April 5, 2021

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

Docket: AMS-NOP-20-0089

Comments to the National Organic Standards Board
Spring 2021

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.

SINCE 1985 Organic trade association

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RE: Compliance, Accreditation & Certification Subcommittee Discussion Document on Supporting the Work of NOSB

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Subcommittee's Discussion Document on Supporting the Work of NOSB. The Board is exploring through a series of questions the merit and acceptability of obtaining outside assistance to support its heavy workload without compromising the integrity of the process or the independent nature of the production and deliberation of its proposals.

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.

OTA strongly supports providing NOSB with technical, legal and regulatory support to ensure NOSB proposals and discussion documents are clear, accurate and written in a way that stakeholders and NOP can understand, and NOP can easily act upon.

Questions for Stakeholders

1. *Is the organic community comfortable with the Board getting support to "to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members?"*

   Yes, absolutely. NOSB members are unpaid volunteers and need all of the support that is available and appropriate to be provided, to ensure they can effectively and efficiently carryout their responsibilities.

2. *If so, what areas are appropriate for the Board to get support?*

   - Technical Information about the manufacturing and composition of substances, as well as any impacts on environmental or human health.
     - OFPA requires that NOSB obtain and utilize technical information in its review of substances (7 USC 6518(3); 7 USC 6518(l)). This information is essential for making

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informed non-arbitrary decisions about whether a substance meets the applicable OFPA requirements.
  - Technical Advisory Panels and/or Technical Reports are the best way for NOSB to obtain thorough and relevant information from impartial independent expert sources. We support use of TR and TAPs whenever possible.

- Legal Information to support NOSB's evaluation of issues that may involve legal interpretations or cross-agency regulations.
  - *Example*: In NOSB's Recommendation on Ion Exchange Filtration, the Board admits it does not have legal capacity for analysis of FDA legal interpretations and technical support from NOP was not provided.
  - It is important to prevent NOSB from pursuing recommendations that may conflict with other legal statutes, or be unworkable, or create new legal challenges that may otherwise be avoided.

- Regulatory language development to ensure NOSB's intent is accurately captured in the recommendations passed to NOP.
  - Regulatory language is very specific and particular in its construction and implications. NOSB members need support from NOP to draft regulatory language that implements the intended requirements and outcomes as recommended by the Board.

3. *For which areas should the Board not use outside support?*

- It would not be appropriate to use outside support for interpretations of how technical or legal information should be evaluated against OFPA Criteria for the National List. Using outside support to compile and organize data resources is perfectly acceptable, but it should be limited to just that.
- It would not be appropriate to use outside support to summarize, abbreviate or translate the content or positions of public comments because this could be misleading and have undue influence over the Board members' interpretation of commenters' positions that may be nuanced. Outside support would be appropriate only for the organizational component of preparing public comments for NOSB member review (i.e. sorting comments by topic; identifying commenter affiliations).
- In all cases, NOSB member must retain their individual independent decision-making capacity.

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

Respectfully submitted,

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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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Docket: AMS-NOP-20-0089

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 key tenants of the proposed definition and listing of paper-based crop planting aids, and commend NOSB's diligence to take in and respond to stakeholder suggestions for improvement.
- ✓ We identify a few non-substantive items for further clarification in the proposed definition and listing, and support NOSB in passing this proposal at this meeting.

We offer the following more detailed comments:

Background

Paper planting pots have been petitioned for inclusion on the National List as an allowed input. Paper pots and other growing container and production aids are used to support seeding, growing and/or transplanting in the field, and are intended to remain in the soil. NOP has authorized continued use of these materials while NOSB completes its deliberation.

Nitten paper chain systems, which are the subject of the petition, are used to facilitate transplanting closely spaced crops such as onions, salad greens, herbs, and others crops. In addition to paper, the

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products are formulated with several adhesives. Newspapers and other recycled papers are already allowed as synthetic substances for use as mulch and as a compost feedstock. Certifiers have historically extended the allowance for paper to its use in transplant pots, even though paper isn't specifically on the National List for this use. This petition was submitted for NOSB to specifically address the use of paper as a production aid for transplants intended to be planted into soil. Throughout the course of NOSB deliberation, the scope has expanded to include other paper-based planting aids such as seed tapes that are incorporated into the soil.

Several discussion documents have previously been presented by the Crop Subcommittee in fall 2018, spring 2019, and fall 2019. A Technical Report was commissioned in 2019 to provide information about the range of synthetic fibers and adhesives used in these types of paper-based crop planting aids. The Board continues to collect and evaluate information to distinguish between synthetic paper fibers and synthetic fibers that are not strictly paper, also whether such fibers are biobased and/or biodegradable.

The first proposal was presented by the Subcommittee in spring 2020 for a new definition and listing to be added to the NOP regulations to allow the use of paper-based planting aids under certain conditions. That proposal did not pass, and a new proposal was presented in fall 2020 that also did not pass. The Subcommittee continues to work diligently to craft an annotation that captures the detailed composition metrics of paper-based planting aids that meet the needs of organic producers and product manufacturers, while complying with Organic Food Production Act criteria for the National List.

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 of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be non-synthetic, other permitted synthetic ingredients at §205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g. laboratory test using ASTM D6866 or composition review by qualified personnel). Added nutrients must comply with §205.105, 205.203, and 205.206.**

Add to §205.601 (National List):

Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without glossy paper or colored inks.

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 (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 crop

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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 are left to degrade in the soil.

We support the key tenants of the proposed definition and listing of paper-based crop planting aids and commend NOSB's diligence to take in and respond to stakeholder suggestions for improvement. The Subcommittee has undertaken thoughtful and science-based consideration of this range of products over the past three 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 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.

We identify a few non-substantive items for further clarification in the proposed definition and listing to ensure clear and consistent implementation, and support NOSB in passing this proposal at this meeting.

- The listing motion should refer to paragraph (o) not (p) on the National List §205.601.

- The phrase in the definition, "other permitted synthetic ingredients at §205.601(j)" is unnecessary, may cause unintended confusion, and can be likely removed without compromising the intent of the Subcommittee. Material reviewers should review intended added ingredients with the relevant subsection of the National List. This is the same argument that has been made in the past about fungicides needing to be reviewed to §205.601.

- The last sentence in the definition, "Added nutrients must comply with §205.105, 205.203, and 205.206" is unnecessary, may cause unintended confusion, and can be likely removed without compromising the intent of the Subcommittee. This statement is establishing compliance of ingredients outside the defined term is inappropriate for definitions section of the regulations and is better suited for a National List annotation. Furthermore, it is unnecessary for every individual National List item to refer back to practice standards as these should be inherent in the initial review and approval of substances by certifiers.

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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
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National Organic Standards Board
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RE: Crops Subcommittee – Biodegradable Biobased Mulch Film (Proposal)

Dear Ms. Arsenault:

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

Summary

- ✓ OTA supports NOSB's efforts to identify and advance regulatory solutions for allowing Biodegradable Biobased Mulch Film as an alternative to plastic mulch.
- ✓ We seek to better understand the information regarding the status of product development that has informed the Subcommittee's conclusion that 80% biobased content is a realistic goal for Biodegradable Biobased Mulch Film that would be allowed under this proposal.
- ✓ We recommend using consistent terminology in the proposal when referring to Biodegradable Biobased Mulch Films.
- ✓ We suggest alternative language to implement the concept of continuous improvement within the proposed annotation.

We offer the following more detailed comments:

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Background

Biodegradable biobased mulch film is currently listed on the National List of allowed materials for crop production as a weed barrier. The final rule to add this substance to the National List was published September 30, 2014, in response to an NOSB Recommendation in fall 2012.

NOP published a Policy Memo in January 2015 to specify that biodegradable biobased mulch films must not contain any non-biobased content (i.e., no petroleum). 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 this material to the National List.

However, products that might meet the 100% biobased requirement are either not biodegradable or are not used in production due to brittleness or other production issues. Most biodegradable mulch films only contain about 20% biobased content (or less) with the remaining portion petroleum-derived. Therefore, there are no commercially viable products on the market that meet the NOP requirement for 100% biobased content. Since this conflict arose, the topic has returned to the NOSB work plan for possible resolution.

A Technical Report was commissioned in 2016 to evaluate long-term biodegradability of petroleum-derived biodegradable mulch films, and was inconclusive 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. A discussion document was presented at the spring 2020 meeting, and reissued in fall 2020, with questions for stakeholder feedback regarding a potential future annotation amendment that would allow biodegradable mulch films that are not 100% biobased. In the meantime, NOSB has renewed this listing at Sunset Review to allow time to identify a suitable solution.

Proposed Definition and Listing

The Subcommittee proposes to:

Revise the definition at §205.2 Terms Defined (bold text added):

> *Biodegradable biobased mulch film.* 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) **Biodegradable plastic mulch films must be at least 80%** biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

And revise the listing to §205.601(a)(2) Mulches (bold text added):

> (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods. **When 100% biobased biodegradable plastic films become available, producers are required to use 100% biobased content BDM plastic films.**

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OTA supports NOSB's efforts to identify and advance regulatory solutions for allowing Biodegradable Biobased Mulch Film as an alternative to plastic mulch. Across the organic industry, organic businesses are exploring options for reducing plastic throughout their value chains, from on-farm uses to retail packaging. The approval of biodegradable mulch is an opportunity to encourage the development of technologies that can reduce pollution in a manner that is compatible with organic principles.

We seek to better understand the status of product development that has informed the Subcommittee's conclusion that 80% biobased content is a realistic goal. The Subcommittee is proposing a minimum requirement of 80% biobased content for biodegradable mulch films, while also recognizing that this limit is aspirational in the sense that no commercially viable products currently meet this criteria. The Subcommittee states that is sees this as a realistic goal but has not explained the technical background or status of product development that has informed the Subcommittee's conclusion. We look forward to better understanding the current status and prospective timeline for availability of products that can actually be approved under this proposal. This information is important to relieve hesitation that this proposal might not be lead to practical outcomes for allowing biodegradable alternatives to plastic mulch.

We recommend using consistent terminology in the proposal when referring to Biodegradable Biobased Mulch Films. The existing regulations refer only to the term "*Biodegradable biobased mulch film."* However, the Subcommittee has introduced different terms (emphasis added)*"*Biodegradable plastic mulch films" and "BDM plastic films." It is critical that the regulatory language is clear and consistent, and that the identity of these materials is grounded in the specific term defined at §205.2, which is "*Biodegradable biobased mulch film*."

We suggest alternative language to implement the concept of continuous improvement within the proposed annotation. The proposed annotation requires producers to use produce of 100% biobased content when they are available. We are supportive of efforts for continuous improvement in sourcing input materials. However, there are two key improvements to the proposed language that will support effective implementation:

- **Use the term "commercially available" instead of "available."** "Commercially available" is a term that is already defined[1] in the regulations at §205.2, and will provide a consistent regulatory basis for certifiers and material reviewers to make determinations.

- **Require operators to use a "higher percentage" whenever it is commercially available instead of only "100%."** The current proposal would only require producers to use 100% when it is available, but does not impose any requirement to use a product that has biobased content greater that 80% but less than 100%. Alternative language to consider could be, "Biodegradable biobased mulch film with the greatest percentage of biobased content commercially available must be used."

[1] *Commercially available.* The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

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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
USDA-AMS-NOP

Docket: AMS-NOP-20-0089

RE: Crops Subcommittee – 2023 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2023 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 2023 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 2023 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.

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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 **19** responses on our 2023 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	Summary of Responses	Average rating of Necessity (from 1 to 5, with 1 being "unnecessary" and 5 being "critical /would leave organic without it")
Copper sulfate for aquatic rice production as an algicide and tadpole shrimp control. One application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a time frame agreed upon by the producer and accredited certifying agent. §205.601(a)(3) & (e)(4)	**8 Responses** received from certified organic operations that produce a variety of aquatic rice including long grain, short grain, medium grain, colored rice, aromatic rice, and other specialty/premium varieties; white, brown, basmati, jasmine, etc. **Copper sulfate is necessary for aquatic rice production because:** - Copper Sulfate control algae blooms which stunt young rice plants reducing yield. Copper Sulfate controls tadpool shrimp which dislodge, eat and strip up muddy water blocking sunlight to seedling rice reducing yields. - Algae control because higher organic soils that crate problems in organic rice production - Copper sulfate, as a bordeaux mix component, is one of a very limited selection of tools available to organic rice growers in California to combat several serious threats to plant health and overall production in California organic rice production systems. - Copper sulfate provides protection from three problems: disease, tadpole shrimp, and algae. These three problems are common, but they don't always need to be treated with copper sulfate -- timing is everything. An organic rice farmer needs to watch newly seeded fields very carefully. If the newly seeded rice field can get established quickly -- these three problems can emerge, but not need copper sulfate. If the newly seeded rice struggles and is slow to grow, the field will likely need the protection provided by copper sulfate. - Helps with scum control on organic rice. Scum usually comes at a critical time during deep water grass control Without this product there could be substantial losses in yields and death to rice in certain areas of our fields. We apply typically once a year during deep water grass control at 10-15lbs to the acre. Some fields we might not get an application but in organic rice it is a critical and tool in our toolbox. - Necessary to control tadpole shrimp. Necessary to control scum - It is the only material that controls tadpole shrimp during rice seedling. - Primarily as an aligicide and shrimp population control. They lay eggs on the stems of rice stems and the larva bore cause plant damage. Prohibiting copper sulfate would virtually eliminate the ability to dry seed fields.	5 **(critical, would leave organic without it)**

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Copper sulfate, continued	**Frequency and application rates:** - Once at 15lbs./ac. - 2 times a season on half of fields. - I generally apply bordeaux mix slightly less than one time per year, per planted field on average. Average application rate when I do apply the material is 10 lbs/acre. - Application Rate: 10 pounds to 15 pounds per acre. Frequency: It is hard to predict how often copper sulfate is needed. The NOSB allows once in a 24 month period. The prescriptive nature of the annotation is a problem. Organic rice farmers rotate their fields -- some more than others. Copper sulfate is not needed during the seasons when aquatic rice is not in rotation. It may be possible for half of my aquatic rice fields to not need copper sulfate in a given year, but I can't predict which ones will need it and which ones won't. On average I may only use copper sulfate on half my fields, but the rule doesn't provide flexibility. - We apply typically once a year during deep water grass control at 10-15lbs to the acre. Some fields we might not get an application but in organic rice it is a critical and tool in our toolbox. - 1-2x per season, per field, at 15 lbs ac. - It would be nice to use it at any frequency that it is needed. 10 to 15 lbs/ac **Alternative are not sufficient because:** - Other substances don't have efficacy on all three problems [disease, tadpole shrimp, and algae]. Copper Sulfate provides overlap for all three -- which provides good value and makes sense. - Organically we rely on copper sulfate. Conventionally, I have tried many other pesticides to control shrimp and scum. Most are not nearly as effective as copper sulfate. Most are more expensive than copper sulfate. - Depends heavily on the soil type and production system. - Transplanting requires a low paid work force to work in water in the heat. - Drill seeding promotes weeds which is unworkable in an organic system. - Draining fields or dry seeding and flushing will control/prevent scum, and shrimp, but in an organic system your fields would be taken over by weeds. Deep water is our only effective means on controlling watergrass organically. - You would have to handplant rice like they do in Indonesia **What are the roadblocks to transitioning to a dry-seeding or transplanting of rice seedlings in U.S. rice production?** - Reduced yields to unsustainable levels. Extreme cost over existing methods. Rice being an aquatic tropical plant needs constant flooded conditions to stabilize temperatures in the shorter growing season of Calif. Rice grown in flooded conditions gives it a growing advantage over its weed competition. - We have no control of rice weeds with dry planting systems. The use of deep water helps sustain some weeds. - The feasibility of drill-seeded and/or dry-seeded organic rice production in most rice-producing regions of California depends most heavily on soil type. There are some regions in California with light soil, capable of wicking moisture where organic rice growers can be successful in drill-seeding. Although drill-seeded organic rice does have associated risks, I would argue that many rice growers wish they could use drill-seeding methods as a part of their organic rice production system. There are many benefits to drill-seeding organic rice when the soil type is right and conditions are favorable. However, the fact is most rice fields in California (80+%) are on heavy clay ground that is not at all suitable for drill-seeding organic rice. In fact, my family has invested a great deal of time (decades), effort, and money into	

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Copper sulfate, continued	developing organic drill-seeded techniques with very little success. To this point, it has been our experience that drill-seeded organic rice on heavy clay ground does not work. - Dry seeding promotes weeds while the seedlings are established. Water seeding provides rice with a competitive advantage over grass weeds. Transplanting is practiced in many rice growing regions of the world. However, transplanting requires workers to work in muddy hot conditions -- not acceptable in the US. Some Asian nations have mechanized transplanting equipment, but it is not practiced on large scale fields as in the US - Equipment and man power. there would still be chances of scum in this system as well and copper sulfate would still need to be used to help fight scum - Costs/efficiency/yields loss/labor/weed control. - No one who has tried dry-seeding or transplanting in my area continues to do them, because the systems seem to have too many failures. - We do use copper sulfate aka: Bluestone, in California rice fields, both conventional and organic, primarily as an algicide, but it will also knock down the shrimp population (they lay eggs on the rice stems and when the eggs hatch the larva bore into the stems and cause damage to the plant). In higher doses Bluestone will also kill crawdads. Algae is typically only a problem early in the season when the rice is just coming out of the water. If the surface algae get too thick the seedlings have trouble breaking through and you could have a significant reduction in field yield. - Dry seeding would not impact algae development as you still have to flood the rice field. The idea behind dry seeding is that you flash flood after the rice is seeded and the weeds will germinate before the rice. When the weeds germinate you hose the field down with herbicide to kill the weeds before the rice emerges. That's obviously not possible in organic production. Intermittent watering, which has been touted lately as a more "sustainable" method of rice production is not possible in organic as the weeds would overtake the rice quickly. The only effective method of weed control in organic rice production is keeping the water deeper in the early stages to flood out the weeds, then backing off once the rice comes through the surface. **If copper sulfate was prohibited:** - Reduced yields to unsustainable levels under our current pricing for the crop. Organic rice prices would have to increase by yield reduction % in order for production to continue. - Eliminate 80 percent of production. May be too risky to making profit. I believe over time we would eliminate organic production. - My organic rice production would be impacted severely if I were unable to use copper sulfate any longer. The increased level of risk in producing organic rice would be severe. Unless the price of organic rice was significantly increased to offset the risk of farming organically without copper sulfate, I would likely be forced to consider moving to conventional rice production even though it would not be my preference. Because I farm on heavy clay soil, there essentially no other crops that I could rotate to instead of rice. - If copper sulfate was no longer allowed, it would become much more risky to farm organic rice. I would expect a much higher failure rate due to loss of newly seeded rice stand. - It would directly affect product quality agronomic, and economically affect our company. It would limit our ability to grown high quality organic rice and bring high quality rice to our customers. - It would cause high yield losses, and in some fields, it would result in complete crop failures. - The risks of crop failure would increase to the point that organic rice might not be possible.	

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Oxone gas an irrigation system cleaner. §205.601(a)(5)-	**1 Response received from certified organic operations.** **The material is necessary because:** - Routine sanitization **Alternative are not sufficient because:** - No alternative substances or practices are sufficient to eliminate need of this substance **If the material were prohibited:** - Economic effects	4
Peracetic acid for use in control fire blight bacteria and for disinfecting equipment, seed, and asexually propagated planting material. §205.601(a)(6) & (i)(8)	**6 Responses** received from certified organic operations that include Peracetic Acid in their organic system plans for producing a wide range of products including apples, pears, cherries, blueberries, wine grapes, vegetables, baby leaf salad mix, peaches, strawberries, tomatoes, etc. **The material is necessary because:** - Used as disinfectant and fire blight control in the apples and pears orchards. - Used in the formulation of hydrogen peroxide which we spray on our apple and pear trees to control fire blight. - As a disinfectant in our berries cherries and grapes to help keep disease and fungi pathogens from spreading - It helps to slow down the decay process on apples and pears by reducing microbial activity. - Control disease - Powdery & downey mildew control - Sanitizer - Principally used as a response to an active bacterial infection. - As a sanitizer of tools and equipment. - We apply directly to apples, peaches and blueberries. Occasional use in strawberries and tomatoes. Principally used as a response to an active bacterial infection. We also use it as a sanitizer of tools and equipment. Apples and peaches - as needed. Typically less than annual use. Blueberries - we use it annually as part of a rotation related to Spotted Wing Drosophila. Other crops - seldom, only during observed infections. **Frequency / application rates:** - We use it as the situation dictates. This could be several times a year during the growing season - Seldom as a post harvest treatment on the packing line. - When certain conditions arise. - Routinely in warmer months. - Routinely (as sanitizer) - annually as part of a rotation related to Spotted Wing Drosophila - seldom, only during observed infections	4.5

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Peracetic acid, continued	**Alternative are not sufficient because:** - Other practices will help take the pressure off of PAA, but not replace it, simply serve to aid in our control measures. - We will look at the chlorines as a substitute for PAA as a disinfectant. We will look at a variety of other materials as alternatives for fire blight control, but only as part of an integrated approach to control of this disease. - Fire blight in apples has limited options. No other management practice would eliminate need for peracetic acid. - Have tried Sulfur, however there are extensive label restrictions - We have used Hydrogen Peroxide, diluted, and chlorine bleach (no response regarding efficacy) **If Peracetic Acid were prohibited:** - As a disinfectant we would have problems replacing it in certain areas. As a component of hydrogen peroxide materials sprayed onto our trees to help control blight, it would create severe issues for our growing practice. - A lot of fruit would be lost contributing to food waste by not having peracetic acid as a too, and the economic impact on the farm returns would be significant as well. - Economic effects - Fewer tools for controlling mildew. - Fewer tools for controlling fireblight. Previously, NOSB removed streptomycin. That was used as a preventative. I was in favor of removing, in part because we have a tool in paracetic acid to respond to fireblight. We could still use hydrogen peroxide, but handling hydrogen peroxide in commercial formulation (typically 35%) can be dangerous to people and harmful to equipment. Paracetic to my knowledge is an effective and safer substitute for Hydrogen Peroxide.	
EPA List 3 Inerts for use in passive pheromone dispensers. §205.601(m)(2)	No survey responses have been submitted so far. **Please also see the separate comment submitted by the Organic Trade Association on this material.**	
Chlorine materials (Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite) for use as a sanitizer and disinfectant. For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum	**4 Responses** received from certified organic operations that include Chlorine materials in their organic system plans for producing organic vegetables, lettuces, other leafy greens, row crops, etc. **Please also see further comments from OTA on chlorine in our Handling Subcommittee Sunset Review comments.** **The material is necessary because:** - Irrigation water sanitation (chlorine dioxide) - Sanitation - Prevention of spread of human pathogens - To bring wash water to potable water standards **Frequency / application rates:** - Routinely - Daily **Alternative are not sufficient because:** - No alternative substances or practices are sufficient to eliminate need of this substance	4.3

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residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions. §205.601(a)(2)	- I have looked, but not been able to find appropriate products that are readily available - Chemical sanitation is the our only option for cleaning our surfaces - we would have to find another way to get water to potable standard **If Chlorine materials were prohibited:** - Economic effects - food safety would be impacted - There would be a significantly increased risk of human pathogen spread.	
Magnesium oxide – §205.601(j)(5)	No survey responses have been submitted so far.	

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

Substance	Summary of responses
Calcium chloride – §205.602	No survey responses have been submitted so far.
Rotenone – §205.602	No survey responses have been submitted so far.

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

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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Appendix A – Sample Survey for Crop and Livestock Inputs

1. Is your operation certified organic? Yes / No

2. Is [SUBSTANCE] included in your organic system plan? Yes / No

3. Which types of organic crops or livestock products do you use [SUBSTANCE] on/for? (e.g., lettuces, fruit trees, broiler chickens)

4. What function does [SUBSTANCE] provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)

5. With what frequency does your operation use [SUBSTANCE]? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)

6. Have you tried using any *other substances* as an alternative to [SUBSTANCE]? (e.g., other substances that are on the National List and/or other natural substances.)
If yes, please describe which substances you've tried and whether it was effective to fulfill the required function:

7. Are there any other *management practices* that would eliminate the need for [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:

8. How would your organic production be impacted if [SUBSTANCE] was no longer allowed? (describe the agronomic, environmental or human health effects, product quality, economic effects)

9. [If applicable - Insert specific questions from NOSB Subcommittee about the necessity of the substances and the availability of alternatives]

10. On a scale from 1 to 5 stars, rate the overall necessity of [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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April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Crops Subcommittees – EPA List 3 Inerts (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 EPA List 3 Inerts.

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

Summary

- ✓ OTA supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review.
- ✓ OTA supports the unanimous 2020 NOSB Resolution calling for NOP action to resolve the longstanding discrepancy with respect to inerts on the National List.
- ✓ OTA's Inerts Task Force is committed to identifying and advancing viable alternative solutions for evaluating inert ingredients to ensure continued safety and availability of critical pest control tools for organic farmers.

We provide more details comments:

Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed. As described in Appendix A to these comments, the current regulatory references on the National List to EPA Lists 3 & 4 are obsolete, and a modernized system for reviewing inert ingredients is not yet in place despite past NOSB Recommendations that had identified viable solutions.

OTA supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review. There is no indication that NOP would be able to complete full implementation of a system of reviewing inerts prior to the sunset date of List 3 inerts in 2023. The prohibition of List 3 inerts prior to establishment of a new system would cause significant disruption to

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the availability of essential pest control tools for organic production. Voting to prohibit this important class of substances is irresponsible and risky when farmers' access to critical tools for organic production is at stake. OTA's Farmers Advisory Council[1] agrees and strongly urges caution to protect continued availability of critical pest control tools for farmers. Therefore, the continuation of the current listings of EPA List 3 inerts is critical for ensuring continued availability of effective and familiar pest control tools for organic producers.

Furthermore, it is important that NOSB acts in a consistent manner across the multiple listings of inerts on the National List. Last year, NOSB voted to relist EPA List 4 and we encourage NOSB to do the same for EPA List 3. This will ensure harmonized and coordinated implementation of a viable solution for both EPA List 3 and EPA List 4 inerts.

OTA supports the unanimous 2020 NOSB Resolution calling for NOP action to resolve the longstanding discrepancy with respect to inerts on the National List. Modernizing the system for review of inert ingredients is a priority of the organic industry. Pesticide product development and innovation are being stifled by the outdated regulatory references for inert ingredients. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products.

OTA's Inerts Task Force is committed to identifying and advancing viable alternative solutions for evaluating inert ingredients to ensure continued safety and availability of pest control tools that organic farmers rely upon when their preventive pest, weed, and disease management practices have failed. The OTA Inerts Task Force established last month is already active in pursuing its mandate to support continuous improvement in pesticide safety by exploring the viability of National List petitions to prohibit inerts that are not appropriate for organic production. The Task Force will also inform OTA's comments to USDA regarding solutions to resolve the longstanding discrepancy on the National List with respect to EPA List 4 inert ingredients in pest controls.

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

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

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APPENDIX A

Regulatory Background:
Inert ingredients in pest control products for organic crop and livestock production

Inert ingredients are necessary for the manufacturing of many various forms of pest control products. Inert ingredients are used in conjunction with active ingredients to facilitate functionality and efficacy of the active ingredient. Pest control products formulated with approved active and inert ingredients are widely used in organic crop and livestock production. 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.

Current Regulations

Inert ingredients in pest control products are subject to individual review and approval in accordance with USDA's National Organic Program (NOP) National List of Allowed and Prohibited Substances. The NOP regulations define inert ingredients are "**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**." Substances that are classified as *nonsynthetic* are permitted unless specifically prohibited under §205.602 or §205.604 of the National List.

The National List provides for certain *synthetic* inert ingredients in accordance with §205.601(m) and §205.603(e) to be used in formulation with permitted active ingredients in organic approved crop and livestock pest control products. Substances on "EPA List 4—Inerts of Minimal Concern" (minus certain revoked inert ingredients) may be used as inactive ingredients formulated with allowed active pesticide ingredients for both crop and livestock production. Substance on "EPA List 3—Inerts of unknown toxicity" have a more limited allowance only in passive pheromone dispensers in crop production.

Regulatory Discrepancy

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 List Category system established in 1987 for the purpose of prioritizing the evaluation of substances based on 4 categories (lists) of toxicological concern. After the NOP regulations were formalized, EPA began a process of reassessing inert ingredient tolerances and tolerance exemptions as required by the Food Quality Protection Act (FQPA). EPA completed its reassessment in 2006, and since then has no longer maintained the List Category system. Under current EPA policy, inert ingredients approved for use in pesticide products applied to food are those that have either tolerances or tolerance exemptions published in 40 CFR part 180 or where no residues are found in food.

According to information contained in the 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."

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Despite the regulatory discrepancy, the listing for EPA List 3 and List 4 inerts have been renewed at each of the previous Sunset Reviews that have occurred over the past twenty years. The renewals of these listings have been critical to allow NOSB and NOP to work towards resolving the outdated reference for inerts without disrupting the availability of critical pest control tools for organic producers.

2015 NOSB Recommendation

Interagency efforts to resolve the regulatory discrepancy were very active between 2010 and 2015. **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 the following annotation:

> *§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]**

A plan for implementing the 2015 NOSB Recommendation was included in the Subcommittee Proposal presented by Crop and Livestock Subcommittee at the fall 2015 meeting and was reiterated by the Board following the vote to adopt the annotation change. The steps include:

- NOP will publish a *Federal Register* Notice to notify stakeholders of the intended revision, to outline the procedure and timeline for implementation (subject to public comment). 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 establish a Memorandum of Understanding with EPA to formalize their relationship between NOP and the Safer Choice Program and allow NOP to rely on EPA's Safer Chemical Ingredient List.
- NOP and EPA will work to develop specific instructions for the portion of the review targeted toward manufacturers of pesticide products used in organic production.
- NOSB will establish a procedure for reviewing 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).
- 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.

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

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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.

2020 NOSB Resolution

At the Fall 2020 NOSB Meeting, the Board narrowly voted to renew the current listing of EPA List 4 Inerts and also voted unanimously in favor of the following resolution:

> In voting to relist EPA List 4 Inerts of Minimal Concern, the NOSB recognizes the vital importance of the substances included in this listing to the organic industry. However, in referencing a list that is no longer maintained, using a list on which no new substances can be added, and not allowing for review of individual or groups of materials, the use of List 4 ingredients on the National List is problematic and outdated. The NOSB recognizes that a viable program allowing for the review and use of these substances must be created before this listing can be removed. Therefore, the NOSB asks that the National Organic Program do the following:
>
> 1) Work with the NOSB to develop a viable alternative process that allows for the review of many of the substances presently on EPA List 4 and has minimal disruption to the organic industry;
>
> 2) For substances that do not meet OFPA criteria for listing, work to provide a sufficient period for industry to change formulations and receive regulatory approval for the new formulations;
>
> 3) Coordinate regularly with the NOSB on progress to develop an alternative to the EPA List 4 Inerts of Minimal Concern that allows for stakeholder input and the removal of the reference to EPA List 4 inerts on the National List.

In response, NOP stated that this as a leading priority and plans to move forward with an Advanced Notice of Proposed Rulemaking (ANPR) to discuss the policy options for resolving the outdated EPA List 4 listing.

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April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Crops Subcommittee – Ammonia Extract (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crops Subcommittee's Discussion Document on Ammonia Extract.

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.

Introduction

OTA appreciates the petitioner giving NOSB the opportunity to weigh-in on the acceptability of novel ammonia extract substances in organic agriculture prior to wide proliferation of this emerging category of products. NOSB plays a critical role in evaluating inputs within the framework established in OFPA.

The purpose of OTA's comments on this discussion document is to ensure that NOSB has complete technical information about products and manufacturing processes that may be implicated by the scope of the petition, and that NOSB's decision-making process is sound and in alignment with OFPA Criteria for the National List. We also provide information about the compatibility and necessity of the petitioned material to help inform NOSB's deliberation of the substance against OFPA Criteria. For comments on environmental impacts and soil health, please refer to The Organic Center.

Our comments identify several significant concerns regarding the compatibility of purified natural ammonia with organic principles, including but not limited to: mimics conventional synthetic Nitrogen fertilizers, requires the removal of carbon value of organic waste, and may be out of step with international norms. NOSB must take these concerns into account as it evaluates the use of the substance against the OFPA Criteria for the National List.

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Background

Synthetic ammonia is prohibited in organic production. The prohibition of synthetic nitrogen fertilizers is a longstanding and strongly-held core principle of organic agriculture. Chemically derived ammonia from the Haber-Bosch process is already prohibited and is not subject of this petition. The subject of this petition is of ammonia that is isolated, captured, extracted, and/or concentrated from natural sources such as manure through physical, mechanical, and/or biological processes that are ultimately classified as *nonsynthetic*. These products represent an emerging category of commercial fertilizers intended for use as water-soluble and bio-available source of nitrogen that is largely in the development phase. The petitioner has elevated this emerging product category to NOSB for consideration prior to wide proliferation of these novel products. Unless specifically prohibited in the organic regulations, *nonsynthetic* substances will continue to be permitted for use in organic production.

The petition being considered by NOSB is to prohibit nonsynthetic forms of "ammonia extract" as inputs in organic crop production. "Ammonia extract" is described in the petition as "a fertilizer produced using a range of methods where the output contains ammonia (NH_3) and/or ammonium (NH_4^+) that has been: 1) Produced through a biological or physical process; 2) Captured in a liquid form; 3) Concentrated and/or extracted; and 4) Packaged for application in a crop system." Other names that may refer to the same substances include "Natural Ammonia," "Captured Ammonia" and "Novel Ammonia Products." The petitioner identifies concerns that these emerging types of ammonia fertilizers do not align with organic production principles, pose risks to the integrity of organic products, and increase the risk of fertilizer fraud. The petition also raises concerns about uncertainty and inconsistent determinations of material review organizations regarding the classification of ammonia extract technologies as nonsynthetic or synthetic.

The NOSB Crops Subcommittee presented a discussion document in fall 2020 to solicit stakeholder input on a series of questions about the ability to distinguish synthetic ammonia sources from non-synthetic sources through testing, the impacts on soil health, and other questions about the classification and other issues related to ammonia extract. A second discussion document is presented at this meeting (spring 2021) that builds on comments received from the last meeting on the topics of soil health and the potential for fraud. A third-party Technical Report was commissioned by NOSB and was publically released approximately one week after the spring 2021 NOSB meeting materials were posted.

Technical Information

The products and manufacturing processes described in the petition and in the technical report represent a wide range of substances that result in synthetic and nonsynthetic forms of ammonia and ammonium compounds. To properly evaluate the petitioned substance, it is important to ensure a complete understanding of the substances that would be classified as "Synthetic" and thus *already prohibited* and outside the scope of this petition, and which substances are classified as "Nonsynthetic," currently allowed, and subject to prohibition under the petition.

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The processes of anaerobically digesting or fermenting agricultural or biological feedstock are nonsynthetic, as these are naturally occurring biological processes. Substances that are derived from sewage waste are prohibited (per 205.105).

The Technical Report (TR) describes "ammonia stripping" and "ammonia concentration" as methods of manufacturing outputs from the original agricultural feedstock. These two processes are both being considered under the umbrella of the petitioned "ammonia extract" category of substances.

The physical and mechanical processes such as heating, pressurization, diffusion, evaporation, cooling, condensation, filtration, reverse-osmosis, etc. involved in "ammonia stripping" and "ammonia concentration" are nonsynthetic processes. However, each process results in a different direct output. The difference in composition of the direct outputs of "ammonia stripping" and "ammonia concentration" (prior to any post-treatment with stabilizers or additives) is important to note:

- The "ammonia stripping" process uses pressured air and/or heat to facilitate evaporation of ammonia from the original agricultural feedstock, followed by a cooling/condensation step to capture the ammonia-containing condensate. **The direct output of the "ammonia stripping" process is a pure ammonia gas (or when cooled and distilled, a pure aqueous ammonia condensate) isolated from the original agricultural feedstock.** Products produced by this method are considered *novel*; new products are only recently being approved and/or are still in development and not yet fully commercialized.

- The "ammonia concentration" process uses physical separation to remove solids from nitrogen-containing liquid waste mixture, and uses pressured air and/or heat to facilitate water evaporation thereby concentrating the liquid ammonia-containing waste solution. **The direct output of the "ammonia concentration" process is a liquid waste filtrate containing ammonia and ammonium compounds and other nutrients and organic compounds retained from the original agricultural feedstock.** Products produced by this method have been OMRI Listed for *nearly a decade* and are not considered to be new or novel.

The direct outputs of "ammonia stripping" and "ammonia concentration" may be further processed and/or treated with additives and stabilizers to formulate a final product. These processes and additives can influence the classification of the end product and may result in a synthetic (prohibited) substance. For example:

- Stabilization of "ammonia stripping" outputs with strong acids such as sulfuric acid or nitric acid is *synthetic and prohibited*. The final output of the "ammonia stripping" processes described in the Technical Report involves the addition of a strong acid that results in a synthetic ammonium compound which is prohibited under current organic regulations.

- Stabilization of "ammonia stripping" outputs using nitrifying bacteria is *nonsynthetic and currently allowed* per commonly accepted material review policies, however this manufacturing process is not addressed in the Technical Report.

- pH adjustment of "ammonia concentration" outputs by organic acids such as citric acid is *nonsynthetic and currently allowed* per commonly accepted material review policies.

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OFPA Criteria for the National List

NOSB plays a critical and unique role in the organic rulemaking process because it advises USDA on which production inputs should be allowed or prohibited in organic farming and processing. The Organic Foods Production Act (OFPA) establishes the evaluation framework for NOSB's open, balanced and transparent process for developing recommendations to amend the National List of Allowed and Prohibited Substances. Within this framework and with the support of public comments and third-party technical information, NOSB develops strong well-supported recommendations.

Current status and restrictions on fertilizers

- Synthetic substances are prohibited unless explicitly on the National Organic Program (NOP) National List of Allowed and Prohibited Substances.
- Nonsynthetic substances are allowed in organic production unless explicitly prohibited on the National Organic Program (NOP) National List of Allowed and Prohibited Substances.
- Liquid fertilizers with a nitrogen analysis greater than 3 percent must comply with additional recordkeeping and inspection requirements in accordance with NOP Guidance on the Approval of Liquid Fertilizers for Used in Organic Production (NOP 5012).
- Use of fertilizers must comply with soil fertility and crop nutrient management practice standards at §205.203.

Criteria to add a new prohibited nonsynthetic substance to the National List

OFPA states that the National List may provide for the prohibition of a nonsynthetic substance *only if* use of the substance "(i) would be harmful to human health or the environment; and (ii) is inconsistent with organic farming or handling, and the purposes of this chapter (§6517(c)(2)(a))."

OFPA identifies seven criteria that NOSB must consider in its evaluation of substances. According to §6518(m), the NOSB *shall* consider:

1. "the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. the effect of the substance on human health;
5. the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. the alternatives to using the substance in terms of practices or other available materials; and
7. its compatibility with a system of sustainable agriculture"

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Compatibility and Consistency with Organic Farming and Sustainable Agriculture

NOSB must evaluate whether the use of a substance is "inconsistent with organic farming and handling (§6517(c)(2)(a)(ii) and consider the substance's "compatibility with a system of sustainable agriculture (§6518(m)(6))."

Some elements of consistency can be explicitly evaluated if OFPA or the NOP regulations include provisions that specifically address the substance. For example, OFPA specifically identifies arsenic and lead salts as substances that crop producers are prohibited from using (§6508). Thus, these nonsynthetic substances are clearly inconsistent with organic farming and would be appropriate to include on the National List as prohibited nonsynthetic substances (which they are).

Other elements of consistency are much more subjective. There are two NOSB recommendations related to this issue that are helpful to identify points that may be considered within the scope of this criterion. These recommendations are also incorporated in to the NOSB Policy and Procedures Manual.

- 2001 NOSB Recommendation: Principles of Organic Production and Handling **(Appendix A-1)**
- 2004 NOSB Recommendation: Guidance on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling **(Appendix A-2)**

Compatibility with Organic Principles

The following concerns regarding the compatibility of the petitioned material with organic principles are identified below with additional information to support a robust deliberation by NOSB on this petition. NOSB must take these concerns into account as it evaluates the use of the substance against the OFPA Criteria for the National List.

Purified natural ammonia and ammonium compounds mimic conventional synthetic N fertilizers

The prohibition of synthetic nitrogen fertilizers manufactured through the Haber-Bosch process is a longstanding and fundamental prohibition in organic agriculture. The proliferation of these fossil-fuel based synthetic fertilizers in conventional agriculture was a primary motivator of the modern organic agricultural movement. The principles of organic (as described in the 2001 NOSB Recommendation) seek to achieve agricultural and environmental goals through the "use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system." Therefore, substances that mimic the chemistry and functionality of synthetic nitrogen fertilizers can understandably be considered as equally incompatible with traditional organic principles.

Objections to the compatibility of these substances with organic principles are serious enough to potentially lead to fragmentation of the organic market. Some companies have indicated they may be prepared to establish private standards that exclude products produced with this input from their supply chain. This is an indication that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether the substance would "satisfy expectations of organic consumers regarding the authenticity and integrity of organic products."

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Nonsynthetic materials that mimic the functionality of synthetic nitrogen fertilizers have been prohibited by NOSB in the past. Sodium nitrate was prohibited in part for this same rationale (other environmental harms were also of consequence). As stated by NOSB in a past review to justify its recommendation to prohibit (emphasis added), the "use and dependence on sodium nitrate also can tend to producers to put off the need for strong soil-building practices, consistent with §205.203, since it behaves similarly to conventional synthetic nitrogen fertilizers[1]." This is evidence that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether "use of the substance is consistent with other substances historically allowed or disallowed in organic production and handling."

Manufacturing of purified ammonia and ammonium compounds requires the removal of carbon value of organic waste

Materials sourced from agricultural waste have been prohibited by NOSB in the past when the carbon value of the original source material is not retained in the final product. Ash from manure burning was prohibited in part for this same rationale. As stated by NOSB in a past review to justify its recommendation to prohibit (emphasis added), "burning [manure] is not an appropriate method to use to recycle organic wastes and would not be considered a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content[2]." This is evidence that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether "use of the substance is consistent with other substances historically allowed or disallowed in organic production and handling."

Allowance of highly soluble ammonia fertilizers may be out of step with international norms

Highly soluble nitrogen sources can present barriers to international trade. For example, sodium nitrate is identified as a critical variance[3] in the US-Canada Organic Equivalency Arrangement: U.S. agricultural products produced with the use of sodium nitrate shall not be sold or marketed as organic in Canada. For this reason, it is possible that ammonia extracts may face scrutiny during international trade negotiations and potentially be viewed as a critical variance. Further, this is an indication that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether the substance would "be consistent with international organic regulations and guidelines."

Allowance of high nitrogen liquid fertilizers creates an increased risk of fraud

Fraud cannot be tolerated in organic at any point in the value chain including the misrepresentation of agricultural inputs as compliant with the organic standards. Past evidence of fertilizer fraud in 2009 holds a prominent place in the organic sector's history of fraud and led to NOP and certifiers strengthening its oversight of high nitrogen liquid fertilizers (HNFL). Under NOP 5012 - Approval of Liquid Fertilizers for Use in Organic Production, all liquid fertilizers with a nitrogen analysis greater than 3 percent must comply with additional recordkeeping, traceability, in-out balance analysis, and onsite inspection requirements (announced and unannounced). There are over 200 HNLF products on OMRI and CDFA's

[1] https://www.ams.usda.gov/sites/default/files/media/Sodium%20Nitrate%20Final%20Rec.pdf

[2] https://www.ams.usda.gov/sites/default/files/media/CSSnst2017RvwOct2015.pdf

[3] https://www.ams.usda.gov/services/organic-certification/international-trade/Canada

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brand name materials lists approved for use in organic production, demonstrating that a broad number of input manufacturers have implemented and successfully achieved compliance with the fraud prevention policies specified in NOP 5012. We support this risk-based approach to strengthening oversight.

OTA also strongly supports processes and systems that prevent fraud in agricultural inputs. In OTA's comments to NOP on the Strengthening Organic Enforcement Proposed Rule, we made recommendations to revise the definition of "fraud" to encompass agricultural input fraud, and fraud prevention plans should address potential risks of fraudulent inputs in an organic system. OTA's private sector Organic Fraud Prevent Solutions program recognizes the importance of input manufacturers in the fight against fraud, and therefore includes OMRI and WSDA-listed companies as eligible for the program alongside NOP-certified operations.

Consideration of other common Nitrogen-containing nonsynthetic fertility inputs

We have questions about how the scope of the petition will impact the evaluation of other common Nitrogen-containing nonsynthetic fertility inputs such as compost teas, manure teas, processed manures, and liquid fish products. These common nonsynthetic inputs contain some amount of ammonia and ammonium nitrogen, are produced through a biological or physical process, and may undergo some form of concentration and/or extraction. The composition of these common inputs retain organic matter and carbon value of the original agricultural feedstock, whereas purified ammonia from the "stripping" process does not, among other differences. We encourage NOSB to explore how technical differences implicate the evaluation of the petition against the OFPA Criteria for the National List.

Necessity for Organic Production

The OFPA Criteria for the National List requires NOSB to evaluate alternatives to substances under consideration when developing recommendations for amending the National List (§6518(m)(6)).

Manufacturers and distributors of ammonia extract fertilizers indicate these products are meant to facilitate precise and responsible application of nutrients, and are not intended to be the sole source of nutrient fertility in a farm system nor preclude other soil-health building practices. They emphasize that these products can be used when Phosphorus is limiting or when Nitrogen applications are restricted and should be part of the larger system of crop rotations, carbon rich nutrient sources (manures) and cover crops.

Initial outreach to OTA members reveals that many growers are not currently using these products and some may not want or need to use these products for reasons including: choosing not to use these products due to incompatibility with organic principles; alternative inputs and practices are sufficient for their soil fertility program. Our member outreach is ongoing.

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Environmental Impact

The OFPA Criteria for the National List requires NOSB to evaluate several aspects of environmental impacts when developing recommendations for amending the National List, including contamination and toxicity to the environment, effects on biological and chemical interactions in the agroecosystem, and physiological effects of the substance on soil organisms (§6518(m)). OFPA authorizes NOSB to recommend prohibition of nonsynthetic substances that are harmful to the environment.

Please refer to comments submitted by The Organic Center for information to support NOSB's evaluation of environmental impacts and soil health.

Conclusion

OTA appreciates the petitioner giving NOSB the opportunity to weigh-in on these novel substances prior to wide proliferation of this emerging category of products. NOSB plays a critical role in evaluating inputs within the framework established in OFPA.

It is important that NOSB ensures it has complete technical information about products and manufacturing processes that may be implicated by the scope of the petition, and that NOSB's decision-making process is sound and in alignment with OFPA Criteria for the National List.

Our comments have identified several significant concerns regarding the compatibility of purified natural ammonia with organic principles, including but not limited to: mimics conventional synthetic Nitrogen fertilizers, requires the removal of carbon value of organic waste, and may be out of step with international norms. NOSB must take these concerns into account as it evaluates the use of the substance against the OFPA Criteria for the National List.

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

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NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING
(NOSB Recommendation Adopted October 17, 2001)

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

1.2 An organic production system is designed to:

1.2.1 Optimize soil biological activity;
1.2.2 Maintain long-term fertility;
1.2.3 Minimize soil erosion;
1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
1.2.7 Minimize pollution of soil, water, and air; and
1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

1.3.1 Providing good quality organically grown feed;
1.3.2 Maintaining appropriate stocking rates;
1.3.3 Designing husbandry systems adapted to the species' needs;
1.3.4 Promoting animal health and welfare while minimizing stress; and
1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;

1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and

1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.

1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.

1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.

1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.

1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.

1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.

1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.

1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

Appendix A-2

NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

(NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices. In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Handling Subcommittee – Ion Exchange Filtration Proposal

Dear Ms. Arsenault:

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

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

Summary

- OTA supports the allowance of ion exchange filtration as an organic processing method.
- OTA supports the Handling Subcommittee's position that ion exchange recharge materials must be on the National List to be approved for use in organic processing.
- OTA understands NOSB's decision to defer back to NOP for clarification on the status of its Food Contact Substance Policy. If food contact substances, per NOP's 2002 policy, are outside of NOSB's scope of review, then ion exchange resins would not need to appear on the National List. Clarification and technical support from NOP on this question have always been needed.
- OTA supports the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency. We respectfully urge NOP to conduct its outreach to the U.S. Food and Drug Administration, take into consideration all of the information NOSB has collected via public comments, and provide certifiers and industry with instruction or policy that is formalized in the NOP Handbook to ensure consistent regulatory decisions.

Introduction

OTA has submitted extensive comments to NOSB in response to the Spring 2020 Discussion Document and the Fall 2020 Proposal. For this meeting, and primarily for the new NOSB members, we are bringing

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forth important background information and key points from our previous comments. OTA's complete comments from the spring 2020 meeting are included as Appendix A.

Although we do not have any new information to add, we would like to reiterate how important it is that NOP provide industry with clarification in a timely manner. The uncertainty of the situation has gone on far too long, and has led to inconsistencies in practice, both at the operator and certifier levels. Action on this matter is needed.

Ion Exchange Filtration and its Use in Organic Processing

Ion exchange is a processing technology used for filtration and purification. It has been allowed in USDA-NOP certified organic processing since the organic regulations were first established. The intent of the technology is not to chemically change[1] a product, but to eliminate unwanted contaminants or impurities through removal of their associated ions.

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

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

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

Ion Exchange Filtration Media: Resins vs. Recharge Materials

The ion exchange filtration process is a technique that involves a column, like a large pipe, packed with **ion exchange resins** that selectively remove unwanted ions from the liquid. The **resin** is an insoluble matrix (or support structure) normally in the form of small microbeads, on which a fixed ion has been

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

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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.[2]' The resins are not added to the organic product and they are not intended to have any technical effect. It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered.

Table 1

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

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 like any piece of equipment, they do not become a part of the processed product if they are properly maintained.

Given the above information, we have arrived at the following conclusions:

⇒ OTA agrees with the Handling Subcommittee recommendation that the **recharge materials** must be on the National List to be allowed in organic processing. This is consistent with current practice and with the training NOP provided to certifiers in 2010.

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

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⇒ OTA also agrees that ion exchange resins are regulated by FDA as food contact substances. According to NOP's 2002 policy statement, food contact substances do not need to appear on the National List. The status of the NOP 2002 Policy and its underpinnings, specifically FDA's classification of ion-exchange resins, continue to be crux of the issue. To the best of our knowledge, the policy has not been formally rescinded by NOP, and FDA has not changed its regulatory oversight of ion exchange resins as food contact substances. It was our understanding that NOP would be providing NOSB with technical support on this matter to help inform the recommendation for this spring 2021 meeting. This apparently did not happen.

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

The 2002 NOP Policy on Food Contact Substances does not waive the review of ion exchange materials. Per the policy, the use of ion exchange in organic processing must be documented and approved in the certified operator's Organic System Plan. Certifiers must review and verify that the recharge materials are on the National List and the ion exchange resins are food contact substances as determined by FDA. To the best of our knowledge, certifiers are also requesting a description of the sanitation and recharge procedures.

Based on the 2010 NOP clarification, most certifiers are currently requiring the recharge materials to be on the National List, but not the resins. The approval process, however, does not start and stop with the NOSB and the National List. Certified operators must disclose the use of the technology and the associated ion exchange media (recharge materials and resins) so certifying agents can conduct a thorough review and ensure that the practices and materials are fully in compliance with the organic regulations. This review includes documented verification that the ion exchange resins are food contact substances.

OTA requests this complete approval process be included in subsequent NOP Policy or Instruction and carried out consistently by all certifying agents.

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

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Conclusion

OTA thanks NOSB for the opportunity to share background, both technical and policy information, to support NOSB's recommendations. In the August 27, 2019 memo from NOP to NOSB, the program 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.

Although we were hoping for a recommendation that would address both the recharge materials and resins, we understand the subcommittee's quandry around the nuances of the FDA regulations and NOP's food contact policy. Based on NOP's response to the NOSB Fall 2020 meeting (December 21, 2020 memo), we expected that NOP would reach out to FDA and provide NOSB with the technical support needed. Since this did not happen, and the status of the ion exchange resins appears to be caught in a matter of legal interpretation and policy, it makes sense to pass the NOSB recommendation and all of the information collected to date to NOP for its final consideration.

Again, we support the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency. OTA supports moving forward with this recommendation at this meeting, and we urge NOP to respond in a timely manner to ensure consistent certification practices.

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

Respectfully submitted,

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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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

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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.

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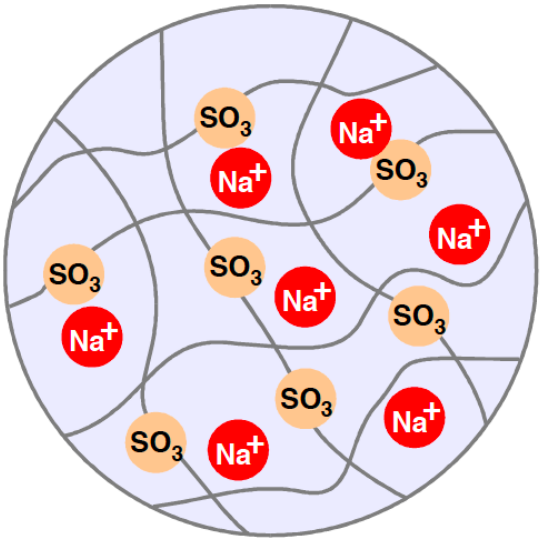
The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. FDA currently regulates ion exchange resins as 'food contact substances.[1]' The resins are not added to the organic product and they are not intended to have any technical effect. It is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

Table 1

Term	***Definition***
Ion Exchange Resin: Considered **food contact substances** by FDA. Historically have not needed to be on the National List, per 2002 NOP policy.	An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. *Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins*
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. *Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)*

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.

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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 s*econdary 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**."

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- **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

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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

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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

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

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

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

Conclusion

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

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

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

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

Respectfully submitted,

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

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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)

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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

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.

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 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Handling Subcommittee – 2023 Sunset Reviews for §205.605

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2023 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 2023 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 2023 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input (**Appendix A**). Our surveys do not address information regarding the impacts on human health or the environment.

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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 **17** total responses on our 2023 Handling Sunset Surveys. Below is a summary of the feedback received via OTA's Sunset Surveys to date on the § 205.605 materials under review.

§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	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being "critical – would leave organic without it")
Agar-Agar	**1 Response** received from a certified operation. **Uses:** - Used routinely in yogurt as a thickener/gelling agent **If the material were prohibited:** - If agar-agar were to no longer be allowed the quality of our products would be altered.	Rating not provided
Animal Enzymes (Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).	**4 Responses** received from certified operations. **Used routinely and/or daily in:** - Cheese – coagulant - Artisan Cheese - The chymosin/pepsin attributes in traditional animal rennet produce positive effects on milk coagulation that are critical to many styles of cheese production that fungi or plant based rennets simply cannot provide. **The material is essential because:** - Helps milk coagulate and turn fluid milk into curds and whey for cheesemaking. No suitable alternatives.	4.8

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	Alternative are not sufficient because: - Some styles of cheese (softer) are able to be produced successfully with non-animal based rennets. Longer aged, harder styles of cheese are unable to be successfully coagulated when being produced with these non-animal based rennets. It is necessary for the production of these styles of cheese. - Microbial rennet and thistle rennet are alternatives. **If the material were prohibited:** - The product quality would be impacted. - It would be catastrophic to the health of our company and our industry. We assume 95%+ of organic cheesemakers across the United States are using animal rennet and would have to stop production if animal rennet was no longer allowed. - It would affect the tradition of cheesemaking as well as product quality. - We would not produce organic cheese anymore.	
Calcium Sulfate-Mined	**1 Response** received from a certified operation. **Uses:** - Used in daily as a coagulant in Tofu products	5
Carrageenan	No responses received so far.	
Glucono-delta-lactone – production by the oxidation of D-glucose with bromine water is prohibited.	**1 Response** received from a certified operation. **Uses:** - Used in daily in tofu products as a coagulant **Alternative are not sufficient because:** - Have not tried alternatives and unaware of any management practices that would eliminate its need	4
Tartaric Acid – made from grape wine	**2 Responses** received from certified operations. **Used in:** - Wine	4

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	- Cookies **The material is essential because:** - Being able to adjust our pH with TA helps us to avoid the use of the synthetic chemical SO2 **Alternative are not sufficient because:** - There are times when we do not need to adjust the pH **If the material were prohibited:** - It would hinder us since we have spent years perfecting a synthetic free wine. **Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?** - Yes, but would need to grow it as a new industry. The organic grapes are used for wine, not for tartaric acid.	

§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	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being "critical – would leave organic without it")
Cellulose (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.	**1 Response** received from a certified operation. **Used routinely in:** - Cheese as an anti-caking agent	4
Chlorine Materials -Calcium hypochlorite. -Chlorine dioxide.	**4 Responses** received from certified organic operations. ***Please also see OTA's comments directly below this survey results table.*** **Used in:** - Lettuces, routine, daily	4.8

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-Hypochlorous acid—generated from electrolyzed water -Sodium hypochlorite	- All of our wash equipment is sanitized with it and leafy greens are dunked in water with a small concentration of Na Hypochlorite in it, daily - Row crops, vegetables, daily - Dairy, eggs - daily **The material is essential because:** - Sanitation, prevention of spread of human pathogens - To bring wash water to potable water standards - Sanitizer, powerful cleaner that is good for milk protein **Alternative are not sufficient because:** - I have looked, but not been able to find appropriate products that are readily available - Chemical sanitation is our only option for cleaning our surfaces - We also use peroxyacetic acid and hydrogen peroxide. All are essential. **If the material were prohibited:** - Food safety would be impacted - There would be a significantly increased risk of human pathogen spread. - We would have to find another way to get water to potable standard - This would be a huge loss, especially on dairy farms. For processing and handling is it very common for equipment and food surface cleaning	
Potassium Hydroxide - prohibited for use in lye peeling of fruits and vegetables.	**3 Responses** received from certified organic operations. **Used in:** - Yogurt, and use potassium hydroxide as a cleaning agent, daily - Beverages - pH adjuster, routinely - Nutritional Products, routinely in most formulas **The material is essential because:** - Chlorinated Alka Plus Foaming Liquid- (Contains Potassium hydroxide & Sodium hypochlorite) this product is used for foam cleaning the exterior of all equipment, then rinsed off with potable water. Foaming products are extremely important to our routine sanitation practices. - There are no management practices that would eliminate the need for this material - Needed to adjust pH and as a source of potassium fortification	4.7

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	Alternative are not sufficient because: - For nutritional products, calcium hydroxide can be used, but it is less soluble than potassium hydroxide and quality (heavy metals) is a concern. We're also not aware of any other management practices that would eliminate the need for potassium hydroxide. **If the material were prohibited:** - We would need to identify something else that could play the same role in sanitization of our equipment. - Without potassium hydroxide we would lose the ability to maintain product stability (i.e., product would coagulate, etc.) - Significant impact to products. Without pH adjustment the product may not survive the manufacturing process leading to unacceptable product quality. We would leave organic if we could no longer use this product.	
Silicon Dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.	**2 Responses** received from certified organic operations. **Used in:** - As a defoamer in Beverages (used as needed when certain conditions arise - As a defoamer in Raw Ingredients (used routinely) **Alternative are not sufficient because:** - There are no other alternatives	4.5
Potassium Lactate - for use as an antimicrobial agent and pH regulator only.	No responses received so far.	
Sodium Lactate - for use as an antimicrobial agent and pH regulator only.	No responses received so far.	

Additional OTA Comments on Chlorine Materials

It is critical that organic producers and handlers have a tool kit of antimicrobials that will allow them to fully comply with all food safety requirements, and have the ability to rotate among several materials to reduce the incidence of microbial resistance. It is also critical that the National List continues to represent the best and least-toxic technology our food system has developed. For this reason, the Organic Trade Association continues to be supportive of NOSB's work to better understand sanitizer (antimicrobial) materials used in organic production and handling systems.

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However, as reflected by several of the questions included under the Sunset Review for chlorine materials, we are concerned that NOSB's "draft framework" document is being prematurely incorporated into the Sunset Process and imposing several questions on the organic community that are outside the scope of the Sunset Review.

We believe that NOSB and organic stakeholders share a common interest in that we prioritize food safety *and* we want to see the least toxic cleaners, sanitizers and disinfectants being used. If this is the goal, and we believe it is, OTA asks NOSB to consider the following:

- For handling operations, cleaners, sanitizers & disinfectants are listed under a National List heading that references "**ingredients**" (§ 205.605). This has been a source of confusion for individuals inside and outside the organic sector for a very long-time. On-going education is necessary.

- For handling operations, any cleaner, sanitizer or disinfectant that is used **in direct contact with an organic** product must be on the National List. Materials that are used on food contact surfaces do not need to appear on the National List, provided they do not come in contact with the organic product (§ 205.272(a)). This is not directly spelled out in the regulations, and although it is well understood by certifiers and experienced organic operations, it continues to be an area where constant education and clarification are needed.

- NOSB does not review the majority of the cleaners, sanitizers or disinfectants used in organic process facilities because they do not come in contact with organic products. They are used on food contact surfaces followed by a rinse or some other intervening event. However, certifiers and inspectors review these materials along with a complete description of how, when and why they are used, and how contamination prevention requirements are met. This is a requirement of the Organic System Plan and applies to ALL cleaners, sanitizers or disinfectants used in organic handling and processing, direct or indirect use.

- There is a facility pest management practice standard (§ 205.271) that requires an integrated approach to pest management. A stepwise preferential approach is applied to preventive measures and mechanical, physical and biological controls, followed by materials that are on the National List followed by materials that are not on the National List. However, the facility pest management practice standard does not apply to cleaners, sanitizers or disinfectants, or at least it has not historically.

- The Canadian Organic Standards – CAN/CGSB-32.310-2020 (under the Permitted Substances Lists – CAN/CGSB-32.311-2020) include a designated list for cleaners, sanitizers and disinfectants (crops, livestock and handling) that is divided into a section for materials permitted without a mandatory removal event and a section for which a removal event is mandatory prior to an organic production load or run. Further, the Canadian Organic Standards are structured like the NOP facility pest management practice standard at § 205.271. Substances on the list are preferred. When they are not sufficient, materials that are not on the National List may be used with documented justification.

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Given the above, OTA asks NOSB to consider the following pathways that could support best use of cleaners and sanitizers:

- Develop research questions and set research priorities about the use and development of cleaners and sanitizers in organic systems, and how to ensure food safety requirements are met in a way that minimizes overall health and environmental risks.

- Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section. This would generally help certified operations understand the cleaners, sanitizers and disinfectants that that may be used, and it would help organic outreach and education efforts. The list could be designed to accommodate an integrated stepwise approach (such as § 205.271) to using cleaners, sanitizers and disinfectants to minimize overall economic, health and environmental risks. A designated list could also provide further opportunity for Materials Review Organizations that maintain brand name product lists *and* for their clients that are in the business of developing NOP compliant products compatible with organic principles. Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards.

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
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Appendix A – Sample Survey for Handling Inputs

1. Is your operation certified organic? Yes / No

2. Is [SUBSTANCE] included in your organic system plan? Yes / No

3. Which types of organic products do you use this substance in/on? (e.g., yogurt, fruit juices, baked goods, etc.)

4. What function does the substance provide in/on your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)

5. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)

6. 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.

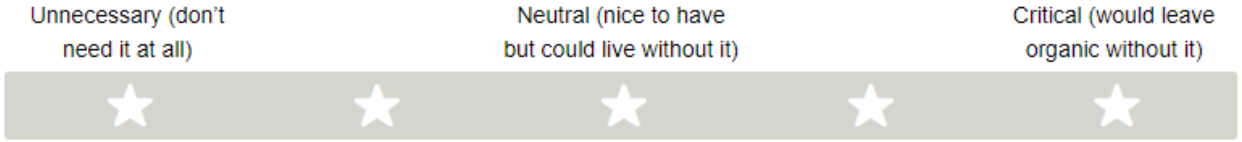
7. Have you tried using any *other* substances as an alternative to [SUBSTANCE]? (e.g. other natural substances if the substance in question is synthetic; or organic substances if the substance in question is natural)

If so, please describe your search and sourcing efforts, which substances you've tried and whether the quantity available was sufficient and/or whether the alternative substance had the quality and form necessary to fulfill the required function of the organic product or process.

8. Are there any other *management practices* that would eliminate the need for [SUBSTANCE]? If so, please describe the efficacy of the alternative management practices:

9. How would your organic handling be impacted if [SUBSTANCE] was no longer be allowed? (describe the effects on product quality, economic effects, environment effects, or human health effects)

10. On a scale from 1 to 5 stars, rate the overall necessity of [SUBSTANCE] for your organic operation:



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April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Handling Subcommittee – Discussion Document on Zein (pronounced **zee-**uhn**)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Discussion Document on Zein (maize protein). The Subcommittee is asking a handful of questions to help determine if zein should be added to the National List at § 205.606 as an allowed non-organically produced agricultural ingredient. The petitioner is requesting that zein be allowed for use as a food coating and processing aid in organically processed products labeled as "organic."

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

Summary

- OTA is not taking a position on whether zein should be added to the National List for use in organic processing. Instead we are responding to the NOSB questions and providing additional insights on evaluation considerations and agricultural vs. non-agricultural determinations.

- OTA encourages NOSB to focus its energy on whether non-organic zein, as a food coating, is a **necessary** ingredient (or processing aid) in organic handling. Questions around its classification are important, particularly in deciding whether it would belong on § 205.605 or § 205.606 of the National List. However, classification questions could become a distraction to the first question to be asked – is the allowance of an additional non-organic food coating necessary or are there organic or natural alternatives?

- With respect to its classification, OTA encourages NOSB to first deliberate on whether Zein, a product derived from dent corn, is 'agricultural' or 'non-agricultural,' and to consider this question in the context of the existing regulatory definitions. To be allowed in products labeled as "organic," it must be on the National List, period. The first determination is whether the substance is agricultural or non-agricultural. The 'synthetic' or 'non-synthetic' determination is arguably less significant when considering the structure of the National List for Handling Materials and the requirements of § 205.605 vs. § 205.606.

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Questions for Stakeholders:

1. **If zein is made from cornmeal that is wet-milled, how much (if any) sulfur residue is left in the final product?**

   OTA does not have data to answer this question. From a classification perspective, a material would be 'non-synthetic' if the synthetic material(s) used for separation/extraction/isolation are removed from the final substance (i.e. sulfur residues) such that they have no technical or functional effect in the final product. Given the specifications of zein and its labeling requirements, presumably any residue left in the final product would not have a technical or functional effect.

2. **What are the hurdles to achieving organic zein?**

   Considering the manufacturing processes described in the Technical Report, the **commercial availability of organic corn gluten** is a major hurdle, and this is largely due to the predominant corn wet milling process, its reliance on sulfur dioxide (a prohibited input in organic processing) and the fact that this process appears to be the most cost-effective method (excluding the cost of externalities). The alternative wet milling methods that employ 'ozone' and 'protease enzymes' (both allowed on § 205.605) could conceivably yield organic corn gluten, provided the corn is certified organic and all other inputs and processes meet the handling requirements of the organic regulations. The same of course applies to the other methods described utilizing distillers dried grains and dry-milled corn, where the use of sulfur dioxide is not needed. Although supply issues are in play for organic ethanol given its high and growing demand, the regulations **do not** include '*cost*' as a factor that justifies the allowance of a non-organic agricultural ingredient in organic processing. The real hurdle in the case of organic ethanol, or rather opportunity, is transitioning enough conventional acres to organic meet market demand.

   If the alternative methods to the corn wet milling process are cost-prohibitive, and organic ethanol poses a cost challenge (at least at this time), adding zein to the National List could potentially create the greatest hurdle to achieving organic zein. Consider:

   - If zein is classified as 'non-agricultural' and added to § 205.605 of the National List (synthetic or non-synthetic), there could be little to no incentive to develop organic zein because there would be no requirement to use it. Unfortunately, organic preference (the requirement to use organic if it exists) does not apply to § 205.605 of the National List. Given this regulatory impediment, exceptions have been made through the use of annotations (i.e. yeast, flavors).
   - If zein is classified as 'agricultural,' and added to § 205.606, organic processors would be required to use organic zein when it is commercially available in the appropriate quality, quantity and form. Cost, however, is not a factor.

   Until a cost-competitive alternative process becomes available in "normal times," or until there is very strong demand for organic, the method utilizing sulfur dioxide will likely be favored by producers and suppliers. This leads to the subcommittee's third question.

3. **What sectors of the organic food market would benefit the most significantly from the addition of zein to the National List and how much will shelf-life be improved?**

   The Organic Trade Association is unaware of any members that are interested in or asking to use the petitioned substance. We appreciate the question though, because it gets to the heart of a fundamental consideration:

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- Given the lack of an organic alternative, would allowing non-organic zein to be used in organic processing significantly expand the variety, supply and functionality of organic products and have an overall net positive impact on the expansion of organic acres and the growth of the organic sector? Would this in turn lead to the availability of organic zein?

OTA will continue our outreach and ensure that organic businesses and other stakeholders are aware of the petition and the potential opportunities. At this time, and to the best of our knowledge, carnauba wax serves as a viable and allowed alternative with equitable performance (edible, non-animal derived, vegan). Further, organic forms of carnauba are available, although not always in the quantity needed. Other alternatives include beeswax (also available in organic form), shellac, waxes, gums and alginates.

4. **Do we need to revisit the classification as a non-synthetic, or is the established precedence sufficient rationale?**

No, we believe NOSB should honor the decision of its previous Board members and view corn steep liquor as a non-synthetic substance. We suggest NOSB focus its evaluation on the use of zein as an ingredient intended for organic handling; the methods that can be used to make it; and the kinds of annotations that might be needed should it meet OFPA criteria and be proposed for addition to the National List.

We offer the following justifications for this view:

- The petitioner is requesting that zein be allowed as a non-organically produced **agricultural** product. In accordance with § 205.2 (Terms defined), an *agricultural product* is any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

- For products labeled as "organic," any non-organic ingredient or processing aid, regardless of its classification, must be on the National List at either § 205.605 (nonagricultural) or § 205.606 (agricultural). It must go on the National List, period.

- For products labeled as "made with organic (specified ingredients or food group(s))," non-organic agricultural ingredients may be used in the 30% non-organic allowed portion. They do not need to appear on the National List and organic forms do not need to be sourced. Therefore, zein is currently allowed for use as a food coating on products that are certified to the "made with…" labeling category, provided it is produced and handled without the use of the "prohibited big-three (excluded methods, sewage sludge and ionizing radiation).

- For the **organic** label, if NOSB determines that zein meets the OFPA criteria (no alternatives, safe for human health and the environment, compatible with organic handling) the first classification question is whether it be placed onto the National List at § 205.606 as a non-organic **agricultural** ingredient that may only be used when organic forms are commercially unavailable, or, whether it be placed on the National List at § 205.605 as an allowed **non-agricultural** ingredient (natural or synthetic). The non-agricultural list was designed for substances that are "not a product of agriculture." The definition of 'non-agricultural' also includes substances that are "extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction." While the latter half of the definition of non-agricultural is painfully ambiguous, we contend that zein ***is a product of agriculture***, and it has not lost its agricultural identity (soft, yellow powder of simple proteins). Furthermore, as a product of agriculture, organic forms are possible.

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- The NOSB recommendation on Corn Steep Liquor passed in spring 2011 was based on a compelling argument that the action of sulfur dioxide in the traditional corn wet milling process provides a buffering action to allow lactic acid fermentation to dominate over putrefaction. The conclusion was that the sulfur dioxide is added at the end of the process and its utility is in holding back a biological process (fermentation) and to prevent putrefaction, not to change the identity of the corn steep liquor. The majority considered that agricultural byproducts, food waste and products from food waste processing should not be considered a synthetic ingredient for the purposes of organic crop production. It is important to note that the information presented in the Technical Report does not capture all of the information that informed the spring 2011 decision. Furthermore, the questions in the TR focus entirely on 'synthetic' and 'non-synthetic' determinations. The TR does not deliberate on the agricultural vs. non-agricultural status of zein, or the corresponding regulatory definitions. This is problematic.

- Historically, synthetic processing aids used in food processing have not been determined to render the agricultural products synthetic. A long-standing example is corn starch (§ 205.606), which is made using the exact same steeping process as corn steep liquor. More recently, as a result of the NOP Classification of Materials Guidance on Agricultural vs. Non-agricultural (NOP 5033-2), if the substance being evaluated is a product of agriculture, but is processed to the extent that its chemical structure has been changed, then it becomes non-agricultural …*unless* the chemical change is the result of naturally occurring biological processes or a result of a mechanical/physical/biological process described under § 205.270(a). Although we appreciate Guidance NOP 5033-2 and its goal of helping with consistent decision making, we believe there are some nuances that still need to be worked out to better align it with the definitions of agricultural and non-agricultural and the structure of § 205.605 and § 205.606. For example, according to the TR, the wet milling method that involves ozone (allowed on the National List at § 205.605), chemically changes the endosperm protein matrix. The corn gluten, as described in the TR and according to NOP 5033-2, would be classified as synthetic, and the resulting zein would also be classified synthetic (non-agricultural). Once placed on § 205.605 as a non-agricultural, there is no requirement to use organic, *even though* this same method could yield certified organic zein if the starting material was organic.

Our answer to question #4 demonstrates how revisiting the 'non-synthetic' classification of corn steep liquor in the context of a petition for zein can quickly become a distraction to more important question – should an exemption be made for an otherwise prohibited non-organic ingredient? If NOSB determines through the comment process that zein is: 1) necessary because of the lack of natural or organic alternatives; 2) not harmful to human health or the environment: and 3) is consistent with organic handling; then we suggest NOSB keep the following questions in mind when considering its classification and placement on the National List:

- The starting material for zein is dent corn, an agricultural product. The intermediate source for zein is corn gluten, also viewed as an agricultural product. The addition of zein to § 205.606 means that it is an agricultural ingredient for which organic forms are not commercially available. The working concept, however, is that organic forms can be commercially developed. The method that raises concern is the corn wet milling process utilizing sulfur dioxide. This is also the method that cannot be certified organic under the organic regulations. One option to consider is adding zein to the National List at § 205.606, but with an annotation restricting its use to forms that do not employ sulfur dioxide. Acknowledging this option is not what the petitioner is requesting, it would be more compatible with organic handling and would potentially create the most realistic on-ramp to an organic alternative.

- As we stated earlier, adding zein to § 205.605 could lock zein in as an allowed 'non-agricultural' substance, with no requirement to use organic, *unless* its listing included an annotation that requires the use of an organic form when commercially available. It is also important to note that classifying the

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petitioned form of zein as 'non-agricultural' (synthetic or non-synthetic) would in turn prevent zein from being allowed in the "made with" labeling category as an allowed agricultural ingredient.

- If the development of an organic form is not in the interest of the petitioner, and/or it is realistically cost-prohibitive to produce organic corn gluten, then perhaps zein should not be added to the National List and non-organic agricultural zein can continue to be used in products that are NOP certified to the "made with" category. The advancement of organic forms of zein and/or other forms that do not employ sulfur dioxide can continue to develop according to market demand.

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

Respectfully submitted,

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

cc: Laura Batcha
Executive Director/CEO
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April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Livestock Subcommittee – 2023 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2023 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 2023 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 2023 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.

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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 **21** responses on our 2023 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	Summary of Responses	Average rating of Necessity (from 1 to 5, with 1 being "unnecessary" and 5 being "critical /would leave organic without it")
Activated charcoal – §205.603(a)(6)	**3 Responses** received from certified organic operations that include activated charcoal in their organic system plan for raising dairy cows. **The material is necessary because:** - One of the only substances to combat toxic gut – used as the primary treatment - Activated charcoal is an important ingredient if we have an animal we are concerned has ingested something causing upset. - To control upset stomach, particularly in calves with e coli scours and other stomach ailments where toxins are causing discomfort and illness. Used as needed when toxins are causing illness, does not occur frequently. **Frequency of use:** - Seldom, as needed - Seldom, only as needed when a certain condition arises - As needed when toxins are causing illness, does not occur frequently **Alternative are not sufficient because:** - There are no other toxin binders - Good management can reduce need but not eliminate need, animals will still get sick sometimes **If the material were prohibited:** - We would lack an option for treating toxic gut in cows	4.3

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	- We would have less in our toolbox to treat an animal that appears to have ingested mold or something unknown which is causing upset or to be off feed. - Animal welfare would be reduced because this product removes toxins causing them illness and there are no other alternatives	
Calcium borogluconate for milk fever treatment. §205.603(a)(7)	**2 Responses** received from certified organic operations that include calcium borogluconate in their organic system plan for raising dairy cows. **The material is necessary because:** - For treatment of milk fever in dairy cows - Extremely necessary for fresh cow management of down cows. **Frequency of use:** - Seldom, only as needed **Alternative are not sufficient because:** - No alternative substances or practices are sufficient to eliminate need of this substance **The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions?** - Calcium borogluconate is the most effective option **If the material were prohibited:** - Could have health implications for cows - We would have less in our toolbox to treat severe milk fever causing the loss of older lactation cows	4.5
Calcium propionate for milk fever treatment. §205.603(a)(8)	**1 Response** received from certified organic operations that include calcium propionate in their organic system plan for raising dairy cows. **The material is necessary because:** - For treatment of milk fever in dairy cows - Extremely necessary for fresh cow management of down cows. **Frequency of use:** - Seldom, only as needed **Alternative are not sufficient because:** - Calcium borogluconate is an alternative	4

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	The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions? - All are necessary **If the material were prohibited:** - Could have health implications for cows	
Chlorine materials (Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite) Allowed for disinfecting and sanitizing facilities and equipment. §205.603(a)(10)	**3 Responses** received from certified organic operations that include chlorine materials in their organic system plan for raising dairy cows and processing milk in to food products such as yogurt. Sodium hypochlorite is specifically referenced as the chlorine material in use by these respondents. **Please also see further comments from OTA on chlorine in our Handling Subcommittee Sunset Review comments.** **The material is necessary because:** - sanitation - COP and manual cleaning - to clean milk pipelines and milking equipment, as well as to clean and disinfect calf hutches between calves. It is necessary for sanitation and disease control - milking equipment sanitizer **Frequency of use:** - Routine, daily **Alternative are not sufficient because:** - No alternative substances or practices are identified as sufficient to eliminate need of this substance - Hydrogen peroxide is not allowed per Federal PMO as a sanitizer, not all certifiers allow phosphoric acid because other inactive ingredients make it prohibited for use as a sanitizer. TWO SETS OF FEDERAL RULES DO NOT ALIGN AND NO ONE WILL TAKE THIS PROBLEM UP! You can't hardly be in compliance with both state inspector and organic inspector when it comes to substance of last contact to dairy equipment as it is. If chlorine is removed, that will never happen. **If the material were prohibited:** - These materials are critical to our sanitation processes and we would encounter quality and food safety issues without them. - We would have a much more difficult time keeping milk lines and equipment clean and sanitized, providing for a safe high quality product for human consumption. - Food borne illness could increase	5 **(Critical, would leave organic without it)**

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Kaolin pectin for use as an adsorbent, antidiarrheal, and gut protectant. §205.603(a)(17)	**1 Response** received from a certified organic operation that includes kaolin pectin in their organic system plan for raising dairy cows. **The material is necessary because:** - Otherwise known as pepto bismal – really important for those rare occasions that cows end up with ulcers – I don't know of other options. **Frequency of use:** - Not used a lot, but important for those situations. Doubt too many people are using it on a prophylactic basis. **Alternative are not sufficient because:** - No alternative substances or practices are identified as sufficient to eliminate need of this substance **If the material were prohibited:** - Could have negative health effects on cows	4
Mineral oil for treatment of intestinal compaction, prohibited for use as a dust suppressant. §205.603(a)(20)	**2 Responses** received from certified organic operations that include mineral oil in their organic system plan for raising dairy cows. **The material is necessary because:** - To treat intestinal compaction - Very necessary for intestinal compaction – other than very invasive surgery – this is the best option. **Frequency of use:** - Seldom, as needed - Very rarely but when it is needed, there is no alternative **Alternative are not sufficient because:** - Natural oils do not work, they get digested and do not move or break up the compaction. - You can take good care of your animals, but compaction can still happen in rare cases. **If the material were prohibited:** - Negative effects on cow health - Animal welfare would be impacted, also economic because the animal would either die or have to be sold if non-organic treatments are used.	4

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Nutritive supplements - injectable supplements of trace minerals, vitamins, and electrolytes. §205.603(a)(21)	**3 Responses** received from certified organic operations that include nutritive supplements in their organic system plan for raising dairy cows. Vitamin D, Vitamin C, Vitamin B, and Multimin are specifically reference by the respondents. **The material is necessary because:** - This is a broad category, but in general I would say yes as organic producers use as a boost to immune systems in animals not as an across the board treatment, but usually to help in an animal having some kind of disease stress. - Injectable vitamin supplements help to boost immune response for animals that are fighting disease. It also helps with our fertility program. We are limited on what we can treat challenged animals with and nutrient supplements helps the animals immune system do the fighting, helping to avoid then need for antibiotics. - Used for dairy cows as an immune system boosts-critical because organic treatment methods work by helping the cow help herself. **Frequency of use:** - As needed - Routinely, as needed when certain conditions arise - Often **Alternative are not sufficient because:** - No alternative substances or practices are identified as sufficient to eliminate need of this substance **Do advances in organic ration formulations change the need for injectable nutritive supplements?** - They are still helpful for animals having some kind of disease stress - Possibly, but not in young calves - No, when animals need large boosts to jump start immune response, injection is the fastest way to get them a boost. Also, sick animals are not likely to eat the amount required so feed rations would not help at all. **If the material were prohibited:** - I believe we would have to treat more animals with antibiotics, making them ineligible for organic production. - Sick animals would no longer be able to be treated with specific vitamins to boost their immune systems at crucial times, there for their welfare would be lower. Injectable vitamins work very well in the organic health management system.	4
Propylene glycol for treatment of ketosis §205.603(a)(27)	**2 Responses** received from certified organic operations that include propylene glycol in their organic system plan for raising dairy cows. **The material is necessary because:** - Necessary for treating ketosis – certainly dextrose is an option as well, but requires IV therapy. One of the two would be critical for fresh cow management. - Propylene glycol is another tool we can use for ketosis when other things don't work.	3.5

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	Frequency of use: - As needed **Alternative are not sufficient because:** - Dextrose - works but requires IV therapy - We have used Ketonic. It is effective but sometimes not effective enough **The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions?** - For ketosis, dextrose is the only other effective option but requirement for IV therapy makes it more complicated to use **If the material were prohibited:** - Would reduce options for treatment of ketosis	
Acidified sodium chlorite as a teat dip. §205.603(a)(28) & (b)(9)	1 **Response** received from a certified organic operation that includes acidified sodium chlorite in their organic system plan for raising dairy cows. **The material is necessary because:** - Certainly Iodine is a preferred method, but this sodium chlorite seems a necessary option in a rotation of pre and post dips against pathogens. **Alternatives:** - Iodine **Have there been changes in the availability of iodine that would reduce the need for acidified sodium chlorite?** - No **If the material were prohibited:** - Could impact milk quality	4
Zinc sulfate as a hoof treatment. §205.603(b)(11)	3 **Responses** received from certified organic operations that include zinc sulfate in their organic system plan for raising dairy cows. **The material is necessary because:** - One of several options for treating hoof rot – most producers us in a rotation. - We use zinc as a foot treatment as needed for dairy cows. In certain occasions it is more effective than copper sulfate - Used for hoof rot.	3.5

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	Frequency of use: - As needed **Alternative are not sufficient because:** - Have tried using copper sulfate, iodine and sugar (no response regarding efficacy) **Has the use of zinc sulfate reduced the use of copper sulfate in treating foot disease in livestock?** - yes **If the material were prohibited:** - We would have a harder time clearing up some hoof issues and may have to cull the cow	

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

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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Appendix A – Sample Survey for Crop and Livestock Inputs

1. Is your operation certified organic? Yes / No

2. Is [SUBSTANCE] included in your organic system plan? Yes / No

3. Which types of organic crops or livestock products do you use [SUBSTANCE] on/for? (e.g., lettuces, fruit trees, broiler chickens)

4. What function does [SUBSTANCE] provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)

5. With what frequency does your operation use [SUBSTANCE]? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)

6. Have you tried using any *other substances* as an alternative to [SUBSTANCE]? (e.g., other substances that are on the National List and/or other natural substances.)
If yes, please describe which substances you've tried and whether it was effective to fulfill the required function:

7. Are there any other *management practices* that would eliminate the need for [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:

8. How would your organic production be impacted if [SUBSTANCE] was no longer allowed? (describe the agronomic, environmental or human health effects, product quality, economic effects)

9. [If applicable - Insert specific questions from NOSB Subcommittee about the necessity of the substances and the availability of alternatives]

10. On a scale from 1 to 5 stars, rate the overall necessity of [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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April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Materials/GMO Subcommittee – Discussion Document on Excluded Methods[1] Terminology

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials/GMO Subcommittee's Discussion Document on Excluded Methods Terminology. The Subcommittee is continuing the work of identifying emerging excluded methods technologies in the food sector and seeking to re-establish the community's understanding of the topic. In doing so, the subcommittee is seeking answers to several questions to aid in further development of its guidance to NOP on excluded methods terminology.

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
OTA recognizes that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and is now outdated. Organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA's National Organic Program (NOP) must have clear and up-to-date definitions to make consistent and concrete determinations regarding compliance with the prohibition of GMOs in organic farming and handling. It is also critical that seed breeders have a clear understanding of the methods that are allowed and prohibited so they can confidently employ innovative and compliant seed breeding techniques and advance the development of organic seed used in organic systems. For this reason, we continue to be supportive of the work being done in this area.

OTA supports the recommendations that have been made to date, and this includes the clarification provided in the 2016 Recommendation that gene editing techniques, such as CRISPR, are currently prohibited under the NOP regulations per the existing definition of "excluded methods." We maintain that gene editing and the other methods that are listed as 'excluded methods' in the terminology chart are inconsistent with our existing definition and are therefore prohibited.

[1] *Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

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As we continue this discussion, it is important that we do not lose sight of the strength of our existing definition ('excluded methods') and the first sentence that needs to be maintained and held central to our decision-making:

> "Excluded Methods: A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production."

Although the definition was written pre-2000, this first sentence provides a key foundation that should be applied to all new and emerging technology. The definition goes on to include *examples* of methods that are prohibited and allowed, but the list is not exhaustive. Guidance to support the definition is helpful because it provides additional examples that can be updated over time.

It is also important that we do not lose sight of the fact that the NOSB recommendation on Excluded Methods Terminology is one of over 20 final recommendations for "practice standards" that USDA has not completed rulemaking on (**see Appendix A**). The lack of progress and improvement in advancing and clarifying the organic standards is disrespectful to the NOSB process, it is harming and fragmenting the organic market, stifling continuous improvement within the industry and leading to inconsistent certification practices. The organic community has spent a tremendous amount of time and resources working together via the NOSB process to make recommendations to USDA on advancing the organic standards. Continuing to work on this proposal to USDA when there is such a significant record of inaction feels futile at best.

As we continue our work on Excluded Methods Terminology, OTA urges NOSB and organic stakeholders to call upon USDA to prioritize rulemaking and develop an action plan for clearing the NOSB backlog of recommendations. The future of organic depends on fixing this partnership and getting USDA to work better for the organic community.

Questions for Stakeholders

1. *What new emerging methods in biotech should be added to the TBD list? Please also describe the primary purpose and how far from commercialization for use in food processing and/or agriculture the method is in its development.*

   OTA is not aware of any new methods to add to the list. USDA's response[2] and overall inaction on this topic calls into question whether the on-going work to update the terminology chart is helping or hindering NOP's acceptance of the 2016 Recommendation. The most effective path forward at this juncture may be to complete this proposal at the fall meeting and focus energy on urging NOP to address the 'package' of excluded methods terminology recommendations passed to date. We also suggest asking NOP for clarification on the status of the NOP Handbook and what the plans are for issuing Guidance under this new administration. To the best of our knowledge, NOP has not worked on or advanced any Guidance in over four years.

2. *Please prioritize the remaining TBD list methods according to the definitions, principles and criteria established in the 2016 Proposal.*

   OTA does not have comments on prioritization at this time.

[2] The last response issued by NOP (August 12, 2019 "Memorandum to the National Organic Standards Board) refers to the on-going recommendations as "additional updates to the list of Excluded Methods that was put forth in its November 2016 recommendation." The consistent response is, "AMS is reviewing the NOSB's recommendation."

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a) *Would methods newly determined to be excluded by the NOSB/NOP be retroactive for commercial varieties already in the marketplace?*

This question is best answered when tied to concrete examples. Our understanding is that the Guidance primarily applies to new and emerging technologies and the situation described should be minimal to none. The NSB recommendations are to clarify the regulatory definition with updated examples of new technologies, not to change the definition or its meaning. We do not want to see this discussion, or a resulting recommendation, move the goal post on what is currently considered an excluded method (per the NOP definition), or what is currently allowed. The recommendation is for Guidance that supports the regulation and it should help inform decision-making moving forward. It is important to note that Guidance does not have the force and effect of law. It is non-binding. This is why we need to stay tethered to, and reference, the USDA organic regulatory definition of "excluded methods."

b) *Should the NOSB grandfather in methods that have long been used in organic plant breeding (e.g., double haploids) and focus its energy entirely on new and emerging technologies?*

Again, we would want to answer this question with a concrete example. Double haploid methods that involve genetic engineering should remain prohibited. A better understanding of the distinction between the various double haploid methods involved will be helpful. In accordance with the definition of 'excluded 'methods,' the use of traditional breeding, conjugation, fermentation hybridization, in vitro fertilization and tissue culture are not considered excluded methods and such practices should continue to be allowed.

Yes, we think the Guidance should focus on clarifying new and emerging technologies. The definition of 'excluded methods' in conjunction with all of the methods in the terminology chart provide solid direction for where we stand today.

c) *How do we regulate technologies used to develop new seed varieties that companies are otherwise under no obligation to disclose?*

Organic certification is voluntary, and companies that sign up to be a part of the system are making a decision to obtain and/or disclose the necessary information and documentation to demonstrate compliance. Seed is a fundamental input of an organic system and it falls under scrutiny to the requirements of the organic regulations. Organic and non-organic seed used on a certified organic farm must be produced without the use of excluded methods. Certifiers and certified operations are obligated to comply with the organic regulations. That said, it is difficult if not impossible for the organic sector to regulate the conventional seed sector. Organic operations are obligated to ensure conventional seed is complaint with the organic regulations, but this can be challenging since its production falls outside of the organic certification system. Our best option for success is to regulate ORGANIC seed and to put our energy into the development of organic seed production and organic seed breeding. This points to the importance of USDA implementing the 2018 and 2019 NOSB recommendations to update and strengthen the organic seed and planting stock regulation.

3. *Are unintentional excluded methods hiding in organic systems when the actual material produced and used has no trace of excluded method in the final organic product? Do we have the inspection, testing, and enforcement tools to keep prohibited methods out of the organic marketplace?*

The Organic Trade Association believes we have many of the inspection, testing and enforcement tools necessary to prohibit the *intentional* use of excluded methods and monitor the success of contamination prevention. Refinement is undoubtedly needed and must be on-going. First and foremost, and to the credit of

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this Discussion Document, the organic sector needs a clear understanding of the definition of "excluded methods," and the "variety of methods" covered under this prohibition so we can definitively articulate the requirements of organic certification. Second, organic certification is process-based, so we need to continue to focus on prohibiting the intentional use of genetic engineering and developing best practices to prevent inadvertent contamination. Third, testing is a critical tool that should be used to monitor the effectiveness of GMO contamination prevention measures and the authenticity of non-GMO practices and claims. Testing is critical, and it is also the area that needs the most development and refinement. Finally, with a clear understanding of the "variety of methods" that are prohibited under the organic regulations, certifying agents should be able to further develop or advance the non-GMO declarations / affidavits used to communicate and verify the prohibition. The use of a "non-GMO affidavit" often falls under scrutiny and is thought of as being less than ideal. However, a "non-GMO affidavit" is a legally binding document, and most people and companies understand the seriousness of such a contract. The construct of the affidavit and the information contained therein, is really where the rubber hits the road. The more specific the affidavit is, the more effective it will be in keeping excluded methods out of organic systems.

4. *Given the lack of transparency around emerging technology entering food and agricultural systems, how can Organic producers, handlers, certifiers, and this Board, etc. stay educated on emerging methods and the potential for contamination?*

   Since excluded methods are prohibited under the USDA organic regulations, it seems reasonable that USDA could provide NOSB with technical support in this area. NOSB could also request information and resources from the organic community on an annual basis, compile it into a resource document and request that it be posted and maintained on the NOSB webpage. USDA should support NOSB in this effort.

Conclusion

OTA remains supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations. Our priority, however, at this time is to ensure that the backlog of NOSB recommendations (including this one, strengthening organic seed usage and GMO contamination prevention) are address by USDA and implemented by a final rule or final guidance.

NOSB plays a critical role in advising USDA on the development of organic regulations. When Congress created NOP housed under USDA nearly 30 years ago, the industry envisioned a process by which public and private stakeholders would work together via the NOSB to make recommendations to USDA on advancing and developing the organic standards. We envisioned a process that would be able to evolve the standards and ensure that the organic label would continuously improve. Unfortunately, this process is stalled. OTA acknowledges all of the National List Recommendations that USDA has addressed, and the incredible dedication and work NOP is accomplishing around organic enforcement and oversight. Now it is time to focus on updating and clarifying the organic standards, and to call upon USDA to commit to an action plan for prioritizing and addressing the NOSB backlog of recommendations

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

Respectfully submitted,

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

cc: Laura Batcha
Executive Director/CEO
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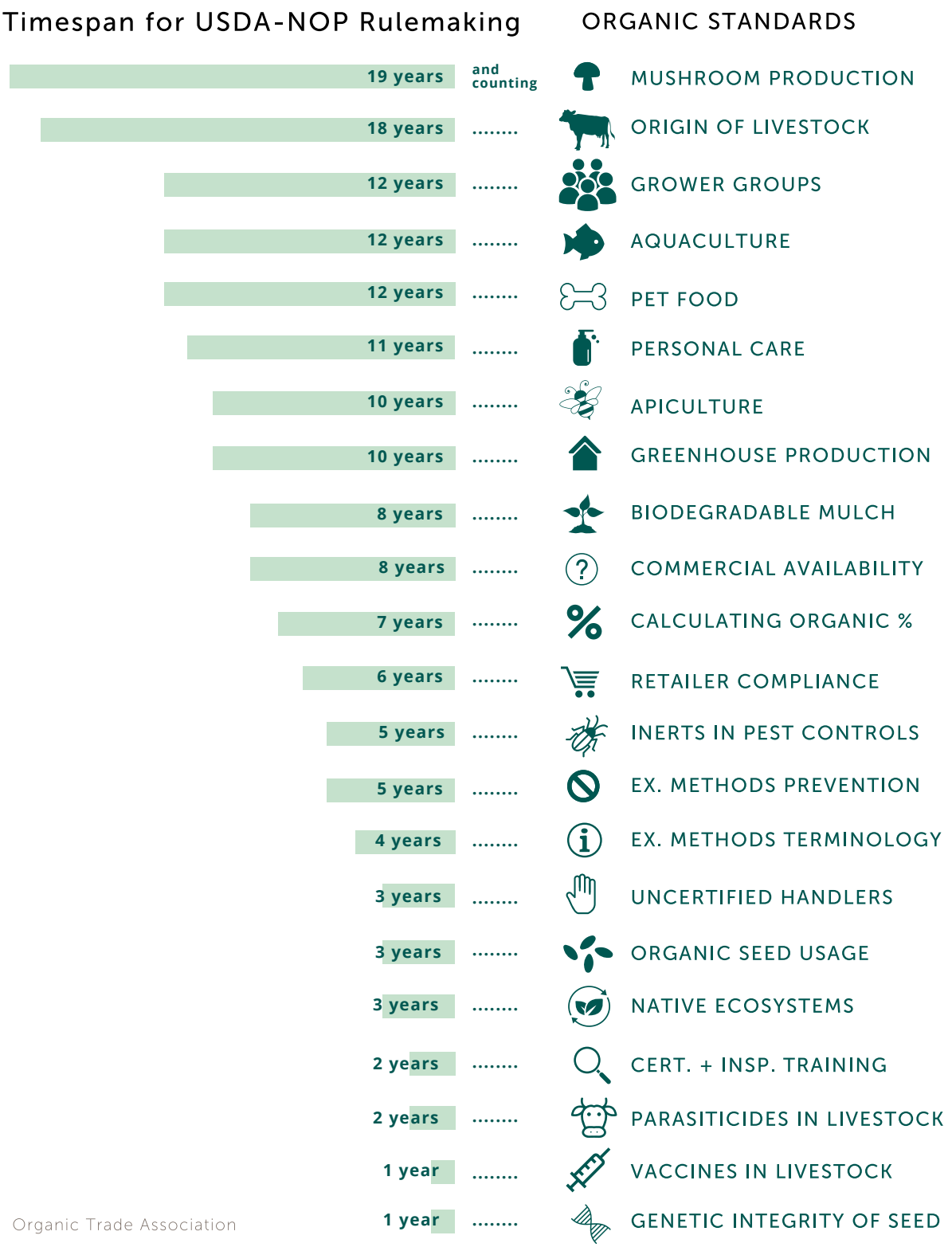
Appendix A: Backlog of NOSB recommendations that have not been implemented



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THE ORGANIC CENTER

April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Crops Subcommittee - Ammonia Extract

Dear Ms. Arsenault:

Thank you for this opportunity to provide comments on the Crops Subcommittee Petitioned Material Discussion Document: Ammonia Extract.

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.

Summary:

- ✓ Based on personal communication with researchers and our review of the scientific literature we conclude that ammonia and ammonia compounds resulting from "extraction" are chemically the same as synthetic ammonia products, and the environmental impacts of these products will depend on the chemical formula of the end-use product resulting from various extraction methods. That is, pure extract ammonia will interact with the environment differently from ammonia concentrate (pure extract + other minerals and organic matter).
- ✓ We offer a summary of science that shows how various forms of ammonia may impact soil health and emphasize the work that suggests negative impacts of adding Nitrogen Fertilizers will be reduced if applied simultaneously with other soil amendments.

We offer the following more detailed comments:

Synthetic ammonia/ammonium is chemically the same as extracted ammonia/ammonium.

Because "ammonia extract" manufacturing processes that capture and purify ammonia from anaerobic digestion or fermentation of agricultural feedstock such as animal manures are in the early commercialization process and their use is limited, there are few if any studies examining their impact on soil health and more research will need to be conducted in organic systems to understand the effects on certified organic soils.

However, because the final products in the extraction of pure ammonia (NH_3) and/or ammonium (NH_4^+) are chemically identical whether synthetically produced or non-synthetically extracted from a natural source, **the final ammonia and ammonium compounds should interact with crops and the environment similarly to synthetically produced ammonia and ammonium** according to several researchers (personal communication).

Professor Antonio Mallarino, Nutrient Management Research and Extension, Iowa State University: "If the product applied is ammonium, how it was synthesized is irrelevant from the perspective of its effects on soil properties and crop growth or nitrogen uptake, except perhaps for impurities that it may have which may vary with the process to produce it. These impurities usually are not an issue, are very low concentrations, and at normal rates applied should not be a problem even with repeated applications."

Professor John Sawyer, Department of Agronomy, Iowa State University: "if applied to soil as ammonium there would be no difference as the chemical formula is the same. There could be some initial differences if the original source were ammonia, urea, uric acid, manure, from digested manure or digested manure itself, etc. But once ammonium, then the microbial nitrification process would be the same and any long-term soil effects the same."

Different ammonia compounds result from different extraction methods

While the petition defines ammonia extract very broadly as "ammonia and ammonium compounds that have been isolated from processes other than the Haber-Bosch process," the main extraction methods described in the technical report, ammonia concentration and ammonia stripping, reflect two main outputs: one of ammonia concentrated amongst other excising compounds including organic matter and other minerals (from "ammonia concentration"), and one of pure ammonium salt (ammonia + acid/base; e.g. ammonium sulfate) solution or dry powder (from "ammonia stripping"). While extracted ammonia and ammonium components are chemically identical to their synthetic forms regardless of extraction methods, the resulting, end-use chemical formulas from these different extraction methods are different (pure extract + organic matter and minerals vs. pure extract) and as such, will interact with the environment differently.

In the instances where ammonia is isolated from anaerobic digestion processes, which is likely to be the common case since trapped ammonia can be a byproduct of generating biogas in anaerobic digesters of animal waste products, the end product will depend on whether the ammonia is stripped or concentrated from the waste product of digestion called digestate. Ghyselbrecht *et al.* 2018 states that "In some cases, however, only approximately 50% of the total organic dry matter is converted into biogas, indicating that the digestate still contains a substantial amount of organic matter." **This organic matter will be absent in a product resulting from ammonia stripping and therefore will differ in its breakdown and interaction with soil and soil organisms.**

The effects of ammonia extract on soil health

To determine environmental impacts of ammonia extract, the chemical formula of the ammonia product must first be defined, as effects depend on the fertilizer type and nature. Importantly, the chemical structure of ammonia from various extraction methods is the same as ammonia that is synthetically produced. There are many forms of synthetic ammonia and ammonium, and research shows that each has specific impacts on soil health. These differences in soil health impacts are often dependent on the individual components of synthetic formulations. We would therefore expect that ammonia extract would vary in its impacts on soil health dependent on its resulting, specific formulations and could not be lumped together in an overall assessment.

For instance, "ammonia concentration" can result in innumerable combinations and concentrations of ammonia salts, minerals, and organic matter depending on the starting feedstock used for the digestate as well as the concentration method (e.g. filtration versus evaporation, etc.), resulting in different types and concentrations of biofertilizers (e.g. liquid versus granular). Therefore, the interactions with plants, soil, and microbial communities will differ depending on the resulting end-use formula of the concentrate. In contrast, "ammonia stripping" results in specific ammonia compounds: some variation of ammonium salt depending on the acid used to trap (stabilize) ammonia gas at the end of the stripping process. Ammonia stripping from anaerobic digestion of animal manure, simply put, converts ammonium from organic matter (NH_4) to ammonia (NH_3) gas, which is then typically absorbed in an acid solution to create ammonium sulfate** or ammonium nitrate* (Baldi *et al.* 2018), though an organic acid like citric acid may also be used, resulting in ammonium citrate. Further description of the stripping process can be found HERE and a simpler explanation from a manure processing company is HERE.

Importantly, Sigurnjak *et al.* 2019 tested the end products from "ammonia stripping" from manure against synthetic ammonium fertilizer equivalents and **found no difference in characterization or performance between the stripped and synthetically produced fertilizers.**

While we recommend additional research, particularly in organic systems, on ammonia concentrates and extracts to understand their true impacts on soil health, initial hypotheses of ammonia from a stripping process may be derived from studies looking at synthetic ammonia products and their impacts **because the chemical structure of the ammonia is the same**.

From the scientific literature:

Science that measures the effects of biofertilizers in the form of **ammonia concentrate** (from anaerobic digestate) on soil health properties is currently lacking. One study conducted by Barzee *et al.* (2019) offered the first examination of various forms of ammonia concentrate, on crop yield and soil quality. This study compared synthetic-N fertilizer to two biofertilizers derived and concentrated from anaerobic digestate: liquid permeate (90% of original volume) and granular concentrate (10% of original volume). Soil fertility/quality metrics (pH and various mineral element concentrations) were measured, but not soil health indicators such as microbial activity/diversity or macrofauna abundance/diversity. The study

found no significant differences in soil properties, however the authors state that the short time frame of the study cannot offer conclusions about long-term effects and more research needs to be conducted to understand the effects of biofertilizers of ammonia concentrate on soil and plant health properties.

Stripped ammonia and ammonia in synthetic nitrogen fertilizer are the same in chemical structure and expected to interact with the environment in similar ways, and because scientific research on the effects of stripped ammonia on soil health are limited, we mainly look to studies that examine the effects of synthetic fertilizer on the soil to represent stripped ammonia.

In general, the application of synthetic N-fertilizers alters soil properties like pH, organic matter content and soil microbial communities often with negative consequences. Additionally, nitrogen will mineralize at different rates ranging from days to years when derived from various types of amendments and applied to soils with varying amounts of soil organic carbon. The rate of mineralization will affect leaching or accumulation potential, ammonia and salinity concentrations, and microbial activity. When nitrogen mineralizes quickly (as in synthetic N fertilizers, and organic slaughter or liquid products) the potential for leaching increases and long-term fertility efficiency can decrease, while nitrogen from amendments like yard clippings and plant-based composts mineralizes more slowly, increasing the potential for accumulation in the soil (Lazicki *et al.* 2019). Studies indicate that carbon to nitrogen ratios in the soil and amendments will influence nitrogen mineralization with more carbon slowing the process and increasing the potential for long-term fertility, while reducing the potential for leaching (Mallory & Griffin 2007). A recent study by Singh 2018 suggests that if **N-fertilizers are applied at or below optimum rates and balanced with the application of additional nutrients in various forms, like organic manures, then the deleterious effects of long-term fertilization are reduced or eliminated**.

Studies on the impacts of long-term chemical fertilization show a reduction in the diversity of plants and microorganisms, negative impacts on the interactions of plants and soil microbes, and reduced capacity of the soil microbiome to cycle nutrients (Molina-Santiago & Matilla 2020, Pierik *et al.*, 2011; Cassman *et al.*, 2016; Wang *et al.*, 2018; Li *et al.*, 2019). Specifically, Wang *et al.* 2018 found that long-term application of N-fertilizers causes an abundance of bacterial groups responsible for the denitrification process, which causes the turnover of nitrogen to increase and results in greater nitrogen loss over time. Essentially, adding more nitrogen fertilizer results in a long term loss of nitrogen while altering other soil components, like decreasing soil pH and C:N ratio. When soil carbon and nitrogen are reduced in response to the application of chemical fertilizers, beneficial enzymatic activity of the soil also decreases (Ozlu *et al.* 2019).

Some studies have found negative impacts of specific fertilizers on soil health such as urea and the two most common products of ammonia stripping: ammonium sulfate and ammonium nitrate. For instance, Singh *et al.* 2013, stated that “urea is consumed by bacteria which convert it to (excrete) anhydrous ammonia and carbon dioxide. Anhydrous ammonia is highly toxic and kills organisms. If urea is applied to the soil surface, the gases quickly dissipate. However, in the presence of high air humidity anhydrous ammonia vapours form. These are heavier than air and can accumulate in low lying areas. If urea is incorporated into the soil, the ammonia gas reacts with water to produce ammonium hydroxide (NH4OH), which has a pH of 11.6. It is highly caustic and causes severe burns. This creates a toxic zone in the immediate vicinity of the applied urea that kills seeds, seedlings and soil dwelling organisms. Within

a few days further chemical reactions in the soil release the ammonium ion NH4+, which then follows the same path as naturally occurring ammonium, with any excess nitrate created in this way leached into the environment."

When compared to organic amendments, synthetic ammonium nitrate reduced soil nematodes involved in nutrient cycling (Wang *et al.* 2006). And Singh *et al.* 2013 describes the interaction of ammonium nitrate as thus: "The nitrates are consumed by soil organisms, leached, or converted to nitrogen gas and volatized. The free oxygen produced through these processes oxidizes the organic matter of the soil and again causes a low level "combustion" (burning) of the organic matter. This is a purely chemical reaction which depletes the organic matter."

And "Ammonium Sulfate (NH4)2SO4 contains 24% sulfur. In the soil, [sulfur] interacts with water to produce sulfuric acid (H2SO4). Sulfuric acid has a pH of less than 1 and it is extremely toxic and kills organisms. Hydrogen ions released from the acid replace alkaline elements on the cation exchange sites, depleting the soil of nutrients. The free oxygen produced in this reaction oxidizes the organic matter of the soil and causes a low level "combustion" (burning) of the organic matter. This is a purely chemical reaction which depletes the organic matter. In calcareous soils (soil with excess calcium) the sulfuric acid reacts with calcium carbonate (CaCO3) to form gypsum (CaSO4). Gypsum is a salt and attracts water to itself and away from soil organisms and plant roots. In anaerobic conditions gypsum and water form hydrogen sulfide (H2S), which is a toxic gas," (Singh *et al.* 2013).

The negative consequences associated with the use of nitrogen fertilizers are more apparent when they're applied in isolation and using these fertilizers in simultaneous combination with other organic amendments or compounds can help reduce adverse effects by adding important carbon to the soil and balancing pH and beneficial microbial populations (Singh 2018).

Optimal range of ammonia concentration for crop use

The range of concentration that would be beneficial versus excessive (or ineffective), would depend on the extract's formula, the form of the end-use product (e.g. gas, liquid, solid), variables such as soil type, temperature, moisture content, and soil organic matter (Wang *et al.* 2018) and the crop type as nitrogen needs for different crops vary. For examples: anhydrous ammonia has about 82% nitrogen, while ammonium sulfate has 21%, and ammonium nitrate around 33%. Nitrate leaching has been found to vary across soil types. Sogbedji *et al.* (2000) found leaching to be higher on sandy loam soil than clay loam soil for corn production.

Glossary of terms: the most commonly used forms of ammonia/ammonium fertilizers

Anhydrous Ammonia- Anhydrous means without water. Ammonia is a gas that when compressed at atmospheric pressure and takes on a liquid form that can be injected into soil for fertilization (note that this form is still NH3 in its pure molecular formula, it is not combined with water in this form, though it is liquid). Once injected under the soil surface, the ammonia (NH3) expands into a gas and will combine quickly with any water present in the soil resulting in the production of ammonium (NH4). (See HERE and HERE for more information)

Aqua Ammonia- This form of ammonia is basically anhydrous ammonia mixed with a small amount of water that converts NH3 to NH4, which reduces the storage pressure of anhydrous ammonia, making it easier to handle. There isn't enough water in this solution to combine with all NH3 molecules, so there is still some free form (anhydrous) ammonia remaining in this solution that can escape into the air. This means that it must also be injected into the soil.

*Ammonium Nitrate- Ammonium nitrate (NH4NO3), a water soluble 50/50 mixture of ammonium and nitrate, is commonly used in fertilizers, pesticides and as an oxidizer in explosives. A concentrated liquid form to be used as a fertilizer is **formed from a reaction between ammonia gas and nitric acid**. Plants readily uptake nitrate in its water soluble form, while ammonium has to first be converted to nitrate by soil microorganisms. Essentially no ammonia volatilization occurs making this a more attractive fertilizer option than urea.

Ammonium sulfate- **Made from reaction between ammonia gas and sulfuric acid ($(NH_4)_2SO_4$. It is an inorganic salt that is used as a dry-form fertilizer, particularly for alkaline soils that benefit from lowering the pH. Ammonium sulfate provides sulfur, an essential plant nutrient.

Diammonium phosphate- **Made from reaction between ammonia gas and phosphoric acid ($(NH_4)_2HPO_4$**). Temporarily increasing soil pH, but over time decreases it, acidifying the soil. Phosphammite is the closest naturally occurring compound, which is related to bat guano.

Urea- Created in vitro via the liver which breaks proteins down into carbon dioxide, water and ammonia. Ammonia is toxic in vitro and so it is recombined with carbon and oxygen to produce urea (CH4N2O or also written as CO(NH2)2). Urea is often used as a component of fertilizer because it is a very nitrogen rich. Once in the soil, urea breaks down into ammonium (NH4) which is taken up by plants. Through oxidation, soil bacteria can break it down further into nitrates, which are also taken up by plants as nutrients. Urea passes through both ammonia and ammonium phases and when it is an ammonia gas, it can be released into the air.

Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center

THE ORGANIC CENTER

April 5, 2021

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

Docket: AMS-NOP-20-0089

RE: Materials Subcommittee – 2021 Research Priorities

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comments on the 2021 Research Priorities Discussion Document.

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 2021.

Summary:

- ✓ The Organic Center supports the subcommittee's proposed 2021 Research Priorities. The proposed priorities are in line with the needs of the organic community, and will serve as an important resource to guide The Organic Center's research priority focus and project development.

- ✓ Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of **benefits and risks of livestock integration into crop rotations, nutritional value of organic animal products (such as dairy, meat, and eggs), protection of organic farmers from chemical contaminants, comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products, and alternatives to conventional celery powder for curing organic meat** be considered for inclusion in the 2021 Research Priorities.

We offer the following more detailed comments:

Current Research Needs

We have reviewed the list of topics included for 2021 Priorities, and we're particularly pleased to see the inclusion of evaluation of bio-based mulch film, whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices, organic no-till practices, plant disease management strategies, relationships between biodiversity and pathogen presence, practices that reduce greenhouse gas emissions, the examination of factors influencing organic food access, and production and yield barriers. 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.

Evaluation of Bio-Based Mulch Film

The Organic Center has been meeting with farmers about their interest in decreasing the use of plastic in organic farming systems. Organic values are based on improving sustainability and reducing reliance on synthetic materials. However, synthetics such as plastic film and mulch is used in the field as weed control. The use of plastic has increased in the field as organic production has expanded. While the organic community is dedicated to finding alternatives to plastic, there has been a paucity of dedicated discussion and strategy investigating available alternative strategies. Additionally, the complexities surrounding the development of plastic alternatives and organic regulations of plastic use require input and collaboration across the organic sector.

In January, the Organic Center submitted a proposal through the Organic Research and Extension Initiative (OREI) to hold a conference that would bring together farmers, processors, distributors, retailers, researchers and policy makers to discuss challenges of plastic from the perspective of waste, climate change, and environmental/human health. The workshops will include explorations of innovative solutions to plastic use and waste, and policy discussions to set the stage for the current global perspective on plastic alternatives and UDSA National Organic Program allowances. Research conducted under this NOSB priority would help further our discussions on reducing plastic use and investigating ways to replace plastic mulch with bio-based mulch films.

Economic, Social, and Environmental Impact of Farming Systems Choices

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

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

Organic No-Till Practices

The Organic Center is collaborating with Dr. Kate Tully's lab at the University of Maryland to examine practices improving soil health on organic farms. We published a scientific article from research on this topic, and one of the areas that we included was the comparison of no- and low-till in organic production versus standard tillage in organic production. Overall, our results suggest that surface-level soil organic carbon levels are higher in low/no-till organic plots compared to standard organic tillage plots. However, we also found that no/low-tillage in organic was associated with significant reductions in yield. These findings suggest that while organic farmers could improve carbon sequestration through no/low-tillage, there needs to be further research to support farmers wishing to make this conversion to ensure that it is a viable and economically feasible option for a wider variety of crops. We are thankful that NOSB included this priority in its 2021 Research Priorities, as it will help encourage research on this critical issue, and provide much-needed tools to help organic farmers realize the benefits of reduced tillage without the threat of reduced yields.

Plant Disease Management

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

Relationships between Biodiversity and Pathogen Presence

Organic farmers face many challenges when it comes to food safety management, but one of the most commonly cited issues is incongruities between third party food safety requirements and the National Organic Program requirements. Unfortunately, food safety regulations and requirements originate from various sources, from federal standards (such as the National Organic Standards and the Food Safety Modernization Act) to third party standards required by commodity groups (such as the Leafy Greens Marketing Association) and private retailers, with varying degrees of stringency in what food producers must do to reduce risk. Third party auditors, consultants, and farm advisors may also have their own interpretations of how certain farming practices affect risk of foodborne illness contamination. While all food producers are subject to food safety rules, organic farmers can face unique challenges in trying to meet both NOP and food safety standards, especially the tensions between supporting biodiversity while

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

The Organic Center recently submitted an OREI grant proposal to bring together organic growers, third party food standards association, researchers, and policy makers to determine which producers are most impacted (product sectors and regions) by disparities between third-party food safety standards and organic biodiversity requirements, which third-party certification requirements are the most difficult to synchronize with the National Organic Program requirements, and research needs for addressing these specific conflicts. The long-term goal of this proposal is to provide organic growers and industry members with organic-appropriate tools and strategies for mitigating food safety risk while retaining third-party certification viability.

We have been involved in research examining pathogen presence in organic soil amendments for several years, and the proposed work will build on our current and past research on pathogen suppression. For example, we are collaborating with the University of California, Davis, among other organizations, to address the need for additional information on raw manure intervals to provide critical information for guidelines on risk mitigation of foodborne pathogens for organic and sustainable agriculture. We have published multiple articles and abstracts on the subject, and are currently developing an education module in collaboration with Cornell University to communicate our findings to a broad audience.

Reducing Greenhouse Gas Emissions

Climate change is having serious consequences on our environment and public health, and we appreciate the inclusion of the "Climate Change" focus in the 2021 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 recently published a project in collaboration with researchers at the University of Maryland

pinpointing 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.

Factors Influencing Organic Food Access

Marginalized populations often lack access to nutritious food, especially higher quality products that are also produced without pesticides and support sustainability, such as organic foods. However, meeting the global goal of ending hunger —while responding to climate change and the COVID-19 pandemic—calls for applying a racial equity lens to organic foods. Increasing equitability of access to organic foods will help ensure that people living with food insecurity can benefit from foods that are affordable, available near their homes, and culturally appropriate. Therefore, we thank the NOSB for including this priority.

Production and Yield Barriers

Organic faces unique challenges in overcoming barriers to pre- and post-farm gate production due to their limited tool availability. One area that could help farmers overcome these challenges are agricultural technology (AgTech) solutions that are in line with the organic values. While there has been a sharp increase in the development of agricultural technologies (AgTech) over the last five years, most of these products and systems are focused on supporting large-scale conventional systems. However, there is an opportunity through AgTech to deliver novel, cost-effective strategies for sustainable production across a diversity of farming systems by allowing for increased production in tandem with reduced reliance on synthetic and labor inputs. These prospects are especially promising for organic farmers, who are limited in the materials they are able to use for addressing on-farm challenges, while needing additional tracking tools for organic regulatory compliance. The intersection of AgTech and organic would serve to expand the technology sector into a rapidly growing farming niche while developing tools that could serve to improve sustainable production across farming systems.

The Organic Center plans to host a series of conferences examining this issue, serving as a bridge toward developing organic-compliant AgTech tools by 1) closing the communication gap between AgTech innovators and organic farmers, 2) matching organic farmer needs with existing technologies or, where technology is yet to be developed, informing AgTech innovators of opportunities to expand their current programming in the organic sector, and 3) creating a roadmap to building and retain long-term collaborations so that future techonological innovations will continue to support farming practices that make the food system more sustainable. We will also focus on solutions to make AgTech accessible across farm scales, demographics, and income levels by developing a framework for improving technological equity, accessibility, and inclusivity.

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 2021 Research Priorities are in line with the needs of the organic industry, and appreciate the release of this report as an important resource to guide The Center's own research

priorities and project development. Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of livestock integration into crop rotations, nutritional value of organic milk and meat, protection of organic farmers from chemical contaminants, comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products be considered for inclusion in the 2021 Research Priorities. We also feel that the focus on alternatives to conventional celery powder for curing organic meat that was included in the 2019 Research Priorities be included in this year's priorities, because, while research is underway, the importance of this topic should not be forgotten.

Livestock Integration into Cropping Systems

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

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

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

Nutritional Value of Organic Milk and Meat

We were pleased to see the inclusion of "Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons" in the 2021 Research Priorities, as we agree with the committee analyses that a better understanding of how pre- and post-farm gate practices impact crop nutrition is needed. However, the committee discussion focuses around fruit and vegetables. We encourage the committee to include animal products such as meat, dairy, and eggs in their priorities, because while

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

Protection of organic farmers from chemical contaminants

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

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

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

Comparisons of synthetic residues in organic and conventional products

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

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

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

Celery Powder

In collaboration with the Organic Trade Association's National List Innovation Working Group and the University of Wisconsin, Madison, we are investigating the potential for developing organically grown

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

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

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

Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center