020):

1. *Given the broad range of views on this topic, please describe if/ or how aquatic plant extracts should be addressed during this Sunset Review.*

As with any Sunset Review, NOSB is responsible for evaluating the substance against OFPA criteria for the National List.

OTA has provided information in **Part II** above about the necessity of alkali-extracted aquatic plant extracts.

On the topic of environmental impact, we encourage NOSB to engage in cross-subcommittee discussions to calibrate decisions on environmental impacts of marine-sourced raw materials across inputs and scopes. As described in **Part III** above, the Crops, Handling, Materials Subcommittees are all actively looking at some aspect of environment impact from sourcing materials from marine environments for use as inputs in organic production and processing. NOSB should avoid making a decision on this 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.

2. *Are aquatic plant extracts still needed in organic crop production?*

Yes. 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. See **Part II** above for more information.

3. *The 2006 [Technical Report](#) states that aquatic plant extracts can be derived naturally by dehydrating seaweeds and grinding them into meal. Meal can be applied directly to the soil or diluted with water and used as a foliar spray or soil drench. Non-synthetic products also may be produced using mechanical disruption, or freezing, pulverization, and clarification of the thawed slurry. The relative efficacy of alkali-extracted versus non-alkali- extracted product has not been consistently demonstrated, perhaps partly as a result of a lack of understanding of the mechanism by which aquatic plant extracts exert any purported beneficial effect (lines 205-12). Do the non-synthetic alternatives to this material provide the same functionality?*

No. The alkali extraction step is critical for releasing the bioactive compounds of seaweed and delivering benefits to crop production systems. Equivalent alternatives are not known to be available. See **Part II** above 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



April 3, 2020

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,

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



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – L-Malic Acid (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Discussion Document on L-Malic Acid. The Subcommittee is evaluating whether L-malic acid has been incorrectly classified as a non-synthetic, and whether the common manufacturing process is more appropriately classified as 'synthetic' based on NOP Instruction on Classification of Materials.

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.

The Handling Subcommittee is presenting four questions to inform its evaluation and proposal for the fall 2020 meeting. In summary:

- OTA's evaluation determined that the two-step production process that involves the synthesis of fumaric acid from petroleum products followed by enzymatic conversion of synthetic fumaric acid to L-malic acid renders it **synthetic**. In contrast, the two-step process involving production of non-synthetic fumaric acid by fermentation followed by enzymatic conversion to L-malic acid results in **non-synthetic** L-malic acid.
- OTA analyzed citric acid, lactic acid, gibberellic acid, yeast and xanthan gum. In doing so, we determined that the classification of L-malic acid, when synthesized as a two-step process starting with petroleum products, should not affect the classification of other substances on the National List. However, the exercise of running multiple substances produced via fermentation through the Classification Decision Tree (Synthetic/Non-synthetic) led us to conclude that there is a need for improved Classification Guidance for fermentation by-products.
- The commercial source of L-malic acid that is predominantly being used in organic processed products is the synthetic form. There does not appear to be sufficient quantities of a non-synthetic L-malic acid available to meet current demand in organic production. More research, however, is needed. One option for addressing the issue as a whole is to list L-malic acid as "synthetic" with an annotated requirement to use a non-synthetic form when commercially available.

We offer the following more detailed response to the Subcommittee's questions:

1. **There still appears to be some disagreement whether the process described in this document results in a synthetic form of L-malic acid. Is the determination that the two-step process described in this document and in the 2019 Technical Report results in a synthetic form of L-malic acid accurate?**

The 2019 Technical Report (TR) presents a one-step fermentation process for L-malic acid as well as two variations of a two-step production process. In the one-step process, L-malic acid is produced via microbial fermentation of glucose (and other sugars) whereas the final isolated L-malic acid product has not been transformed into another substance (no chemical change). The one-step fermentation method, from our viewpoint, is unquestionably non-synthetic.

In the two-step process for producing L-malic acid, fumaric acid is produced in the first step and then enzymatically converted to L-malic acid. The TR presents two options for the production of fumaric acid: 1) fumaric acid is produced via glucose fermentation; and 2) fumaric acid is synthesized from petroleum products. The first option using fermentation, as described in the TR and by our analysis, is clearly non-synthetic. The point of disagreement, or rather discussion, is found in the second option, when the precursor for enzymatic conversion is **synthetic** fumaric acid, derived from **petroleum products**. The question arises around the interpretation of NOP Guidance 5033-1 and what is considered the "natural source."

In evaluation #2 of the TR, on Page 9, two interpretations are presented:

- a. If synthetic fumaric acid, as a microbial substrate, is considered the source, then L-malic acid is synthetic.
- b. If, however, the microbial product (i.e. column effluent) the L-malic acid is extracted from is considered the source, L-malic acid could be considered synthetic. As previously discussed, the second phase of this production methods involves conversion of fumaric acid to L-malic acid followed by extraction of L-malic acid using non-synthetic methods.

The Organic Trade Association views L-malic acid from synthetic fumaric acid production to be **SYNTHETIC**. The enzymatic conversion of a synthetic substance derived from a petroleum source should not be compared to a substance produced via microbial fermentation.

First and foremost, we believe the two-step process needs to be viewed as one process with two steps. From this perspective, the "source" should be identified in the first step of the process. In the fermentation option, the L-malic acid is produced via a naturally occurring biological process. The source is ultimately glucose fermentation that produces non-synthetic fumaric acid that is converted to L-malic acid. In second option, the ultimate source of the L-malic acid is petroleum products whereas fumaric acid is synthesized from petroleum and converted to L-malic acid. In other words, we do not think the fumaric acid should be identified as the "source." Fumaric acid is an intermediate substance in a two-step process. Fumaric acid is, in fact, the substance or source that the L-malic acid is directly derived (converted) from, but it is a two-step production process from start to finish.

To further address the question of whether fumaric acid is the microbial substrate or a microbial product (column effluent), we suggest it most closely resembles the reference to “microbial substrate.” More precisely however, fumaric acid is a substance (direct source) that is enzymatically converted. It is a component of the column effluent along with a preparation of immobilized cells that produce the fumurase (catalyst) that carries out the enzymatic conversion of fumaric acid to L-malic acid. In a microbial preparation for fermentation, as well as a preparation for enzymatic conversion, there are several starting inputs that make up the starting media / substrate / effluent. In all cases, however, there is the primary substrate or substance that is converted - glucose in the case of fermentation and fumaric acid in this case of enzymatic conversion. If fumaric acid is removed from the effluent, L-malic will not be produced. There is an important distinction between the ‘fumaric acid’ specifically and the ‘column effluent’ in general.

2. Would classification of L-malic acid when manufactured from synthetic fumaric acid as a synthetic substance affect the classification of other substances currently on 205.605(a)?

We do not believe so, as long the synthetic form is clearly tied to L-malic acid produced from synthetic fumaric acid (as opposed to the one-step fermentation methods). Our determination is based on an analysis we conducted looking at citric acid, lactic acid, gibberellic acid, yeast and xanthan gum. We reviewed the technical resources available for all substances and ran each one through the Classification Guidance for Synthetic / Non-synthetic (NOP 5033-1). The important distinction is that all of the National List examples listed above are produced via microbial fermentation, whereas the primary substrate is natural (typically glucose, sucrose or some other sugar or carbohydrate source). In no other non-synthetic example is the primary food source a petroleum product, or a synthetic substance converted from a synthetic source.

The exercise of running multiple substances produced via fermentation through the Classification Decision Tree (Synthetic/Non-synthetic) led us to conclude that there is a need for improved Classification Guidance for fermentation by-products. The problem is that for fermentation and other naturally occurring biological processes, the starting material (referred to as the substrate, medium, culture broth, etc.) will typically involve multiple inputs that may be synthetic and non-synthetic. For example, starting inputs may include the microorganism, glucose, nitrogen source, oxygen source, trace minerals etc. In this case, the primary substrate or food source is glucose, but other proteinaceous and complex nutrients are also required and consumed by the organisms to successfully carry out the fermentation process. This relates to the question of “source” and how to distinguish one component of a substrate from another.

The first question of NOP 5033-1 asks, “Is the substance manufactured, produced, or extracted from a natural source?” This is a straight-forward question when the source is a plant, animal or mineral. However, when applied to a substance produced via fermentation, the question of source can be complex because it can include multiple food sources and inputs. In simple terms, we believe the primary focus for classification should be on the breakdown of the essential carbohydrate source, or in the case of hydrolysis, the substance that is being converted. Additional guidance on the classification of fermentation by-products and review of the substrate is an area NOSB could consider for further work.

3. If the Subcommittee recommends an annotation that limits sources of fumaric acid used in the production of L-malic acid to non-petroleum sources, are there sufficient quantities to meet current demand in organic production?

The Organic Trade Association will need to continue to gather information to evaluate whether there are sufficient quantities of non-synthetic L-malic acid (non-petroleum source) to meet the demand in organic product. Based on the information NOSB received from certifiers during the spring 2019 meeting, we do not believe so. At that time, certifiers reported that it is unlikely that there are commercially available non-synthetic sources of L-Malic Acid. One certifier said they ““are confident that all commercially available sources are produced with petroleum as the starting material. Even when supporting documentation for L-malic acid says, “produced naturally via enzymatic fermentation,” that only refers to the second half of the process.””

OTA is aware of at least 70 NOP certified operations that are using L-malic acid in NOP certified products; however, we do not have access to information detailing the exact form being used. Regardless, a classification change that would inadvertently prohibit the form(s) being used would have a significant and potentially harmful impact on many organic processors. Therefore, a well-informed answer to this question is critical. NOP certified products that currently use L-malic acid include wine, juices, dietary supplements, personal care products, energy drinks, granola, gummy products, spice blends and others.

One option is to retain the listing on § 205.605(a)(non-synthetic), and add an additional listing at §205.605(b)(synthetic) with an annotated requirement to use a non-synthetic form when commercially available. Alternatively, a listing on 205.605(b) with a requirement to use non-synthetic forms when commercially available would likely suffice. Both approaches would not only maintain an allowance for non-synthetic L-malic acid, but *require its use* unless commercially unavailable. Maintaining a listing on 205.605(a) would reflect a clear allowance for the non-synthetic form, as reviewed by NOSB, in addition to an allowance for the synthetic form when non-synthetic is commercially unavailable.

We recognize that commercial availability requires additional time and resources of certifiers and certified operators. Therefore, we do not take this suggestion lightly in the grand scheme of advancing organic. However, it does present a reasonable path for honoring the intent of the law (“natural” preference) should sufficient quantities of the natural form not be available. A classification and listing of L-malic acid as “synthetic” only could not only raise questions around the allowance of a natural form, but also remove the incentive to use the natural form.

4. How much time would be required for the industry to meet current and expected commercial demand of non-synthetic L-malic acid produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*?

We are not yet able to answer this question. More research and outreach are needed. See our response to Question #3.



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, which appears to read "Gwendolyn V. Wyard".

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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



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

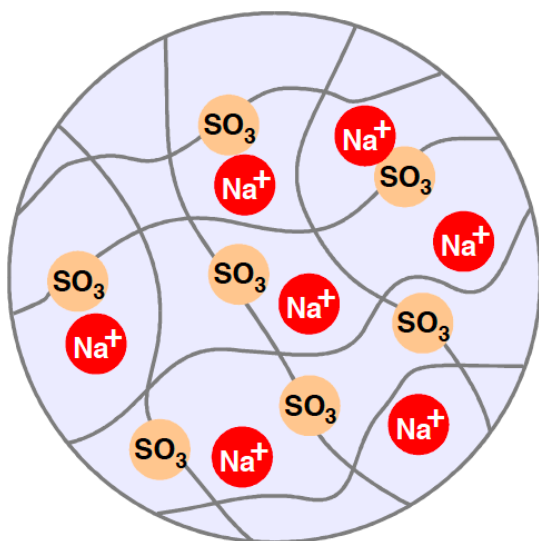
Ion exchange filtration is a food processing (purification) technique used to facilitate removal of unwanted salts, proteins, colors, flavors, odor compounds, acids, heavy metals, and other impurities using a chemical exchange process. The process involves a column, like a large pipe, packed with **ion 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

<i>Term</i>	<i>Definition</i>
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 electrodialysis. 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

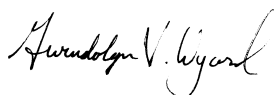
The topic of ion exchange filtration in organic processing is complex from both a technical and regulatory perspective, and there is a long history around its use and allowance. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as a processing technology. 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,

A handwritten signature in black ink, appearing to read "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: 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



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – Fish Oil Annotation (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 Fish Oil annotation change. Fish oil is currently on the National List at §205.606(e) as an agricultural substance allowed for use in organic processed foods only when the product is not commercially available in organic form.

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 spring 2020 meeting, the NOSB Handling Subcommittee presents a [discussion document](#) that proposes new restrictions on fish harvested for use as fish oil in organic processing in order to address concerns about the environmental impacts of harvesting fish directly for their oil: *"Sourced from fishing industry by-product only. Where within NOAA's jurisdiction, only from fish species and regions not listed on NOAA's current "Overfishing" or "Overfished" list. Where outside NOAA's jurisdiction, only from fish species and regions not listed on FAO's "Overexploited," "Depleted," or "Recovering."* Notably, the Crops Subcommittee is concurrently evaluating the environmental impact of fish harvested for use in crop fertilizers. There does not appear to be cross-referencing of technical information or attempts to align decisions on environmental impact between the Subcommittees.

In lieu of providing direct responses to the Handling Subcommittee's questions regarding its proposed annotation for fish oil on §205.606, OTA would like to **encourage NOSB to engage in cross-subcommittee discussions to calibrate decisions on environmental impacts of marine-sourced raw materials across inputs and scopes**. More information about our suggested approach to cross-subcommittee evaluation of environmental impacts is provided below.

Cross-Subcommittee Evaluation of Environmental Impact of Marine Materials

Across the history of NOSB since 2016, there have been at least *16 topics* across *three subcommittees* when a marine-sourced material was evaluated against OFPA criteria for environmental impact. As NOSB has evaluated materials sourced from marine environments, the question of environmental

impact has been scrutinized to varying degrees. Seaweed and fish have both received increased scrutiny for similar concerns about the impact that harvesting these material has on marine ecosystems. Third-party Technical Reports were commissioned for some topics but not others. Harvesting methods and frequencies were elevated as an issue of concern for some topics but not others. For more information on the history of NOSB topics related to marine materials, please see the attached document: **NOSB TACKLES SEAWEED & FISH-BASED INPUTS**.

It is clear that NOSB, across subcommittees, is interested in protecting marine environments and ensuring that use of marine materials in organic production is not harmful to the environment. OTA agrees with the goal of continuously improving the sustainable sourcing of inputs. It is also clear that it is a complex topic with many intersecting issues at play. NOSB must approach the issue carefully, using science-based information and thoughtful consideration of the global industry impacts of any new regulatory requirements, so that organic operations continue to have reliable access to essential tools for production and processing.

To achieve NOSB's goal of ensuring that the use of marine materials in organic production is not harmful to the environment, NOSB must change its evaluation approach to be more inclusive of materials sourced from marine environments for use in organic production and processing. Meaningful outcomes can't be achieved by just looking at individual inputs in isolation.

OTA encourages NOSB to engage in cross-subcommittee discussions to calibrate (standardize, harmonize) **decisions on environmental impacts of marine-sourced raw materials across inputs and scopes**. A collaborative approach across subcommittees will support consistent and balanced decision-making on common questions around the environmental impact of harvesting marine materials. A common process for collecting and sharing technical information should be established for subcommittees to be working from a common base-line understanding of evidence about environmental impacts of various materials and sourcing methods across regions. Collaborative discussions could also serve to establish a common base-line for evaluating the extent to which sourcing of a marine materials is "harmful," so that subcommittees have a common starting point when making use/scope-specific decisions about how the environmental criteria are balanced against other OFPA criteria. 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.

As the vehicle for such cross-subcommittee discussions, perhaps the Materials Subcommittee could expand the Marine Materials work agenda item to look at all uses of marine materials across scopes instead of focusing just on seaweed in fertilizers. Or, establish a Joint Subcommittee, Task Force, or Working Group to support this effort and bring in outside experts. In any case, a centralized group should be responsible for leading the discussions and calibrating decisions on environmental impacts of harvesting inputs from marine environments. This centralized group can take actions to more broadly address environmental impacts of marine materials across scopes/uses, such as:

- Collect **technical information** about environmental impacts to support informed policy-development processes.
 - Establish the scope of information needed to make informed decisions about the environmental impact of marine materials (e.g., Conclusions about the environmental harm

from seaweed or fish harvesting should be informed by 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.)

- Compile available technical information on environment impact of seaweed and fish harvesting. (e.g., Significant amounts of technical information have already been submitted to NOSB through public comments over the course of many meetings, and this information could be summarized and reflected back to NOSB and the public in a synthesized and thorough manner)
 - Commission Technical Reports as needed to fill information gaps.
 - Identify items to add to NOSB Research Priorities as needed to address areas where information is not currently available.
-
- Develop recommendations to clarify the **taxonomic nomenclature** of marine materials on the National List across crops, livestock, and handling scopes. NOSB began this work in 2016 and it has not yet been completed. A Discussion Document was posted in fall 2016, and proposals were presented by each the Crops and Handling Subcommittees in spring 2017 although both were sent back to subcommittee for further work. Inconsistencies still persist, and there is still a need for clear and accurate terms and definitions for marine materials in the NOP regulations.
 - Explore options to address in a consistent manner the environmental impact of inputs sourced from natural substances such as mineral, plant, or animal matter. What does it look like to ensure “not harmful to environment” of non-synthetic inputs not on the National List? Could there be a uniform approach to all non-synthetic inputs, such as a preference for less harmful or certified organic substances based on commercial availability? Could there be special annotations carved out for high risk substances, such as those sourced directly from native wild ecosystems?
 - Explore opportunities for NOP certification to be better positioned as a tool for ensuring sustainable agriculture in marine environments. Continuous improvement of the regulations and guidance are needed to accommodate the unique conditions of marine agriculture. Additional guidance on the certification of marine plants under crop and wild crop standards would assist the organic community in ensuring that NOP certification can provide certain outcomes for sustainability.
 - Work with NOP to explore the legal authority under OFPA to require organic certification of an ingredient in a product that is not intended for livestock or human consumption, such as crop fertilizers. This information is essential for informing future discussions and whether organic certification is a viable solution for verifying environmental impacts of materials used in crop fertilizers.

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

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – 2022 Sunset Reviews for §205.605 and §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.

Results of OTA Sunset Surveys

OTA has received 54 responses on our 2022 Handling Sunset Surveys. Below is a summary of the feedback received via OTA's Sunset Surveys to date.

§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 (from 1 to 5, with 5 being “critical – would leave organic without it”)
Kaolin	0		
Sodium bicarbonate	5	<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 (from 1 to 5, with 5 being “critical – would leave organic without it”)
Ammonium bicarbonate	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as leavening agent to make cookies, crackers, baked goods <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 	4

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	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a sanitizer <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	4	<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 - Balances pH in infant formula powder <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 <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. 	4

		<ul style="list-style-type: none"> - You'd be hard pressed to make Oreo/Hydrox type products without the black cocoa - It would change the production of the product 	
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§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	2	<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 <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Organic carnauba wax is available consistently 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. <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. 	2.5
Colors	20	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Coloring agents are used in fruit snacks, candy, yogurt, juices, cereal, plant-based ice cream and yogurt, baby teether crackers, crackers, baked goods - Responses addressed colors generally and also specifically for: Beet juice extract color, Beta-carotene extract color, Black currant extract color, Black/Purple carrot juice color, Blueberry juice color, Carrot juice color, Cherry juice color, Chokeberry aronia juice color, Elderberry juice color, Grape juice color, Paprika color, Pumpkin juice color, Purple sweet potato juice color, Red cabbage extract color, Red radish extract color, Turmeric extract color. <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. 	4

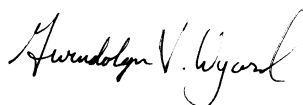
		<p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would have to reformulate, if possible, or convert to conventional - Would have to discontinue products 	
Glycerin	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a solvent, carrier in manufacturer of 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. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some manufacturers are currently using organic glycerin. However, other 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. <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. 	4
Inulin-oligofructose – enriched (IOE)	2	<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 - Provides fiber - Provides mouthfeel/bulking to help with sweetness perception <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. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Unable to produce products 	5
Kelp	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>Note: In addition to survey responses summarized here, OTA would like to encourage NOSB to engage in cross-subcommittee discussions to calibrate decisions on environment impacts of marine-sourced raw materials across inputs and scopes. More information about our suggested approach to cross-subcommittee evaluation of environmental impacts is available in our comments on the Fish Oil Discussion Document submitted separately to the Handling Subcommittee.</p>	
Orange shellac - unbleached	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
Cornstarch	5	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Thickener in macaroni and cheese, tortillas, baking mixes, and baked goods - 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. - 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 	4.3
Sweet potato starch	0		
Turkish bay leaves	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)	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for nutrition in baby food <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>According to one 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
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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 essentially 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.



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Livestock Subcommittee – Fenbendazole (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Discussion Document on Fenbendazole, which has been petitioned for use in organic poultry 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.

Fenbendazole is a parasiticide currently allowed in organic production for emergency treatment for dairy and breeder stock and fiber-bearing animals under the restrictions at §205.603(a)(23). A petition has been submitted to expand its use in laying hens and replacement chickens intended to become laying hens. A discussion document was presented at the fall 2019 NOSB meeting to solicit feedback on questions regarding the necessity of the material, effectiveness of alternatives, and whether a withdrawal time is needed. A second [discussion document](#) is being presented for the spring 2020 NOSB meeting with the same discussion questions. NOSB has also requested a Technical Report that is currently under development and will be limited in scope on the use of fenbendazole in poultry production.

OTA submitted comments last fall responding to the NOSB's discussion questions (Attachment A). OTA does not have any new comments to provide during this comment period. We look forward to reviewing the findings of the forthcoming Technical Report, and will continue to engage throughout the NOSB's evaluation of the petitioned material.

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



ATTACHMENT A

October 3, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-19-0038

RE: Livestock Subcommittee – Fenbendazole (Petitioned Material Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Petitioned Material Discussion Document on Fenbendazole. The subcommittee is inviting discussion on a petition requesting a revision to the annotation for fenbendazole to expand the use to poultry.

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.

NOSB is considering a petition requesting a revision to the annotation for fenbendazole at §205.603(a)(23)(i) to include an allowance for use in laying hens and replacement chickens intended to become laying hens. The petition does not request changes to the current restrictions on fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation.

Fenbendazole is currently allowed in the NOP regulations under the following restrictive conditions at §205.238(b) and §205.603(a)(23)(i) for use in breeder stock, dairy animals, and fiberbearing animals.

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

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

§205.603(a)(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber-bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

At this point, OTA does not have concerns with the petitioned allowance of fenbendazole for these reasons:

- Fenbendazole is already permitted under restricted conditions for other livestock species, hence it has already satisfied criteria for the National List in terms of not being harmful to the environment or human health, and being compatible with organic farming principles. In terms of essentiality for production of organic laying hens, we will continue to conduct member outreach and encourage organic egg producers to submit comments regarding the need for this input.
- The petitioned use would still be subject to the existing restrictions for fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Under these highly restricted conditions, poultry operation would still be required to establish preventive health care conditions as required by the NOP regulations and fundamental to organic production principles. Fenbendazole would be a new tool for emergency situations to control internal parasites. Organic livestock producers need adequate tools in their restricted toolbox to control infestations, and ensure animal safety and wellbeing.

Discussion Questions

The NOSB Livestock Subcommittee has requested feedback on the following discussion questions.

1. Is this material needed by organic poultry producers? If so, why?

OTA members in the organic egg sector have expressed a need for this material. Organic poultry producers identify a need for additional effective internal parasite treatment tools to address emergency situations when preventive practices have failed. Roundworm is a specific internal parasite for which organic poultry producers need better treatment tools, particularly for flocks exposed to outdoor access.

2. Do currently allowed alternatives work to control internal parasites? And at what level of effectiveness?

Alternative substances such as diatomaceous earth, essential oils, and apple cider vinegar have limited efficacy for preventing parasites or decreasing worm levels. There are no allowed alternative tools that have been identified that are effective in treating and eliminating parasites once they have infected flocks.

3. What are some of the “emergency” events that would trigger use of this product? And how would producers determine those events?

Poultry producers regularly monitor flock health and could establish an action threshold based on health deterioration, mortality, decreased egg production, lethargy, stool analysis, measurement of confirmed parasite presence, or other factors that could be described in an operation’s Organic System Plan.

For guidance on determining whether an event qualifies as an “emergency,” producers and certifiers can refer to the Spring 2018 NOSB Recommendation that includes the following definition of emergency treatment for parasite control in organic livestock, “An urgent, non-routine situation in which the organic system plan’s preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.”

Furthermore, as OTA commented in fall 2017 and spring 2018, we see value in developing guidance on “routine use of parasiticide” which is currently defined in §205.2 as “the regular, planned, or periodic use of parasiticides,” so that certifiers can consistently identify and take corrective actions against noncompliant routine uses of parasiticides. Tying the justification for use of a synthetic parasiticide to actions taken by producers (i.e. routine use of parasiticides) rather than an occurrence (i.e. an emergency) better matches how organic system plans are reviewed and verified, and would give certifiers better ability to ensure that synthetic parasiticides are not misused. Records and inspections can be used to justify a conclusion that parasiticides were “routinely used” much more easily than they were used in the absence of a legitimate “emergency.” Guidance that addresses both how producers can justify the “emergency” use of parasiticides as well as how certifiers can consistently identify “routine use of parasiticide” will ensure a level playing field for organic producers.

4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

At this point, we have not received indications of concern from our members.

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



April 3, 2020

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

Docket: AMS-NOP-19-0095

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 8 responses on our 2022 Livestock Sunset Surveys. 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	2	<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. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Alternatives are not as strong for use in more severe cases <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
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. 	4

		<ul style="list-style-type: none"> - 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 	
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> <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 	4

§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)
★	★	★



April 3, 2020

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,

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



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Materials Subcommittee – NOSB Research Priorities 2020 (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials Subcommittee's Discussion Document on NOSB Research Priorities 2020.

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 2020.

Summary:

- ✓ The Organic Center supports the subcommittee's proposed 2020 Research Priorities. The proposed priorities are in line with the needs of the organic industry, and will serve as an important resource to guide The Center's 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 soil health, 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 2020 Research Priorities.

We offer the following more detailed comments:



Current Research Needs

We have reviewed the list of topics included for 2020 priorities, and we're particularly pleased to see the inclusion of "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," "Pathogen prevention," 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.

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 recently [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 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 a record of addressing 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 recently 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 recently 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, some third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers 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 relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and 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.

We also recently applied for a grant to examine and communicate the safest strategies for application of aged manure. Currently, the FDA does not recognize aging manure as a way to reduce pathogens, but aged manure is the most commonly used animal-based soil amendment used on organic farms. Understanding potential benefits to pathogen reduction through aging (rather than full composting of the manure) could help organic farmers understand the full suite of options for controlling pathogens while managing soil health and crop nutrients.

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 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 ISOFAR 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 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 soil health, protection of organic farmers from chemical contaminants, and comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products be considered for inclusion in the 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.

Soil Health

The U.S Department of Agriculture’s Natural Resource Conservation Service (USDA NRCS) defines soil health as “the continued capacity of the soil to function as a vital living ecosystem that sustains plants, animals and humans.” While many other definitions of soil health exist, the majority of modern definitions exemplify the ecological attributes of soils, recognizing that their importance extends far beyond simple crop production.

A growing body of scientific literature evaluates the relative contribution of different management practices for improving soil health. However, significant variation in characteristics



assessed and the methods used to gauge those means that oftentimes results across different studies are not comparable. Even when scientific studies do use comparable measures of soil health, they may come to contradictory conclusions. Management decisions that lead to an improvement in soil quality in one study may be less effective in another, suggesting that some protocols must be carefully considered based on localized conditions to achieve best results. As such, reaching solid conclusions on best-management practices for achieving optimal soil health and fertility can be difficult, particularly for organic farmers who cannot rely on formulaic recommendations for fertilizer application.

To address this, The Organic Center is collaborating with researchers from the University of Maryland–College Park to conduct a comprehensive review of the most current science that evaluates organic compliant methods for optimizing soil health to develop best practices for organic farmers. Specifically, this project seeks to (1) review the literature comparing soil health on organic and conventional farms and discussing practices that differ between them that could be contributing to this difference; (2) understand variance in characterization of soil health and indicators used to assess it within the scientific literature; (3) identify science-supported best practices for maintaining and building soil health in organic systems; (4) identify practices that lead to variable results based on geography, climate, soil type, or commodity grown and therefore must be optimized based on local variables, and (5) identify areas where more research is needed.

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 recently submitted 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 pesticide, antibiotic, and synthetic growth hormone 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 recently 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.

Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center

NOSB TACKLES SEAWEED & FISH-BASED INPUTS

The ocean is a vast resource where seaweed, fish, and other natural resources are harvested for use in a wide range of agricultural inputs and food ingredients. Seaweed-based soil conditioners and liquid fish fertilizers are common crop production inputs on farms. Kelp and fish meal are common nutritional feed supplements for livestock. Food for human consumption also relies on fish-based oils, edible seaweed, and seaweed derivatives like alginates. Inputs used in the production of certified organic crops, livestock, and processed food products must comply with the National Organic Program (NOP) National List of Allowed and Prohibited Substances.

In recent years, the environmental impact of harvesting seaweed and fish has received increased scrutiny. Extracting natural resources (including terrestrial resources like mined minerals and forest products) will impact the environment to some extent. The Organic Foods Production Act (OFPA) authorizes the National Organic Standards Board (NOSB) to recommend the allowance or prohibition of substances on the National List to ensure that use of input materials in organic production and processing is not harmful to the environment.

CRITERIA FOR NOSB REVIEW OF INPUT MATERIALS

The organic law and regulations include a number of factors NOSB must consider when making a recommendation on the allowance of an input material. In sum, the conditions that must be met fall into three main criteria:

- 1) The input is **not harmful to human health or the environment**
- 2) The input is **necessary (essential)** for production and processing of organic products because of the unavailability of natural or organic alternatives
- 3) The input is **consistent (suitable)** with organic farming and handling and a system of sustainable agriculture

NOSB uses technical information to inform its evaluation of an input material against this criteria, and publishes its proposal for public comment. Final recommendations to amend the National List of Allowed and Prohibited Substances are submitted to USDA for implementation through rulemaking.

INPUT APPROVAL VS. ORGANIC CERTIFICATION

Inputs include but are not limited to fertilizers, pest controls, livestock treatments, processing aids, and ingredients. These inputs are used in the production of crops, livestock, or processed food products. These inputs themselves are not *certified organic*, but rather they are *approved for use* in a certified organic production or processing system. The outputs of such system (e.g., apples, milk, granola bars) are what ultimately get certified and labeled as organic.

Can seaweed be certified organic? YES – The NOP regulations for crop production and wild-crop harvesting are applicable to any plant or non-animal species (e.g., macroalgae, fungi) harvested from terrestrial or aquatic areas. Certifiers use the NOP regulations as the basis for verifying, inspecting, and certifying cultured and wild crop harvested aquatic plants (Ref: [NOP Policy Memo 12-1](#))

Can fish be certified organic? NO – The NOP regulations for livestock production specifically exclude aquatic animals. NOSB has passed recommendations for aquaculture standards but NOP has not yet implemented them. Until aquaculture standards are codified in the NOP regulations, fish and other seafood are not eligible for organic certification.

NOP REGULATIONS FOR SEAWEED AND FISH-BASED INPUTS

Inputs used in organic production and processing are subject to the requirements of NOP regulations. In general, synthetic substances are prohibited in organic crop and livestock production, and non-synthetic (natural) substances are allowed. Exceptions are codified on the National List (§205.601-205.604). Livestock feed has an additional requirement that agricultural ingredients must be certified organic. Ingredients and processing aids used in further manufacture of food for human consumption must be certified organic unless there is an exception codified on the National List (§205.605-205.606).

NOSB has worked on many topics related to the use of seaweed and fish-based inputs across the National List. Related NOSB Topics are identified in the table below and further explained in the next section.

TABLE 1: REGULATIONS FOR SEAWEED AND FISH USED AS INPUTS	SEAWEED (including any macroalgae and derivatives)	FISH (including any seafood and derivatives)
CROP PRODUCTION INPUTS (e.g. fertilizers, soil amendments, pest and disease controls)	<p>Seaweed is allowed provided that it has not been synthetically processed and no prohibited additives.* [See NOSB Topic #1,2]</p> <p>If used as a fertilizer or soil amendment, seaweed may be extracted with potassium hydroxide or sodium hydroxide per §205.601(j)(1).* [See NOSB Topic #3,4]</p>	<p>Fish is allowed provided that it has not been synthetically processed and no prohibited additives.* [See NOSB Topic #5]</p> <p>Liquid fish products may be pH adjusted with sulfuric, citric or phosphoric acid per §205.601(j)(8). [See NOSB Topic #6]</p> <p>Squid byproducts from food waste processing may be pH adjusted with sulfuric, citric or phosphoric acid per §205.601(j)(10) [See NOSB Topic #7]</p>
LIVESTOCK PRODUCTION INPUTS (e.g. feed additives, medical treatments, external pest control)	<p>Seaweed is allowed provided that it has not been synthetically processed and no prohibited additives.*</p> <p>If used as a livestock feed ingredient, seaweed must be <u>certified organic</u>.**</p>	<p>Fish is allowed provided that it has not been synthetically processed and no prohibited additives.*</p>
INGREDIENTS & PROCESSING AIDS IN FOOD FOR HUMAN CONSUMPTION (including dietary supplements and any other organic processed products)	<p>Seaweed and any derivatives must be <u>certified organic</u>, <u>except</u> for certain substances that are listed on the National List:</p> <ul style="list-style-type: none"> - Agar-agar [See NOSB Topic #8] - Carrageenan [See NOSB Topic #9] - Alginates [See NOSB Topic #10] - Alginic acid [See NOSB Topic #11] - Kelp [See NOSB Topic #12] - Pacific Kombu seaweed [See NOSB Topic #13] - Wakame seaweed [See NOSB Topic #14] 	<p>Fish and any derivatives must be <u>certified organic</u>, <u>except</u> for certain substances that are listed on the National List:</p> <ul style="list-style-type: none"> - Fish oil [See NOSB Topic #15,16] <p>(Note: Gelatin and Beta-carotene Color may also be sourced from fish or algae, respectively.)</p>

* **Note about non-synthetic crop and livestock inputs:** Materials that are classified as “non-synthetic” according to NOP Instructions on Classification of Materials are allowed unless they are specifically listed on the National List as a prohibited substance. No such listings for non-synthetic seaweed or fish-base inputs appear on the National List, so they are allowed without needing NOSB review or NOP rulemaking.

** **Note about livestock feed:** Agricultural ingredients in livestock feed are not subject to NOSB review and do not have individual listings on the National List. There is an overarching requirement at §205.237(a) that all agricultural products in organic livestock feed must be certified organic, and this includes kelp. NOP has explicitly classified kelp as an agricultural substance in [NOP Guidance 5027](#).

NOSB TOPICS

NOSB has had many work agenda topics related to the development of recommendations for the allowance or prohibition of seaweed and fish-based inputs used in organic production and processing. Most of these topics are routine Sunset Reviews of current listing on the National List which is required every 5 years to ensure continued compliance with OFPA criteria. Other topics may emerge from petitions or other NOP-directed or NOSB-requested work agenda items.

#1: Marine Materials in Crop Production

The NOSB Materials Subcommittee is evaluating the environmental impact of harvesting marine materials (seaweed, kelp, macroalgae) to ensure that the use of these materials in seaweed-based fertilizers is not harmful to the environment. Despite the generic “marine materials” title, this NOSB topic is focused only on seaweed materials and has not included fish.

This topic has been on the NOSB Materials Subcommittee work plan since 2018, although the topic originated from the Crops Subcommittee in 2015 during its Sunset Review for Aquatic Plant Extracts (See NOSB Topic #3), when concerns were raised about the increase in global harvesting of seaweed and the accelerated potential for destruction of marine ecosystems.

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 9 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 is 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 ingredient 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 is not yet apparent. The spring 2020 NOSB Meeting agenda does not include this topic.

#2: Laminarin

Laminarin is a **brown seaweed extract** manufactured by an acid-base reaction. In 2013, it was petitioned for allowance as a pre-harvest pesticide to stimulate the plants' natural disease defense mechanisms. A [Technical Report \(2015\)](#) was commissioned to clarify the whether the extraction and purification process resulted in a synthetic material, and to examine the environmental effects of seaweed harvest and processing.

At the fall 2015 meeting, NOSB made a [final recommendation](#) to classify the substance as "non-synthetic" and allow its use. No further rulemaking action is needed to permit a non-synthetic substance in crop production. On the question of environmental impact, NOSB stated that "the potential impacts are similar to many other non-synthetic inputs used in organic agriculture that are harvested or mined from the earth and sea," and ultimately voted that the substance satisfied OFPA criteria for not harming the environment (9 yes, 3 no, 2 abstain).

#3: Aquatic Plant Extracts – Sunset Review §205.601(j)(1)

Aquatic plant extracts are currently listed on the National List at §205.601(j)(1) as allowed as plant or soil amendments 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 last Sunset Review was conducted in 2015 when NOSB approved it for relisting but only by a slim margin ([NOSB Final Recommendations on Crop Sunset Reviews, starts on Page 21](#)). On a motion to remove the listing, the votes were 5 to remove, 6 to keep, and 3 abstentions. NOSB indicated concerns around overharvest of seaweed for this purpose but acknowledged aquatic plant extracts are still necessary for organic production of organic fruits and vegetables. Comments about the environmental impact concerns were very regional in nature. At the time, NOSB indicated it would be requesting a Technical Report to examine the environmental impact of harvesting certain species of aquatic plants.

The [Technical Report](#) was completed and published in 2016. A [discussion document](#) posted for the fall 2016 NOSB meeting addressed the 9 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.

To address nomenclature questions for the crop listing, NOSB's Crops Subcommittee presented a [proposal](#) in spring 2017 to limit the §205.601(j) listing of aquatic plant extracts to only brown seaweed. Public comments revealed that aquatic plant input products also use green and red algae, so the proposal was sent back to subcommittee to re-examine its approach to the issues. [[Read OTA's Comments](#)]

Since 2018, there has been extensive discussion within the Materials Subcommittee about the environmental impact of harvesting aquatic plants for use in crop fertilizer products. [See NOSB Topic #1]

For the spring 2020 NOSB Meeting, the Crops Subcommittee presents its [Sunset Summary and Request for Comments on Aquatic Plant Extracts \(starts on Page 27\)](#).

#4: Brown Seaweed Extract (with Sulfuric Acid)

In 2014, Brown Seaweed Extract was petitioned for use as a fertilizer. The specific petitioned formulations are manufactured in a three-step process whereby 1) seaweed is harvested and extracted w/tap water whose pH is lowered to a 3.5 minimum by adding a low concentration of sulfuric acid, 2) the mixture is centrifuged to separate seaweed insoluble from liquid extract, and 3) potassium hydroxide is added to adjust the pH of the liquid extract to near neutral.

At the fall 2015 meeting, NOSB unanimously passed a [final recommendation](#) to classify the petitioned substance as synthetic and to prohibit its use in organic production. The reason for prohibition is cited as "Because OFPA prohibits the use of any fertilizers containing synthetic ingredients, Brown Seaweed as petitioned cannot be added to the National List." On the question of environmental impact, the NOSB recommendation indicates that the substance satisfied OFPA criteria for not harming the environment.

#5: Wild, Native Fish in Liquid Fish Products

The NOSB Crops Subcommittee is evaluating the use of wild, native fish harvested for use in fertilizer to ensure that liquid fish and other fish-based fertilizer products used in organic crop production are not harmful to the environment. This is a new NOSB topic being presented for the first time on the spring 2020 Meeting agenda.

This topic evolved out of the Sunset Review for Liquid Fish Products in 2018 (See NOSB Topic #6), when concerns around the harvesting of wild fish exclusively for organic fertilizer production prompted NOSB to collect more information on how much this happens, and whether additional restrictions would be needed so that growth in organic production does not negatively impact wild fish stocks. NOSB requested development of a Technical Report on the composition, usage, and sourcing of fish-based fertilizers.

The [Technical Report](#) was completed and released in 2019. The report found that wild, native fish are not harvested solely for fertilizer production, and that fish waste or otherwise unusable material generally is used as the starting material for fish-based fertilizers.

For the spring 2020 NOSB meeting, the NOSB Crops Subcommittee presents a [Discussion Document on Wild, Native Fish for Liquid Fish Products](#) that includes the following questions for stakeholder feedback on any next steps the subcommittee should take on this issue.

#6: Liquid Fish Products – Sunset Review 205.601(j)(8)

Liquid fish products are currently listed on the National List at §205.601(j)(8) as allowed as plant or soil amendment for organic crop production: "*Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.*" A [Technical Report](#) was commissioned in 2006 for Liquid Fish Products.

The last Sunset Review was conducted in 2018. At the spring 2018 meeting, NOSB posed several questions for public comment regarding the harvesting of fish species for use in liquid fish products. Ultimately at the fall 2018 meeting, NOSB unanimously approved it for relisting ([NOSB Final Recommendations on Crop Sunset Reviews, starts on page 20](#)). Despite wide support for continued allowance of liquid fish fertilizers, concerns around the environmental impact of harvesting wild fish exclusively for organic fertilizer production prompted NOSB to pursue a separate work agenda item on this subject. [See NOSB Topic #5]

#7: Squid Byproducts

NOSB received a petition to add squid products to the National List for use as a fertilizer. A [Technical Report](#) was commissioned and published in January 2016. The [NOSB Final Recommendation on Squid Byproducts](#) was passed in spring 2016 (votes were 11 in favor and 4 against). On the question of environmental impact, NOSB's intent was only to allow squid from the processing waste stream; the proposal was not intended to allow the use of whole squid in the manufacture of fertilizers.

NOP completed final rulemaking on December 27, 2018 to implement the NOSB Recommendation. Squid byproducts are now currently listed on the National List at §205.601(j)(10) as allowed as plant or soil amendment for organic crop production: *Squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.*

#8: Agar-agar – Sunset Review §205.605(a)

Agar-agar is currently listed on the National List at §205.605(a) as an allowed non-synthetic substances in organic processed foods. Agar-agar is derived from **red seaweed**. The last [Technical Report](#) was completed in 2011.

The last Sunset Review was conducted in 2016 when NOSB unanimously approved it for relisting ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 2). On the question of environmental impact, NOSB stated that the "Technical Report indicated limited evidence of effects on biodiversity; All marine materials on the National List, including agar-agar, are currently being reviewed as a group by the Handling Subcommittee. Included in the review is the consideration of sustainable harvesting." This topic is not currently an active work agenda item for the Handling Subcommittee; The Materials Subcommittee is only looking at seaweeds used in crop production.

#9: Carrageenan – Sunset Review §205.605(a)

Carrageenan is currently listed on the National List at §205.605(a) as an allowed non-synthetic substances in organic processed foods. Carrageenan is derived from **red seaweed**. A [Technical Report](#) was completed in 2011 and a Limited Scope Technical Report on Human Health was completed in 2016. See also NOSB Topic #17 regarding nomenclature of marine materials on the National List.

The last Sunset Review of carrageenan was conducted in 2016 when NOSB voted to remove the listing due to a lack of essentiality for processing organic products and the availability of alternatives ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 4). On the question of environmental impact, NOSB concluded that "The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance; there may be negative impacts on the environment from harvesting wild seaweed. Indications are that most of this species of seaweed is now farmed, and some farming methods are more sustainable and ecologically sound than others."

Despite the NOSB recommendation, NOP renewed the listing because it found sufficient evidence in public comments to NOSB that carrageenan continues to be necessary for handling agricultural products because of the unavailability of wholly natural substitutes.

#10: Alginates – Sunset Review §205.605(b)

Alginates are currently listed on the National List at §205.605(b) as an allowed synthetic substance in organic processed foods. Alginates are alkali-extracted from the cell walls of **brown seaweed**.

Alginates have been approved for use in organic foods since the National Organic Program rule was published in 2000. A 2015 [Technical Report](#) detailed the production of, use of, and alternatives to alginates. See also NOSB Topic #17 regarding nomenclature of marine materials on the National List.

The last Sunset Review was conducted in 2018 when NOSB unanimously approved it for relisting ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 12) despite its conclusion that “issues of sustainable harvesting of seaweeds, disturbances of marine ecology through their harvesting, and bioaccumulation of contaminants such as heavy metals and radioactivity should be accounted for in the review of this material.”

#11: Alginic acid – Sunset Review §205.605(b)

Alginic acid (CAS #9005-32-7) is currently listed on the National List at §205.605(b) as an allowed synthetic substances in organic processed foods. Alginic acid is derived from **brown seaweed** through alkali treatment and acid precipitation. A [Technical Report](#) was completed in 2015. The listing for alginic acid used to appear on §205.605(a) as a non-synthetic, but was reclassified to §205.605(b) as a synthetic based on an NOSB Recommendation from fall 2015 and was implemented through NOP final rulemaking on December 27, 2018. See also NOSB Topic #17 regarding nomenclature of marine materials on the National List.

The last Sunset Review was conducted in 2019 when NOSB unanimously voted to remove the listing due to a lack of essentiality for processing organic products ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 12). In the subcommittee review preceding the full board vote, the subcommittee identified concerns in the public comment about potential over-harvesting and impacts on local ecosystems, although these concerns were not a determining factor in final NOSB decision to remove the listing. NOP has not yet begun rulemaking to implement this recommendation.

#12: Kelp – Sunset Review §205.606(k)

Kelp is currently listed on the National List at §205.606(k) as an allowed thickener and dietary supplement in organic processed foods only when certified organic forms are not commercially available. See also NOSB Topic #17 regarding nomenclature of marine materials on the National List. A dedicated Technical Report has not occurred since its pre-NOP technical advisory panel report in 1995, although kelp is generally addressed in the [Marine Plants and Algae Technical Report \(2016\) \(Crops and Handling\)](#) along with 8 other substances.

The last Sunset Review for the §205.606 listing of kelp was conducted in 2015 when NOSB approved it for relisting ([NOSB Final Recommendations on Handling Sunset Reviews \(starts on Page 49\)](#)). On a motion to remove, the votes were 4 to remove, 8 to keep, and 2 abstentions. Questions of environmental impact were not raised or documented in the subcommittee proposal of final NOSB recommendation.

For the spring 2020 NOSB Meeting, the NOSB Handling Subcommittee presents its [Sunset Summary and Request for Comments on Kelp \(starts on Page 73\)](#).

#13: Pacific Kombu seaweed – Sunset Review §205.606(r)

Pacific Kombu seaweed is currently on the National List at §205.606(r) as an agricultural substance allowed for use in organic processed foods only when the product is not commercially available in organic form. See also NOSB Topic #17 regarding nomenclature of marine materials on the National List. A dedicated Technical Report has not occurred, although kelp is generally addressed in the [Marine Plants and Algae Technical Report \(2016\) \(Crops and Handling\)](#) along with 8 other substances.

The last Sunset Review was conducted in 2019 when NOSB approved it for relisting by a vote of 9-3 with 1 abstention and 1 absence ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 25). Commercially available certified organic forms are not available, but some members of NOSB want to see these materials being certified organic under the wild crop standard. On the question of environmental impact, the NOSB stated, "As a marine material, use of Kombu seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials, and whether standards preventing overharvesting are needed to protect ocean environments." This topic is not currently an active work agenda item for the Handling Subcommittee; The Materials Subcommittee is only looking at seaweeds used in crop production.

#14: Wakame seaweed – Sunset Review §205.606(v)

Wakame seaweed (*Undaria pinnatifida*) is currently on the National List at §205.606(v) as an agricultural substance allowed for use in organic processed foods only when it is not commercially available in organic form. A dedicated Technical Report has not occurred, although kelp is generally addressed in the [Marine Plants and Algae Technical Report \(2016\) \(Crops and Handling\)](#) along with 8 other substances.

The last Sunset Review was conducted in 2019 when NOSB approved it for relisting by a vote of 9-3 with 1 abstention and 1 absence ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 26). Commercially available certified organic forms are not available, but some members of NOSB want to see these materials being certified organic under the wild crop standard. On the question of environmental impact, the NOSB stated, "As a marine material, use of Wakame seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials, and whether standards preventing overharvesting are needed to protect ocean environments." This topic is not currently an active work agenda item for the Handling Subcommittee; The Materials Subcommittee is only looking at seaweeds used in crop production.

#15: Fish Oil – Sunset Review §205.606(e)

Fish oil is currently on the National List at §205.606(e) as an agricultural substance allowed for use in organic processed foods only when it is not commercially available in organic form. It is used as a nutritional supplement to increase the content of omega-3 fatty acids in a variety of food products. The listing reads: *Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.* A [Technical Report](#) was completed in 2015.

The last Sunset Review was conducted in 2019 when NOSB approved it for relisting by a vote of 11-0 with 2 abstentions and 1 absence ([NOSB Final Recommendations on Handling Sunset Reviews](#), starts on Page 12). Because there are no aquaculture standards under the National Organic Program, it is not possible to require organic certification of fish or fish oil, and therefore organic alternatives remain absent. In the public comment during the sunset review, several interest groups questioned the environmental impact from overfishing, prompting NOSB to develop a separate work agenda item on this issue (See NOSB Topic #16).

#16: Fish Oil annotation change

The NOSB Handling Subcommittee is evaluating the use of fish harvested for its oil to ensure that fish oil used as an ingredient in organic food is not harmful to the environment. This is a new NOSB topic being presented for the first time on the spring 2020 Meeting agenda. This topic evolved out of the Sunset Review for Fish Oil in 2019 (See

NOSB Topic #15), when environmental and conservation concerns were raised about the harvesting of fish directly for their oil.

For the spring 2020 NOSB meeting, the NOSB Handling Subcommittee presents a [Discussion Document on Fish Oil Annotation Change](#). The Handling Subcommittee is proposing new restrictions informed by classifications used the National Oceanic and Atmospheric Administration (NOAA) and United Nations Food and Agricultural Organization (FAO). The Handling Subcommittee proposes the following new annotation (**bold text is new**) and presents several questions for stakeholder feedback.

§205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. **Sourced from fishing industry by-product only. Where within NOAA's jurisdiction, only from fish species and regions not listed on NOAA's current "Overfishing" or "Overfished" list. Where outside NOAA's jurisdiction, only from fish species and regions not listed on FAO's "Overexploited," "Depleted," or "Recovering."**

#17: Nomenclature of Marine Algae Listings on National List

This topic is a result of a [discussion document](#) posted for the fall 2016 NOSB meeting that addressed the 9 separate listings for marine materials on the National List (Crops and Handling), and posed questions about the naming conventions 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. (See NOSB Topic #3 for crop listing).

To address nomenclature questions for the handling listing, NOSB's Handling Subcommittee presented a [proposal](#) in spring 2017 to clarify and annotate the marine algae listing on §205.605-606 through use of Latin binomials (**bold text is new**):

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups))."

(a) Nonsynthetics allowed:

Acids (Alginic; ...). **Derived from brown seaweeds, class Phaeophyceae**

Agar-agar. **Derived from red seaweeds, class Rhodophyceae**

Carrageenan. **Derived from red seaweeds, class Rhodophyceae.**

(b) Synthetics allowed:

Alginates. **Derived from brown seaweeds, class Phaeophyceae.**

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

(d) Colors derived from agricultural products-must not be produced using synthetic carriers and solvent systems or any artificial preservative.

(2) Beta-carotene extract color derived from carrots or algae (pigment CAS 1393-61-1).

Derived from green algae, class Chlorophyceae.

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

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

(x) Wakame Seaweed (*Undaria pinnatifida*)

The Subcommittee's proposal also recommended that NOP develop guidance to clarify the term "kelp" as used in organic production and wild harvesting. The proposal was ultimately referred back to subcommittee for further work. This topic is not currently an active work agenda item for the Handling Subcommittee.