September 30, 2021

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

Docket: AMS-NOP-21-0038

Comments to the National Organic Standards Board
Fall 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.
CONTENTS (please note the PDF bookmark feature to navigate comments):

Compliance, Accreditation, and Certification Subcommittee
- Letter to Secretary Vilsack regarding USDA Climate Change Initiatives (Proposal)
- Oversight improvements to deter fraud (Discussion)

Crops Subcommittee
- Ammonia Extract - petitioned (Proposal)
- Biodegradable Biobased Mulch Film annotation change (Proposal)
- Sodium Nitrate (Proposal)
- 2023 Crops Sunset Review
- EPA List 3 Inerts (Sunset Review)

Handling Subcommittee
- Zein - petitioned (Proposal)
- 2023 Handling Sunset Review

Livestock Subcommittee
- 2023 Livestock Sunset Review

Materials Subcommittee
- Excluded Methods (Discussion)

Policy Development Subcommittee
- Public Comment Process (Discussion)

Additional Comments from The Organic Center are also included:
- Ammonia Extract (Proposal)
- 2021 Research Priorities (Proposal)
- Letter to Secretary Vilsack regarding USDA Climate Change Initiatives (Proposal)
September 30, 2021

Ms. Michelle Arsenault  
National Organic Standards Board  
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RE: Letter to Secretary Vilsack regarding USDA Climate Change Initiatives

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Compliance, Accreditation & Certification Subcommittee (CACS) Proposal - Letter to Secretary Vilsack regarding USDA Climate Change Initiatives.

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

OTA supports the adoption of the CACS Proposal - Letter to Secretary Vilsack regarding USDA Climate Change Initiatives. We wholeheartedly agree that organic agriculture must be a key part of the solution to tackle climate change, and stronger federal support is needed for organic to reach its full potential to fight against climate change.

OTA has been active in advocating for USDA and Congress to recognize and support organic agriculture as a growing opportunity to mitigate climate change while creating economic, environmental, and health benefits for all food system participants. OTA’s board of directors recently adopted a set of guiding principles for policy solutions to fight climate change and formed a member-wide Climate Change Task Force of over 65 members representing fiber and textiles, grains, dairy, specialty crops, retailers, input suppliers, consumer packaged goods companies, and more. We have also hosted virtual fly-ins for OTA members to meet with Congress to advocate for organic as a climate solution, as well as submitted extensive written comments to USDA with specific recommendations for supporting organic.

To support the CACS’s work in advancing the letter, we provided comments in August to the CAC’s preliminary draft letter dated July 13, 2021. We provided the following links to several resources that OTA has prepared on the topic of organic and climate change. Our comments to USDA on Tackling the Climate Crisis at Home and Abroad include detailed policies to advance organic, encourage voluntary transition to organic and support the adoption of climate-smart agricultural practices. Further comments call for big and bold investments in organic and identify specific recommendations of areas to support supply chain resiliency of the organic sector that will drive climate benefits. Our white paper is a comprehensive resource about the benefits of organic in fighting climate change and identifies the 10 core principles for policymakers to consider in developing good climate policy.
List of resources (click to download)

- OTA’s Comments to USDA on Tackling the Climate Crisis at Home and Abroad (2021)
- OTA’s Comments to USDA on Supply Chains for the Production of Agricultural Commodities and Food Products (2021)
- OTA’s White Paper: Advancing Organic to Mitigate Climate Change (2020)

Please also refer to comments submitted from The Organic Center for additional references emphasizing the benefits of organic as supported by scientific research.

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
September 30, 2021

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

Docket: AMS-NOP-21-0038

RE: CACS Subcommittee – Discussion Document Modernization of Organic Supply Chain Traceability

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) CACS Discussion Document on Modernization of Organic Supply Chain Traceability. The subcommittee is seeking feedback from organic stakeholders on the best way to utilize and integrate technology to further modernize the organic verification and traceability system for complete supply chain traceability and support the implementation of the Strengthening Organic Enforcement (SOE) Rule.

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 appreciates the subcommittee’s proactive work to explore the use of electronic tracking systems and the best way to modernize organic supply chain traceability. Prior to engaging in the discussion, OTA would like the following information to work with:

1. A final SOE rule so we can tether the conversation to a known outcome and better identify holistically where the gaps are and what is needed;
2. A detailed accounting on how the $5 million from the 2018 Farm Bill was spent; and
3. A detailed update on the status of electronic import certificates and the CBP-ACE system.

We offer the following more detailed comments:

OTA is a long-time supporter of technology upgrades at NOP to support data collection and tracking systems. We have consistently worked with Congress to advocate for increased funding for NOP to collect data as well as make important investments in technology to ensure the data is accessible. In both the 2014 and 2018 Farm Bills, OTA successfully advocated for Congress to include $5 million in mandatory funding to support technology upgrades at NOP. The funding was used to create the Organic Integrity Database (OID) and recent funding included in the 2018 Farm Bill was provided for NOP to make upgrades and maintain OID while also investing in technology to set up a tracking system for
electronic import certificates through the U.S. Customs and Border Protection’s Automated Commercial Environment (CBP-ACE) system.

NOP’s annual budget is provided by Congress through discretionary appropriations. Over the past five years, NOP funding has increased by more than 30% due to OTA’s advocacy. In the 2018 Farm Bill, OTA secured an authorization to increase NOP’s budget by 10% per year to keep pace with market growth. Continued Congressional support for NOP funding is vital to ensure that the requirements of the proposed rule related to data collection and tracking are achievable, and the federally operated databases upon which the SOE Rule relies (OID & CBP-ACE) can continue to provide the critical functionality and data that the industry requires.

All of this said, OTA appreciates the subcommittee’s proactive work on this topic. Investments in technology and access to data to improve tracking of organic trade are necessary to ensure a transparent marketplace and to prevent fraud. We agree with CACS that “it is imperative to continuously improve and modernize transparency in a post-SOE implementation world,” and we think that digital ledger technology could play an important role in supply chain traceability if it is applied appropriately. However, we would like to first understand the requirements and capabilities of SOE as presented in a final rule, and to see the return of investment to the funding NOP has been provided with to date.

Some questions and considerations we are tracking around SOE include:

- Will the final rule require mandatory data reporting to NOP by crop type, acreage and location; and number of animals by livestock type and location, at least on an annual basis to the Organic Integrity Database? A requirement for certifying agents to report production area certified by crop/livestock and location, on an at least an annual basis, to the OID is one of the most impactful single actions that can be taken to increase the integrity in the global organic control systems.

- Will the OID provide for global use? If not, then we recommend investing in some additional system that gives organic operations and certifying agents access to the same type of information about certified operations around the world that are operating under equivalency arrangements and selling products into the United States.

- Will NOP require uniform organic certificates generated through OID, and if so, what will they look like and what kind of interface will it have with certifier systems? There are many unanswered questions and unknowns about the OID. Given the developments underway, it seems prudent to first understand how OID will allow entities to quickly access, approve and verify that organic certificates and transactions are valid.

- Will the final rule include more specific fraud prevention criteria or detail on what a robust plan for supply chain oversight will look like? OTA’s position is that the best line of defense to organic fraud is prevention. Technology plays a role as an important tool, but we believe it must be used in the context of process-based prevention.

- What is the status of the NOP electronic import certificates and the CBP-ACE system? To date we have not seen or been involved in any kind of industry pilot group nor do we have visibility on its progress. It is essential to have a clear picture on the status of the CBP-ACE system as well as the OID. Only at that time could we begin to envision how to connect data streams and build on existing investments and capabilities.
Conclusion
For the past four years, OTA has prioritized significant time and resources into actions that will help mitigate and prevent organic fraud. Our work ranges from our successful legislative efforts in the 2018 Farm Bill that authorized key provisions of the SOE rule, to our work with NOSB and our member task force to help inform the SOE proposed rule, to our major private-sector initiative that has evolved into an industry-wide fraud prevention program, called Organic Fraud Prevention Solutions. The program provides businesses with a systematic approach for carrying out a fraud vulnerability assessment and developing an Organic Fraud Prevention Plan.

OTA remains committed to proactively confronting the fraud challenge with effective solutions, and doing our part as leaders of the organic industry to prevent the organic fraud opportunity. We applaud NOSB for its efforts to explore resiliency of the tools at hand, and how they can be applied to strengthen supply chain traceability systems. For now, OTA is focused on understanding the outcome of the regulations and the tools and technology we have already invested in.

Once we have a final SOE Rule, including an implemented CBP-ACE system for electronic import certificates, and a detailed report on how the $5 million from the 2018 Farm Bill was spent, it will make much more sense to engage in a conversation about an Organic Link System.

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

Laura Batcha
Executive Director/CEO
Organic Trade Association
September 30, 2021

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

Docket: AMS-NOP-21-0038

RE: Crops Subcommittee – Ammonia Extract (Proposal)

Dear Ms. Arsenault:

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

Summary of Organic Trade Association Positions

<table>
<thead>
<tr>
<th>NOSB Crops Subcommittee Motions</th>
<th>OTA Position</th>
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<tbody>
<tr>
<td>#1. Motion to prohibit at §205.602: Stripped Ammonia – created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation.</td>
<td>Support Prohibition (Not compatible)</td>
</tr>
<tr>
<td>#2. Motion to prohibit at §205.602: Concentrated Ammonia – contains greater than 3% ammoniacal nitrogen and the total nitrogen content is predominately (i.e., &gt;50%) in the ammonia or ammonium form.</td>
<td>Support Prohibition (Not compatible, and more complicated)</td>
</tr>
<tr>
<td>#3. Motion to add practice standard at §205.203(f): Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs.</td>
<td>Important Topic but Still Needs Work. Keep on NOSB Work Plan.</td>
</tr>
</tbody>
</table>

Please see below for more detailed comments on Ammonia Extract.

Separate comments have been filed on the proposal for Sodium Nitrate. OTA is supporting the Subcommittee proposal to reinstate the listing of sodium nitrate for the purpose of clarifying its regulatory status.
I. Introduction

Ammonia extract has been petitioned for inclusion on the National List as a prohibited nonsynthetic input in organic crop production. It is critical to first note that synthetic ammonia fertilizers are already 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 petition challenges the allowance of nonsynthetic ammonia products that are isolated, captured, extracted, and/or concentrated from natural sources such as manure through physical, mechanical, and/or biological processes. More details about the technical characteristics of these products are available in Section II of this comment.

Nonsynthetic ammonia extracts, for the most part, represent an emerging category of commercial fertilizers intended for use as water-soluble and bio-available sources of nitrogen. The petitioner has elevated this emerging product category to NOSB for consideration prior to wide proliferation of these novel 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. Unless specifically prohibited in the organic regulations, ammonia extracts that are nonsynthetic are permitted for use in organic production.

NOSB plays a critical role in evaluating inputs within the framework established in the Organic Foods Production Act (OFPA) for making recommendations to the Secretary for proposed amendments to the National List of Allowed and Prohibited Substances. Based on OFPA, a nonsynthetic material such as ammonia extract may be recommended for prohibition only if use of the substance would be harmful to human health or the environment and is inconsistent with organic farming or handling. More details about the OFPA criteria are provided in Section III of this comment.

Summary of NOSB Crops Subcommittee’s 2021 Proposals

The NOSB Crops Subcommittee presents proposals regarding the prohibition of ammonia extracts. The proposal defines the two common manufacturing methods for ammonia extracts (stripped ammonia and concentrated ammonia) and proposes to list them individually on the National List at §205.602, nonsynthetic substances prohibited for use in organic crop production, under a new sub-section for prohibited ammonia fertilizers. If both definitions are passed, NOSB suggests that NOP could combine them into a single listing during rulemaking.

According to the Subcommittee’s proposal, an abundance of caution warrants prohibition of these materials. They acknowledge this is a complex issue and are taking a conservative approach to the questions about impact on soil and crop health. The Subcommittee identifies a lack of consistent/conclusive research showing positive benefit to environment, soil health, and biodiversity and some research indicates their negative effects on soil health. In terms of consistency with organic farming principles, the Subcommittee concludes that ammonia extract does not positively contribute to soil or plant health over the long term, and does not encourage or enhance preventive
techniques for crop management. The long-time concern for use of highly soluble plant nutrients is also a driving factor of the Subcommittee’s proposal.

The Subcommittee is also proposing an amendment to the NOP regulations, at §205.203 (soil fertility and crop nutrient management practice standard), that takes a broader approach to limiting all nitrogen products used in organic production systems. The proposal is that nitrogen products with a Carbon to Nitrogen (C:N) ratio of 3:1 or less are limited to a cumulative total use of 20% of crop needs. The purpose is to limit the use of materials likely to deliver bio-available nitrogen to plants and set a precedent to limit the potential overuse of the materials.

![Ammonia Extracts Diagram]

Fig 1: OTA’s Summary of 3 NOSB Motions for Ammonia Extract
II. Technical Background

Ammonia extract is described in the petition as “a fertilizer produced using a range of methods where the output contains ammonia (NH₃) and/or ammonium (NH₄⁺) 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 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 was presented at the spring 2021 meeting that builds on comments received from the prior meeting on the topics of soil health and the potential for fraud. A third-party Technical Report was commissioned by NOSB and was also publicly released in spring 2021. NOSB indicated at the spring 2021 meeting that they are wrestling with technical aspects of this category substance as well as a fundamental question of whether these substances are compatible with organic principles and a system of sustainable agriculture. NOSB also acknowledged concerns about the definition of ammonia extract as presented in the petition being overbroad and expressed its intent to narrow the definition to avoid implicating non-target materials like compost tea or fish emulsion. A proposal consisting of one classification motion and three national list motions is presented for vote at the fall 2021 NOSB Meeting.

Manufacturing Processes of Ammonia Extracts

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. The Technical Report 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. If the ammonia extract material is ultimately classified as “nonsynthetic” per NOP 5033 and NOP 5033-1 by an accredited certifier or material review organization, the material would be impacted by the petition. If “synthetic,” it is already prohibited and would need to be petitioned to §205.601 in order to allow.

Conventional manure is a common starting material for ammonia extracts described in the petition, technical report, and public comments. 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 physical and mechanical processes such as heating, pressurization, diffusion, evaporation, cooling, condensation, distilling, filtration, reverse-osmosis, etc. involved in “ammonia stripping” and/or “ammonia concentration” are also nonsynthetic processes. Use of processing aids, extractants, stabilizers, pH adjusters or other additives are subject to review and can influence the classification of the end product.

In general, ammonia extracts from “ammonia stripping” (steam stripping, distillation, etc.) are made using pressured air and/or heat, or other thermo-mechanical derivations of the steam-stripping technology,
to facilitate evaporation of ammonia gas from an agricultural feedstock followed by a cooling/condensation step that captures the ammonia gas as a purified ammonia-containing condensate. Resulting products encompass a wide variation of “purified” forms of aqua ammonia or ammonium-compound solutions, and may or may not may retain traces of carbon from original agricultural feedstock. Products produced by ammonia stripping are considered novel; new products are only recently being commercialized or are still in development.

Ammonia extracts from “ammonia concentration” in general are made using solids-filtration and pressurized air and/or heat to facilitate evaporation of water from an agricultural feedstock (solids removed) thereby concentrating the liquid ammonia-containing waste solution. Resulting products are concentrated nitrogen-containing liquid waste filtrates that contain ammonia and ammonium compounds, other nutrients and organic compounds retained from the original agricultural feedstock. Products produced by this method are not considered new or novel, as at least one product has been on the OMRI List of approved brand name materials for nearly a decade (See Impacted Products below).

Technical difference between stripped and concentrated ammonia extracts will vary depending on the particular products being compared. In general, based on information in the petition, technical report, and in public comments, concentrated ammonia products may have lower ammoniacal nitrogen levels than stripped ammonia products and may have more carbon and other secondary nutrients.

**Impacted Products**

To the best of our knowledge using information from the petition and publicly-available comments from past NOSB meetings, the following products may be included within the scope of the petition on ammonia extracts. To be clear, the National List must only refer to generic materials and the exact impact on brand name products will be determined by the material review organizations responsible for evaluating compliance of brand name products in accordance with final regulations.

Table 1: Impacted Products on OMRI and CDFA Lists

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Year Listed</th>
<th>Product Name</th>
<th>Year Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>EarthWise Organics Thriva N 7-0-0</td>
<td>2021</td>
<td>Phytamin Pure 5-0-0</td>
<td>2020</td>
</tr>
<tr>
<td>BenVireo TerraPreme 8-0-0</td>
<td>2021</td>
<td>Phytamin Premier 5-0-0 (DER;MR)</td>
<td>2020</td>
</tr>
<tr>
<td>Farmilizer 10-0-0</td>
<td>2021</td>
<td></td>
<td></td>
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<tr>
<td>TerraPreme Liquid 8-0-0</td>
<td>2020</td>
<td></td>
<td></td>
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<tr>
<td>BioStar Organics Perfect Blend</td>
<td>2012</td>
<td></td>
<td></td>
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<tr>
<td>SuperSix Plus 6-0-0 Liquid Organic</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Fertilizer*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioStar Organics SuperSix Liquid</td>
<td>2019</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organic Fertilizer*</td>
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</table>
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. (See Appendix A for full text)

III. NOSB’s Decision-Making Framework (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.

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 (See 12 Questions below & the NOSB Principles of Organic Production in Appendix B)
NOSB Guidance on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling
(Ref: NOSB Recommendation, Adopted April 29, 2004 and incorporated in to the NOSB Policy and Procedures Manual)

The OFPA Criteria for the National List requires NOSB to evaluate whether the substance is compatible with a system of sustainable agriculture and consistent with organic farming practices (OFPA §6517(c)(2)(a)(ii); §6518(m)(6)). The following 12 questions were developed by NOSB to assist in determining the compatibility of materials with organic practices.

1) Does the substance promote plant and animal health by enhancing the soil’s physical chemical, or biological properties?
2) Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
3) 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?
4) Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
5) Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
6) Does the substance allow for an increase in the long-term viability of organic farm operations?
7) Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
8) If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
9) Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
10) Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
11) 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?
12) Does use of the substance have a positive impact on biodiversity?
IV. Organic Trade Association Positions

1. Stripped Ammonia

NOSB is considering a motion to add stripped ammonia as a prohibited substance at §205.602: “Stripped Ammonia – created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation.”

Compatibility with Organic Principles

The OFPA Criteria for the National List requires NOSB to evaluate whether the substance is compatible with a system of sustainable agriculture and consistent with organic farming practices (§6517(c)(2)(a)(ii); §6518(m)(6)). Using the OFPA criteria and the NOSB’s own guidance for assessing compatibility with organic principles, OTA finds that stripped ammonia is not compatible with organic principles. The driving factors of this conclusion are concerns about inconsistency with historically allowed substance and international standards, moving organic regulations away from promoting soil health and preventive management practices, eroding consumer trust and expectations of organic integrity, and threatening long-term viability of the organic sector.

a) Consistency with Historically Allowed Substances and International Standards
(NOSB 2004 Questions 9 & 10)

The NOP regulations reflect a long history of prohibition or restriction of highly soluble crop nutrients and soil amendments. Section 205.203 specifically references mined substances of high solubility, and the National List of Prohibited Substances either previously or currently lists Calcium chloride, Potassium chloride, and Sodium nitrate.

Although not explicitly written into the NOP regulations, organic production systems have had special concern for nitrogen inputs – fertilizers that deliver significant levels of plant-available nitrogen – as a main point of differentiation from conventional agriculture. The prohibition of synthetic nitrogen fertilizers manufactured through the Haber-Bosch process is a long-standing 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. Purified natural ammonia and ammonium compounds mimic these conventional synthetic nitrogen fertilizers, and therefore embody similar concerns regarding compatibility with organic farming principles.

Nonsynthetic materials that mimic the functionality of synthetic nitrogen fertilizers have been a concern for NOSB in the past. Sodium nitrate was recommended for prohibition 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, 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 fertilizers1.”

Highly soluble nitrogen sources are out of step with international norms and can present barriers to international trade. For example, sodium nitrate is identified as a critical variance2 in the U.S.-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.

b) Promoting Soil Health and Preventive Management Practices
(Ref: OFPA 6518(m)(7) & NOSB 2004 Question 2 & NOSB 2001 Principle 1.1)

The unrestricted allowance of ammonia extract fertilizers is a practice that we believe will move the organic regulations farther away from, not closer to, the principles of fostering physical, chemical, biological systems of soil as the basis of soil and plant fertility, and emphasizing preventive management practices in crop operations. The regulations at §205.200 require organic operations to maintain or improve the natural resources of the operation, including soil and water quality, and §205.203 & §205.205 require producers to manage soil fertility and crop nutrients with cultural and preventive practices including crop rotations, cover crops, the application of compost and manure soil amendments, and tillage. In the absence of more explicit standards that prevent farmers from over-using highly soluble nitrogen inputs, there is a risk that the allowance of these materials could be used as a means of avoiding or deprioritizing these key organic management practices that improve soil health outcomes. Of course, not all operations would do this, but it does point to the need for a more comprehensive standards development process to address the role of appropriate (compatible) soluble nutrient inputs across organic crop production systems. Such safeguards may be accomplished through further work within the NOSB’s subsequent proposal on a new practice standard.

c) Expectations of Consumers for Organic Integrity
(Ref: NOSB 2004 Question 5)

The allowance of ammonia extract fertilizers threatens consumer trust and expectations of organic integrity. The environmental benefits of farming practices that improve water quality and soil health are a motivating factor when shoppers choose Organic, along with health, nutrition, and avoidance of harmful chemicals and artificial ingredients. Soil, water and climate health are all motivators that have begun to climb appreciably in the last 3 years, particularly as widespread climate disasters have taken a more prominent place in the news.

Objections to the compatibility of these substances with organic principles are serious enough to potentially lead to fragmentation of the organic market. If organic shoppers do not correlate these values with the Organic label, it will drive proliferation of soil health (“regenerative”) add-on labels that we already see in the marketplace. Some companies have indicated they may be prepared to establish private standards that exclude products produced with ammonia extracts from their supply chain.

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1 https://www.ams.usda.gov/sites/default/files/media/Sodium%20Nitrate%20Final%20Rec.pdf
2 https://www.ams.usda.gov/services/organic-certification/international-trade/Canada
d) **Protecting Long-term Viability of Organic Sector**  
(Ref: NOSB 2004 Question 6)

For organic farming to remain viable, organic integrity and consumer confidence must be upheld by strong standards. The organic sector is already threatened by a stagnant standards development process that is not keeping up with industry needs or consumer expectations, and the resulting proliferation of add-on labels and market fragmentation. We have sincere concerns that allowing a controversial material such as stripped ammonia would exacerbate issues that already fragment the organic market and may cause long-term harm to organic integrity. We believe that the allowance of stripped ammonia will not protect long-term viability of the organic sector.

e) **Resource Efficiency and Innovation**  
(Ref: NOSB 2004 Question 3 & NOSB 2001 Principle 1.2.6)

Ammonia extracts made from renewable resources, e.g. manure, are compatible with organic principles of using renewable resources and recycled materials. Ammonia extracts also allow for precision nutrient applications by isolating Nitrogen from Phosphorus, allowing each nutrient to be applied independently to the areas where it is needed, avoiding over or under-applications of either nutrient. By stabilizing nitrogen early in the manure life cycle, ammonia extract products prevent nitrogen loss from erosion and ammonia volatilization. We do not discount or dismiss the very valuable resource efficiency attributes of ammonia extract products.

When taking all of the factors of compatibility with organic principles into account, the positive attributes of ammonia extracts in terms of resource efficiencies do not outweigh the other concerns regarding compatibility with organic principles, particularly: consistency with historically allowed substances and international standards, promoting soil health and preventive management practices, consumer expectations of organic integrity, and protecting long-term viability of the organic sector. Resource efficiency is incredibly important, and fostering the cycling of resources is a foundational aspect of the organic regulations. However, it is not the organic farm’s responsibility to recycle the waste streams of the conventional livestock farming industry, especially when the use of such recycled waste streams has the potential to conflict with organic farming practices and principles. The organic regulations already require organic livestock operators to manage manure in a manner that optimizes recycling of nutrients and does not put soil or water quality at risk (§205.239(e)). OTA is committed to exploring and supporting other means and innovations to improve resource efficiency of organic farm inputs without compromising organic principles.

a) **Fraud Prevention**

The potential for fraud is not directly referenced in the NOSB’s compatibility criteria but must be considered to ensure that organic integrity is maintained. 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 (HNLF). 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 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 and expand 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 Prevention 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.

**Necessity for Production and Availability of Suitable Alternative Materials and Practices**

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)).

Many growers are not currently using these products and some may not want or need to use these products; alternative inputs and practices are sufficient for their soil fertility program. We recognize that stripped ammonia products represent an emerging product category and for the most part are not widely used, although there may be a few products in commercial use within recent years. As described in the Technical Background section of these comments (See Section II Impacted Products), products with high ammoniacal nitrogen (other than ammonia concentrates) appear to have only been OMRI or CDFA listed since last year (2020).

Other growers do see ammonia extracts as a potential helpful tool in narrow limited scenarios when plant-available nitrogen supplementation might be needed. For example: in cold soils when carbon-based fertilizers are not breaking down; after large rain events that remove all of the available nitrogen from the soil; as a supplement to a regular fertility program for high nitrogen requiring crops, like broccoli; as a rescue treatment for any reason where nitrogen is low; and for specialty organic crops like blueberry, which don’t utilize nitrate to any great degree and grow better on a fertility program that provides ammoniacal nitrogen. 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.

Overall, our concerns about incompatibility with organic principles outweigh the potential need for using this particular fertility tool. This is an extremely difficult position as we do not take lightly the significance of removing farmer tools. OTA is committed to exploring and supporting solutions that can help organic farmers’ ability to overcome these production challenges with tools that are compatible with organic principles.
Environmental and Human Health Impacts

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.

Scope of Impact

We agree with the Subcommittee’s assertion that the effectiveness of a prohibition or limitation is dependent on an exact definition of ammonia extracts and that unintended consequences must be avoided. Based on the Subcommittee’s proposed annotation language for “stripped ammonia” at §205.602, along with the classification motion language, the body of the proposal, the technical report, previous discussion document, and the petition, we believe we can understand the scope of “stripped ammonia” materials intended to be prohibited by this proposal.

As written in the Subcommittee’s motion to classify stripped ammonia as nonsynthetic, “Stripped ammonia is intended to encompass a wide variation of novel thermo-mechanical derivations of steam stripping technology that result in ammonia-containing condensate, aqua ammonia, ammonium-compound solutions, or any products thereof, such as further isolation of ammonium compounds into a solid by precipitation or solvent evaporation, and/or treatment with nitrifying bacteria.”

We understand the intent is to prohibit products made using ammonia stripping (steam stripping) technology to recover and purify ammonia from an agricultural feedstock. The products listed in Section II of this comment are examples of the recently-approved products that we understand may be impacted (note there are products in Section II that are identified as not stripped and therefore we wouldn’t expect to be prohibited).

We understand the intent is not to prohibit traditional manure products or other agricultural feedstocks that are processed only by physical filtering or removal of water. We also expect this would not prohibit long-time allowed inputs such as compost teas, liquid fish products, or manure slurries because only traditional means of physical filtering and/or removal of water are used and novel ammonia stripping (steam stripping) methods are not used.

Conclusion

OTA supports the NOSB’s proposal to prohibit stripped ammonia primarily on the basis of incompatibility with organic principles. We recognize that the assessment of compatibility is subjective. However this criteria is still grounded in law and in the NOSB’s legal decision-making framework. OFPA
criteria at §6517(c)(2)(a) (which references inconsistency) are specific to non-synthetic materials and §6518(m) (which addresses compatibility) apply to any substance both synthetic or non-synthetic.

Material review organizations such as OMRI confirm that they are able to understand, implement, and enforce the language of the proposed listing as presented in the Subcommittee’s motion. We support further clarifications (non-substantive) to be included in NOSB’s final recommendation as needed to ensure consistent implementation based our understanding of the scope of impact described above.

2. Concentrated Ammonia

NOSB is considering a motion to add concentrated ammonia as a prohibited substance at §205.602: “Concentrated Ammonia – contains greater than 3% ammoniacal nitrogen and the total nitrogen content is predominately (i.e., >50%) in the ammonia or ammonium form.”

Compatibility with Organic Principles

Concentrated ammonia products, as defined by the proposed listing motion, represent inputs that deliver significant levels of plant-available nitrogen which are not compatible with organic principles for the same reasons described previously for stripped ammonia. Despite technical differences that may exist between the manufacturing processes and outputs of stripped versus concentrated ammonia, there is no difference in the conclusion that these materials are not compatible with organic principles. The driving factors of this conclusion, as with stripped ammonia, are concerns about inconsistency with historically allowed substance and international standards, moving organic regulations away from promoting soil health and preventive management practices, eroding consumer trust and expectations of organic integrity, and threatening long-term viability of the organic sector.

Complications that arise from classifying long-time allowed substance as “incompatible”

Products produced by the ammonia concentration method have been OMRI Listed for nearly a decade and are not considered to be new or novel, yet the organic sector is just now identifying and addressing these materials as a result of a petition. We encourage ongoing conversation to identify the learning opportunities from this situation and implement solutions to prevent similar situations in the future. If the organic regulations had included a comprehensive standard regarding the role of highly soluble nutrients in organic farming systems, could this situation have been avoided? Perhaps, and we believe such standards can be developed through further work within the next proposal on new practice standard.

The NOP framework also needs to be evaluated for improvements to the feedback loops between certifiers, material reviewers, and NOP when a material review decision is questioned or a concern is raised. Stripped ammonia was brought to NOP’s attention in 2018 before any products were approved by material review organizations, but no action was taken to require NOSB’s evaluation (see Appendix C of the Petition); now at least 6 products – and counting – are approved (See Section II of this comment). NOP intervention could have ensured timely review of these substances prior to commercial proliferation.
The inherent structure of the National List allows all nonsynthetic materials unless specific action is taken to prohibit individual generic materials, and the National List reserves a section for the “exceptions” -- nonsynthetic that are prohibited. The development of the National List included proactive review of certain types\(^3\) of nonsynthetic materials, resulting in several listings of prohibited naturals. We need an ongoing mechanism for proactively identifying and reviewing incompatible nonsynthetic substances, instead of waiting for individual petitions.

**Necessity for Production and Availability of Suitable Alternative Materials and Practices**

As described previously for stripped ammonia, our concerns about incompatibility of high ammoniacal nitrogen inputs with organic principles outweigh the potential need of these tools. This is an extremely difficult position as we do not take lightly the significance of removing farmer tools. OTA is committed to exploring and supporting solutions that can help organic farmers’ ability to overcome these production challenges with tools that are compatible with organic principles.

**Environmental and Human Health Impacts**

As described previously for stripped ammonia, please refer to comments submitted by The Organic Center for information to support NOSB’s evaluation of environmental impacts and soil health.

**Scope of Impact**

As we understand it, this proposal for prohibiting “concentrated ammonia” would expand the scope of prohibited products (from the stripped ammonia proposal) to other nonsynthetic ammoniacal-nitrogen-containing inputs that may not already be covered (prohibited) by the proposal on stripped ammonia. This proposal would prohibit ammonia fertilizers (including those made without stripping technology) that exceed the numerical thresholds in the listing. The definition provided in the NOSB Subcommittee’s motion effectively serves as a “quantitative backstop” to prohibiting fertilizers that might not already be prohibited by process-based definition of stripped ammonia. The quantitative definition is beneficial because it has been difficult to define concentration (by its process) without implicating other items outside scope of petition. Water evaporation and solids filtration are very common processes with dozens of other nonsynthetic plant and animal materials.

It is absolutely critical that this quantitative definition not prohibit other common Nitrogen-containing nonsynthetic fertility inputs that are outside the intended scope of the petition and this proposal, 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 through traditional processes such as

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\(^3\) OFPA §6518(k)(4) Special review of botanical pesticides - The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticide should be included in the list of prohibited natural substances.
physical filtering or removal of water. If a product is made using these traditional means (i.e. not stripped) and does not exceed the numerical thresholds, it would not be prohibited by this proposal.

<table>
<thead>
<tr>
<th>Example of non-target material:</th>
<th>Total N %</th>
<th>Ammonical N%</th>
<th>Outcome under Concentrated Ammonia Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Nitrogen Liquid Fish Fertilizer</td>
<td>4%</td>
<td>Between 1-1.5%</td>
<td>Not prohibited but still subject to HNLF requirements</td>
</tr>
<tr>
<td>Manure Slurry</td>
<td>1%</td>
<td>Less than 0.5%</td>
<td>Not prohibited</td>
</tr>
<tr>
<td>Blended Fertilizer with Soluble Protein</td>
<td>12%</td>
<td>Less than 1%</td>
<td>Not prohibited</td>
</tr>
<tr>
<td>Compost Tea</td>
<td>Less than 1%</td>
<td>Less than 1%</td>
<td>Not prohibited</td>
</tr>
</tbody>
</table>

Also, it is important to ensure a common understanding about the status of stripped and concentrated ammonia if NOSB passes both the stripped and concentrated ammonia proposals and NOP combines into a single listing at §205.602. Our understanding is that stripped ammonia products would be prohibited full stop, and stripped ammonia products would not be allowed even if they are formulated below the numeric thresholds identified in the concentrated ammonia listing. Products that contain less than 3% Ammonical nitrogen would be allowed -- unless they are made by stripping in which case they’d be prohibited by the prohibition on stripped ammonia.

**Conclusion**

OTA supports the NOSB’s proposal to prohibit concentrated ammonia primarily on the basis of incompatibility with organic principles.

By looking at the classification language, the body of the proposal, the technical report, and the petition, we believe we can understand the scope of “concentrated ammonia” materials intended to be prohibited by this proposal. Material review organizations such as OMRI confirm that they are able to understand, implement, and enforce the language of the proposed listing as presented in the Subcommittee’s motion. We support further clarifications (non-substantive) to be included in NOSB’s final recommendation as needed to ensure consistent implementation based our understanding of the scope of impact described above. We also support the further development of best practices (such as updating NOP Guidance 5034 & NOP 5034-1) for sound and sensible implementation of this proposal, especially for common non-target materials that don’t readily have ammoniacal N analysis data available such as on-farm manure.

It is critical that the proposed language does not implicate any non-target materials outside the intended scope of the petition. If substantive edits are needed to ensure confidence, we support the Subcommittee in continuing to work on the language.
3. Practice Standard

NOSB is considering a motion to add a new practice standard to §205.203(f): “Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs.”

The development of practice standards regarding the use of highly soluble plant-available nutrients is an extremely important topic for NOSB consideration and focus. We agree that we need to be thinking about highly soluble nutrients in a comprehensive manner given the long-standing concern in the NOP regulations with these materials and the emergence of inputs other than mined minerals that deliver highly soluble nutrients. This entire issue of nutrient solubility in relation to the National List must be clarified in the future for growers across production systems to have clear standards. We can’t continue to create a standard via the National List and annotations. Many concerns regarding the use of highly soluble plant-available nutrients previously mention in regard to stripped and concentrated ammonia could be addressed through the development of practice standards.

The particular language in this proposed practice standard is not ready for implementation. Outlined below are the question that we have about the language, enforceability, and effectiveness of the proposal to advance organic standards.

We have questions about whether certifiers, inspectors, operators have the information and tools to understand, demonstrate, and verify compliance with this language.

- What is the definition of a “nitrogen product”? Which products are subject to verification?
- How are C:N ratio expected to be confirmed? This information is not readily available. Are labs required or may operators use third-party references? Which references appropriate?
- We need a stronger and more confident understanding of materials that would get restricted, especially for materials are on the “borderline” of 3:1 (guano, protein meals, protein hydrolysates, etc.)
- Is the calculation method clear? The 20% restriction has been a challenge to verify in the past of sodium nitrate. This language will expand and increase complexity of this verification practice to all operators even if they aren’t using sodium nitrate.
- What is the purpose of ingredient-level verification in final blended products that are above 3:1?

We also have questions about whether NOSB has enough technical information to inform a recommendation on this topic. Important areas of information may include:

- Difference between plant-availability and water-solubility of nutrients
- Definition of “highly soluble” substances
- Science-based and data-driven thresholds to distinguish target materials (e.g. is 3:1 the right line to draw?)
- Understanding of how highly soluble and plant-available nutrients are used across different soil types, crop types, and crop growth rates
- Understanding of international organic standard schemes related to use of highly soluble plant nutrients
- Research on environmental impacts of highly soluble nutrients in organic systems
We also have questions about applicability of this practice standard across crop production systems. As proposed, this practice standard would appear at §205.203. However, this section of the regulations is apparently not universal (e.g. NOP has said some provisions are not applicable to container-based production systems), so there is a risk this would only apply to operations that plant in the ground and create an uneven playing field. NOP needs to comment directly to this question before NOSB recommendations are developed so that intended outcomes can be realistically understood. Furthermore, the ongoing absence of standards specific to container and greenhouse production is extremely problematic. The wide variation and significant inconsistencies in certifiers’ implementation of the crop production standards is resulting in an un-level playing field among operators and confusion among consumers.

OTA support sending back to subcommittee for further work and keeping this topic on the work plan. The language presented in the Subcommittee’s third motion needs additional work but we strongly encourage this topic to stay on the NOSB work plan. This topic represents an extremely important area of work that is critical to advancing the organic standards.

V. Conclusion

OTA supports the NOSB’s proposal to prohibit stripped ammonia and concentrated ammonia primarily on the basis of incompatibility with organic principles. The driving factors of this conclusion are concerns about inconsistency with historically allowed substance and international standards, moving organic regulations away from promoting soil health and preventive management practices, eroding consumer trust and expectations of organic integrity, and threatening long-term viability of the organic sector. We also recognize the additional complications that arise from classifying long-time allowed concentrated ammonia products as incompatible with organic production principles.

We believe that many concerns regarding the use of highly soluble plant-available nutrients can be addressed through the development of practice standards. The concepts and language presented in the Subcommittee’s third motion need additional work but we strongly encourage this topic to stay on the NOSB work plan. This topic represents an extremely important area of work that is critical to advancing the organic standards.

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       cc: Laura Batcha
Farm Policy Director       Executive Director/CEO
Organic Trade Association       Organic Trade Association
Appendix A

§205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:
   (i) Applied to land used for a crop not intended for human consumption;
   (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
   (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that:
   (i) Established an initial C:N ratio of between 25:1 and 40:1; and
   (ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or
   (iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

(1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;

(2) A mined substance of low solubility;

(3) A mined substance of high solubility: Provided, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;

(4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: Provided, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(5) A plant or animal material that has been chemically altered by a manufacturing process: Provided, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in §205.601.

(e) The producer must not use:

(1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and

(3) Burning as a means of disposal for crop residues produced on the operation: Except, That, burning may be used to suppress the spread of disease or to stimulate seed germination.
Appendix B

NOSB Principles of Organic Production
(Ref: 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.
September 30, 2021

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

Docket: AMS-NOP-21-0038

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 do not oppose the NOSB’s proposal but 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 offer the following more detailed comments:

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. A proposal was presented in spring 2021 that proposed a minimum requirement of 80% biobased content and that 100% be required if and when these materials become available, but that proposal was sent back to subcommittee for further work.

**Proposed Definition and Listing**

The Subcommittee proposes to revise the definition at §205.2 (bold underlined 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. Must be **at least 80%** biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

No changes are being proposed to the current listing at §205.601(a)(2) Mulches:

(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

The Subcommittee’s proposed minimum requirement of 80% biobased content for biodegradable mulch films is the same minimum requirement that NOSB recommended for paper-based planting aids. The 80% limit is aspirational in the sense that no commercially viable products currently meet this criteria. The Subcommittee retains this limit due to ongoing concerns about the possibility of these films to decompose thoroughly, the comparative risk to soils and environment from these films versus risk from Polyethylene (plastic) mulch, and concerns about the precedent of allowing petroleum-derived products to be added directly to soils.
OTA Position

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 don’t oppose the NOSB’s proposal but seek to better understand the status of product development that has informed the Subcommittee’s conclusion that 80% biobased content is a realistic goal. We recognize the consistency that the 80% threshold has with the previous paper pots recommendation, but consistency for consistency’s sake is not useful if this does not lead to practical outcomes. Therefore, we warn against NOSB passing this proposal without more fully explaining the current status of product development, prospective timelines for availability of 80% biobased products, and other technical information that gives confidence to the Subcommittee’s conclusion that commercial products can actually be approved under this proposal. This information is important to relieve hesitation that this proposal might not lead to practical outcomes for allowing biodegradable alternatives to plastic mulch. Transparency and accountability on the part of NOSB is critical for assuring stakeholders and USDA that this proposal is actually heading down a path that will put tools in growers’ hands and that resources spent on rulemaking are worthwhile.

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
September 30, 2021

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

Docket: AMS-NOP-21-0038

RE: Crops Subcommittee – Sodium Nitrate (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crops Subcommittee’s Proposal on Sodium Nitrate.

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 agrees that the current situation regarding the sodium nitrate listing on the National List is confusing, and that the NOSB’s proposal will help alleviate confusion.

✓ OTA supports the subcommittee proposal to reinstate the listing of sodium nitrate for the purpose of clarifying the status of sodium nitrate.

Please see below for more detailed comments on Sodium Nitrate.

Background

Sodium nitrate (a.k.a. Chilean nitrate) is a mined mineral of high solubility. In the early years of developing the National List, it was added to §205.602 as a prohibited nonsynthetic substance with the following annotation: “use is restricted to no more than 20 percent of the crop’s total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.” The 20% restriction was a common restriction found in private certifier standards prior to the implementation of the NOP.

In spring 2011 during the Sunset Review of sodium nitrate, NOSB recommended by unanimous vote to relist sodium nitrate without the annotation, thereby entirely prohibiting its use, due to environmental and human health concerns and the lack of international harmonization of standards regarding this material. NOP never took action to renew the listing, therefore the listing became invalid on its sunset date of October 12, 2012. NOP issued a memo explaining the unusual circumstances of dealing with the invalid listing until NOP can complete rulemaking to prohibit sodium nitrate. NOP still not acted on the NOSB’s
recommendation, so the listing with the annotation still physically appears on the National List at §205.602 even though it is invalid.

Currently, sodium nitrate is permitted for use without specific restriction beyond the general requirements for organic operations to maintain or improve the natural resources of the operation, including soil and water quality (§205.200) and to manage crop nutrient and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water (§205.203).

OTA Position

The current situation regarding the sodium nitrate listing on the National List is confusing is confusing, and lacks oversight and transparency. When one reads the organic regulations and sees sodium nitrate listed with its restriction, its status as “invalid” is completely obscure. Organic stakeholders need to be able to look at the standards and readily understand the compliance requirements.

The NOSB’s proposal is to remedy and clarify the regulatory status of sodium nitrate. We support the NOSB’s motion to reinstate the listing of sodium nitrate as it appears at §205.602 with the restriction that it is not used for more than 20 percent of the crop’s total nitrogen requirements. This ensures that sodium nitrate isn’t allowed for unlimited use and will ensure ongoing sunset reviews. To be clear, this action would not actually expand the allowance, but it’s actually further restricting it from its current status as an unrestricted nonsynthetic substance.

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
September 30, 2021

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

**Docket: AMS-NOP-21-0038**

**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.
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 23 responses on our 2023 Crops Sunset Surveys (4 are new responses since the spring meeting). Below is a summary of the feedback received via OTA’s Sunset Surveys to date.


<table>
<thead>
<tr>
<th>Substance</th>
<th>Summary of Responses</th>
<th>Average rating of Necessity (from 1 to 5, with 1 being “unnecessary” and 5 being “critical /would leave organic without it”)</th>
</tr>
</thead>
</table>
| 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 tadpole 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. | 5 (critical, would leave organic without it) |
<table>
<thead>
<tr>
<th>Copper sulfate, continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 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.</td>
</tr>
</tbody>
</table>

**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.
Copper sulfate, continued

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 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.
<table>
<thead>
<tr>
<th>2. <strong>Response received from certified organic operations.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The material is necessary because:</strong></td>
</tr>
<tr>
<td>- Routine sanitization</td>
</tr>
<tr>
<td>- Irrigation water sanitation for specialty produce - vegetables and leafy greens. Currently use very infrequent. Would use if needed and as alternate to Chlorine based materials in the future.</td>
</tr>
<tr>
<td>- Important option sanitizer for irrigation lines and post-harvest handling. Important material option for food safety.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alternatives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- No alternative substances or practices are sufficient to eliminate need of this substance</td>
</tr>
<tr>
<td>- Peracetic acid and chlorine are alternatives, water treatments pre-irrigation to sanitize, other equipment sanitizers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If the material were prohibited:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Economic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. <strong>Responses</strong> 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, specialty crop vegetables, leafy greens, baby leaf salad mix, peaches, strawberries, tomatoes, etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The material is necessary because:</strong></td>
</tr>
<tr>
<td>- Used as disinfectant and fire blight control in the apples and pears orchards.</td>
</tr>
<tr>
<td>- Used in the formulation of hydrogen peroxide which we spray on our apple and pear trees to control fire blight.</td>
</tr>
<tr>
<td>- As a disinfectant in our berries cherries and grapes to help keep disease and fungi pathogens from spreading</td>
</tr>
<tr>
<td>- It helps to slow down the decay process on apples and pears by reducing microbial activity.</td>
</tr>
<tr>
<td>- Control disease</td>
</tr>
<tr>
<td>- Powdery &amp; downey mildew control</td>
</tr>
<tr>
<td>- Sanitizer</td>
</tr>
<tr>
<td>- Principally used as a response to an active bacterial infection.</td>
</tr>
<tr>
<td>- As a sanitizer of tools and equipment.</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- plant disease control and disinfecting equipment</td>
</tr>
</tbody>
</table>
### Peracetic acid, continued

**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
- Routinely for equipment disinfection/sanitation

**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)
- Chlorine under restriction for equipment sanitation
- Development of less toxic sanitizers would eliminate need of peracetic acid

**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.
- Increase use of other synthetic sanitizers

**EPA List 3 Inerts** for use in passive pheromone dispensers. §205.601(m)(2)
- No survey responses have been submitted.
- 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 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) |
|---|---|
| Responses received from certified organic operations that include Chlorine materials in their organic system plans for producing organic specialty crop 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 |
| - equipment and facility sanitation for control of food borne pathogens and other microbiological concerns faced in farming and processing environments (Sodium hypochlorite) |
| Frequency / application rates: |
| - Routinely |
| - Daily |
| - Daily |
| Alternatives: |
| - No alternative substances or practices are sufficient to eliminate need of this substance |
| - I have looked, but not been able to find appropriate products that are readily available |
| - Chemical sanitation is the only option for cleaning our surfaces |
| - We would have to find another way to get water to potable standards |
| - Chlorine dioxide, peracetic acid - both are effective, both are synthetic, comes down to availability, ease and safe handling and training of materials |
| If Chlorine materials were prohibited: |
| - Economic effects |
| - Food safety would be impacted |
| - There would be a significantly increased risk of human pathogen spread |
| - Costs of alternative materials would increases cost and business operations |
| Magnesium oxide – §205.601(j)(5) |
| No survey responses have been submitted so far. |

<table>
<thead>
<tr>
<th>Substance</th>
<th>Summary of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride – §205.602</td>
<td>No survey responses have been submitted so far.</td>
</tr>
<tr>
<td>Rotenone – §205.602</td>
<td>1 survey response received from a certified organic operation:</td>
</tr>
<tr>
<td></td>
<td>- Continue prohibition on rotenone. Alternatives are available.</td>
</tr>
</tbody>
</table>

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       cc: Laura Batcha
Farm Policy Director       Executive Director/CEO
Organic Trade Association      Organic Trade Association
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

<table>
<thead>
<tr>
<th>Unnecessary (don’t need it at all)</th>
<th>Neutral (nice to have but could live without it)</th>
<th>Critical (would leave organic without it)</th>
</tr>
</thead>
<tbody>
<tr>
<td>★</td>
<td>★</td>
<td>★</td>
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<tr>
<td>★</td>
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<td>★</td>
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<tr>
<td>★</td>
<td>★</td>
<td>★</td>
</tr>
</tbody>
</table>
September 30, 2021

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

Docket: AMS-NOP-21-0038

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 strongly supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review.

✓ OTA supports NOP’s prioritization of rulemaking on inerts and our member Task Force is poised to respond to the forthcoming Advanced Notice of Proposed Rulemaking.

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 strongly 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 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.

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. The [unanimous 2020 NOSB Resolution](https://www.ota.com) recognizes that a viable program allowing for the review and use of inerts must be created before the current listings are removed.

**OTA supports NOP’s prioritization of rulemaking on inerts and our member Task Force is poised to respond to the forthcoming Advanced Notice of Proposed Rulemaking.**

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. We appreciate that USDA has included Inerts on its [Unified Agenda](https://www.ota.com), but recognize its status as a “Long-Term Action” and the Advanced Notice of Proposed Rulemaking (ANPR) has yet to be published. It is critical that NOP continues to prioritize and proceed in a timely manner to resolve this longstanding regulatory discrepancy.

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 Task Force will inform OTA’s comments in response to the forthcoming ANPR. The Task Force has been meeting regularly since March 2021 and have made progress in establishing principles and criteria for evaluating effective and viable systems for reviewing inert ingredients. We have also explored several policy options for replacing EPA List 3 & 4 listings, and are collecting data about the impacts of each option on currently allowed and in-use inert ingredients. We look forward to providing substantive and constructive comments to support the NOP rulemaking process.

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, OTA

cc: Laura Batcha  
Executive Director/CEO, OTA

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\(^1\) 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](https://www.ota.com/FAC)
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. Substances 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.”
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
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.
September 30, 2021

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

Docket: AMS-NOP-21-0038  

RE: Handling Subcommittee – Proposal on Zein  

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee’s Proposal on Zein (maize protein). The Subcommittee is proposing to classify zein as a non-agricultural, non-synthetic substance, and to add it to § 205.605(a) of the National List, annotated as, “Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker.”

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 continues to be unaware of any member companies that are in need of or interested in using zein. We do not support adding a material to the National List unless there is a clear need, as expressed by organic certificate holders.

• If NOSB intends to keep with the precedent established for end products of the corn wet milling process (e.g. corn steep liquor) and classify zein as ‘nonsynthetic,’ then the material must also be classified as ‘agricultural’ and with a listing motion to § 205.606 of the National List.

• OTA does not support the addition of zein to the National List at § 205.605 (nonagricultural) because: 1) it is agricultural; and 2) the development of organic zein is possible. Although certified organic zein is not currently available, the Technical Review describes processes and materials that could comply with the organic product composition and processing standards. Adding zein to the National List at § 205.605 would discourage the development of organic zein because there would be no requirement to use it. Organic preference does not apply to § 205.605 of the National List.

• OTA does not support the allowance of zein in products that are NOP certified organic (95%+). Organic nutraceutical and pharmaceutical companies currently have the option to use non-organic agricultural ingredients in products certified to the “made with” (70%+ organic) label category. OTA would like to maintain the current course and let the USDA Organic seal and consumer demand drive the development and use of organic zein.
We offer the following more detailed comments:

**Zein is not necessary in organic handling**

The Organic Trade Association continues to be unaware of any member companies that are interested in or asking to use the petitioned substance. We have carried out extensive outreach to our Dietary Supplements Council and our membership as a whole, and we have not received a single response or comment in favor of adding zein to the National List.

To be clear, we do not support adding zein to the National List. We do however want to see an accurate classification for the record.

**Zein should be classified as agricultural (nonsynthetic)**

The petitioner is requesting that zein be allowed as a non-organically produced agricultural product. If NOSB intends to keep with the precedent that has been established for end products of the corn wet milling process (e.g. corn steep liquor) and classify zein as ‘nonsynthetic,’ then according to NOP Guidance 5033-2 (*Classification of Agricultural and Non-agricultural Materials*), the correct classification should be agricultural (non-synthetic).

When making classification decisions, it is important to start with the regulations before moving to guidance. 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. Zein meets this definition.

The definition of ‘nonagricultural’ is “A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product.”

Zein is not a mineral and it is not a bacterial culture. The definition goes on to include 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 ‘nonaggricultural’ is painfully ambiguous, we contend that corn gluten is a product of agriculture, and it has not lost its agricultural identity. Furthermore, because it is a product of agriculture and alternative methods that do not employ sulfur dioxide may be used (e.g. enzymatic corn wet milling, ozone wet milling), organic forms are possible.

With the regulation front and center, we can now turn to guidance. The classification tree for agricultural vs. non-agricultural addresses the second half of the ‘nonagricultural’ definition by saying that an agricultural product becomes nonagricultural if it is chemically changed via processes other than mechanical/physical/biological processes described under § 205.270. **In other words, if the substance is synthetic, then it is non-agricultural.**

In the case of Corn Steep Liquor, the precedent (and NOP directive) established is a ‘non-synthetic’ classification. A chemical reaction occurs, however, the non-synthetic determination was made on the argument “that lactic acid (fermentation) is the driving force behind the chemical change rather than the sulfurous acid.” This same argument must be applied to the agricultural vs. nonagricultural classification of zein, since it is also a product of corn, and the wet milling process.

Use of the **Agricultural vs. Non-agricultural Decision Tree** demonstrates the point:

1. Is the substance a mineral or bacterial culture as included in the definition of non-agricultural substance at section 205.2 of the USDA organic regulations? **NO (next question)**
2. Is the substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?

**NO**, it is a class of proteins found in the corn kernel (next question)

3. Is the substance a crop or livestock product or derived from crops or livestock?

**YES**, derived from corn /corn gluten meal (next question)

4. Has the substance been processed to the extent that its chemical structure has been changed?

**YES**, during the wet milling process disulfide bonds are broken, reducing the molecular weight of the resulting proteins (next question to determine how the chemical change was brought about)

5. Is the chemical change a result of a naturally occurring biological processes such as fermentation or use of enzymes; or a result of mechanical/physical/biological processes described under 205.270(a)?

**YES**, based on the analysis that informed the 2011 NOSB subcommittee recommendation, lactic acid (fermentation, biological process) is the driving force of the chemical change. Sulfur dioxide is added at the end of the process to stop the fermentation and prevent putrefaction. Therefore, consistent with the NOP Directive, zein should be classified as nonsynthetic. Although corn steep liquor and corn gluten meal are two separate byproducts of wet milling, both undergo a steeping step where the chemical change occurs. If chemical change is the result of a biological process, then both materials are nonsynthetic. If a material is classified as nonsynthetic, then it must also be classified as agricultural.

**Adding zein to § 205.605(a) would be technically incorrect and would stifle organic innovation**

In addition to being technically incorrect as described above, if zein is classified as nonagricultural and added to § 205.605 of the National List (synthetic or non-synthetic), there would be little to no incentive to develop organic zein. Unfortunately, organic preference does not apply to nonagricultural substances listed on § 205.605 of the National List. Commercial availability requirements apply only to § 205.606, unless the 205.605 substance is annotated otherwise (e.g. yeast). Therefore, if zein is placed on § 205.605 and organic zein were to become commercially available, certified operations would not be required to use it. The National List at § 205.606 was created to house agricultural ingredients that are commercially unavailable in organic form. As organic forms develop and become commercially available, the ingredient can sunset or be petitioned off the National List. Again, OTA does not support adding zein to the National List because there does not appear to be a need for it. However, from a classification perspective, if it is classified as nonsynthetic and added to the National List, it should be placed on § 205.606 where commercially availability would appropriately apply to an agricultural ingredient.

**Zein may be used in NOP certified products labeled as “made with organic ingredients.”**

Organic nutraceutical and pharmaceutical companies that would like to utilize zein for microencapsulation currently have a certification option under the National Organic Program in the “made with (70%+) labeling category.

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. For the “made with” label, agricultural ingredients 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 in or 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).”
If the development of an organic zein is not in the interest of the petitioner, because it cost-prohibitive to produce, then we suggest that zein not be added to the National List. Instead, it can continue to be allowed only in the 30% of 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
Organic Trade Association
September 30, 2021

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

Docket: AMS-NOP-21-0038

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.
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 30 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)).

<table>
<thead>
<tr>
<th>Substance</th>
<th>Summary of responses</th>
<th>Average rating of Essentiality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agar-Agar</strong></td>
<td><strong>3 Responses</strong> received from certified operations.</td>
<td>Rating not provided</td>
</tr>
<tr>
<td>Uses:</td>
<td>Used routinely in yogurt as a thickener/gelling agent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Used routinely in snack bars as a thickening agent in the binder so that the bar will maintain its shape and provide the chewy texture desired.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enriched agar growing medium for mushroom cultures</td>
<td></td>
</tr>
<tr>
<td><strong>If the material were prohibited:</strong></td>
<td>If agar-agar were to no longer be allowed the quality of our products would be altered.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>It would impact product quality. Snack bars would be deformed and break apart more easily, and not have the quality (chewy texture) desired.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agar-agar is the basis for standardized culturing of fungus. I don't know of another way to propagate and store cultures.</td>
<td></td>
</tr>
<tr>
<td><strong>Animal Enzymes</strong></td>
<td><strong>5 Responses</strong> received from certified operations.</td>
<td>4.8</td>
</tr>
<tr>
<td>(Rennet—animals derived; Catalase—bovine liver;</td>
<td><strong>Used routinely and/or daily in:</strong> Cheese – coagulant</td>
<td></td>
</tr>
</tbody>
</table>

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Member Services - 28 Vernon St., Suite 413, Brattleboro VT 05301 • (802) 275-3800 • fax: (802) 275-3801  
www.OTA.com
Animal lipase; Pancreatin; Pepsin; and Trypsin).

- 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.
- Used in various cheese ingredients, as a thickener, across multiple items daily to weekly

**The material is essential because:**
- Helps milk coagulate and turn fluid milk into curds and whey for cheesemaking. No suitable alternatives.

**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.
- Unaware of any alternatives or management practices that would eliminate its need

**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.
- Fruit Juices as a stabilizer

<table>
<thead>
<tr>
<th>Calcium Sulfate-Mined</th>
<th>Response received from a certified operation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Used in daily as a coagulant in Tofu products</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Carrageenan</th>
<th>Response received from a certified operation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In Fruit Juices as a stabilizer</td>
</tr>
<tr>
<td><strong>Glucono-delta-lactone</strong> – production by the oxidation of D-glucose with bromine water is prohibited.</td>
<td>Alternative are not sufficient because:</td>
</tr>
<tr>
<td></td>
<td>- There are no alternatives available, but have not tried any.</td>
</tr>
<tr>
<td>If the material were prohibited:</td>
<td>- Separation. Neutral on essentiality, nice to have it but could live without it.</td>
</tr>
<tr>
<td><strong>Tartaric Acid</strong> – made from grape wine</td>
<td>1 Response received from a certified operation.</td>
</tr>
<tr>
<td>Uses:</td>
<td>- Used in daily in tofu products as a coagulant</td>
</tr>
<tr>
<td>Alternative are not sufficient because:</td>
<td>- Have not tried alternatives and unaware of any management practices that would eliminate its need</td>
</tr>
<tr>
<td>The material is essential because:</td>
<td>- Being able to adjust our pH with TA helps us to avoid the use of the synthetic chemical SO2</td>
</tr>
<tr>
<td>Alternative are not sufficient because:</td>
<td>- There are times when we do not need to adjust the pH</td>
</tr>
<tr>
<td>If the material were prohibited:</td>
<td>- It would hinder us since we have spent years perfecting a synthetic free wine.</td>
</tr>
<tr>
<td></td>
<td>- There would be a change in defining character and flavor of the product</td>
</tr>
<tr>
<td>Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?</td>
<td>- Yes, but would need to grow it as a new industry. The organic grapes are used for wine, not for tartaric acid.</td>
</tr>
</tbody>
</table>
§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)).

<table>
<thead>
<tr>
<th>Substance</th>
<th>Summary of responses</th>
<th>Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)</th>
</tr>
</thead>
</table>
| 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. | **3 Responses** received from certified operations. Used routinely in:  
- Cheese as an anti-caking agent  
- Pizza, bagels, salad dressing  
- Cheese as an anti-caking agent  

The material is essential because:  
- There are no other alternatives. Clumped cheese would cause uneven ingredient distribution and can lead to greater manufacturing variability  
- No other alternatives. Would consider alternative as available  

If the material were prohibited:  
- Clumped cheese would not mix well contributing to inconsistent product quality; increase in production losses (product not meeting weight standards, downtime)  
- Would result in increased costs and negative impacts to business operations | 4.5 |
| Chlorine Materials  
- Calcium hypochlorite.  
- Chlorine dioxide.  
- Hypochlorous acid—generated from electrolyzed water | **6 Responses** received from certified organic operations. Please also see OTA’s comments directly below this survey results table. Used in:  
- Lettuces, routine, daily  
- 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  
- Processed vegetables and baby lettuce items for water sanitation and equipment cleaning; daily | 4.8 |
Sodium Hypochlorite

**The material is essential because:**
- Sanitation, prevention of spread of human pathogens – food safety
- 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.
- Alternative sanitizer materials exist with comparable effectiveness. We have tried chlorine dioxide and peracetic acid - preference for chlorine-based materials for effectiveness, availability, training.

**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
- Impacts to food safety and business operations

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
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.

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)
- As a defoamer in all products as needed
- As routinely as a flow agent (processing aid) used in the cheese drying and the cheese filling and pouching. It keeps the product from clumping in process, packaging and when consumer prepares finished product.

Alternative are not sufficient because:
- There are no other alternatives for our purposes
- Unknown whether there is a consistent commercial availability of organic rice hulls
- Research was conducted on organic rice hulls, but the results did not match in process performance. There are no other management practices that would eliminate the need for this material.

If the material were prohibited:
- We would not able to continue to use this material, cheese would not flow through the dryer efficiently. Cheese would not fill into pouches and clog filling system. Cheese would clump or cake in pouch and cheese would not mix well when making sauce.
**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.

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 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.

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
Organic Trade Association

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:
September 30, 2021

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

Docket: AMS-NOP-21-0038

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.
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 32 responses on our 2023 Livestock Sunset Surveys (11 are new responses since the spring meeting). Below is a summary of the feedback received via OTA’s Sunset Surveys to date.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Summary of Responses</th>
<th>Average rating of Necessity (from 1 to 5, with 1 being “unnecessary” and 5 being “critical /would leave organic without it”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated charcoal – §205.603(a)(6)</td>
<td>3 Responses received from certified organic operations that include activated charcoal in their organic system plan for raising dairy cows.</td>
<td>4.3</td>
</tr>
</tbody>
</table>

**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
| **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.  
- For healthy dairy cows  

**Frequency of use:**  
- Seldom, only as needed  
- 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 (Critical, would leave organic without it)  

| **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.  
- Used in treating sub clinical milk fever in fresh cows. To aid in maintaining normal Ca cycling within the body when blood Ca is nearing a critical level  

**Frequency of use:**  
- Seldom, only as needed  
- Less than 10% of fresh cows receive this.  

4
_alternatives:
- Calcium borogluconate is an alternative
- Calcium gluconate, but is more invasive to the cow to administer

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
- As long as these are maintained on the approved list
- It would increase the risk of at risk cows developing clinical milk fever, an animal welfare concern

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)

_4 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
- Chlorine materials are vital to maintain a clean and sanitary environment that promotes health and safety of people and animals.

frequency of use:
- Routine, daily
- As needed

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

### Kaolin pectin

<table>
<thead>
<tr>
<th>2 Response</th>
<th>received from a certified organic operation that includes kaolin pectin in their organic system plan for raising dairy cows.</th>
</tr>
</thead>
</table>

#### 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.
- As needed

#### 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

### Mineral oil

<table>
<thead>
<tr>
<th>2 Responses</th>
<th>received from certified organic operations that include mineral oil in their organic system plan for raising dairy cows.</th>
</tr>
</thead>
</table>

#### 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
- as needed
<table>
<thead>
<tr>
<th>Alternatives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Natural oils do not work, they get digested and do not move or break up the compaction.</td>
</tr>
<tr>
<td>- You can take good care of your animals, but compaction can still happen in rare cases.</td>
</tr>
<tr>
<td>- Organic rice Bran; Laxid Bolus. not as effective</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If the material were prohibited:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Negative effects on cow health</td>
</tr>
<tr>
<td>- Animal welfare would be impacted, also economic because the animal would either die or have to be sold if non-organic treatments are used.</td>
</tr>
<tr>
<td>- would eliminate an effect health treatment for dairy cattle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutritive supplements - injectable supplements of trace minerals, vitamins, and electrolytes. §205.603(a)(21)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nutritive supplements</strong> - injectable supplements of trace minerals, vitamins, and electrolytes. §205.603(a)(21)</td>
</tr>
<tr>
<td><strong>4 Responses</strong> received from certified organic operations that include nutritive supplements in their organic system plan for raising dairy cows. Vitamin D, Vitamin C, Vitamin B, Vit B12 and Multimin are specifically reference by the respondents.</td>
</tr>
<tr>
<td><strong>The material is necessary because:</strong></td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- Used for dairy cows as an immune system boosts-critical because organic treatment methods work by helping the cow help herself.</td>
</tr>
<tr>
<td>- helps animals with shipping fever and low energy when animals have been immunocompromise</td>
</tr>
<tr>
<td><strong>Frequency of use:</strong></td>
</tr>
<tr>
<td>- As needed</td>
</tr>
<tr>
<td>- Routinely, as needed when certain conditions arise</td>
</tr>
<tr>
<td>- Often</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alternative are not sufficient because:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- No alternative substances or practices are identified as sufficient to eliminate need of this substance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do advances in organic ration formulations change the need for injectable nutritive supplements?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- They are still helpful for animals having some kind of disease stress</td>
</tr>
<tr>
<td>- Possibly, but not in young calves</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
</tbody>
</table>
Feed Rations alone do not replace the need for injectable nutritive supplements such as when an animals become ill or refuses feed.

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, thereby their welfare would be lower. Injectable vitamins work very well in the organic health management system.

<table>
<thead>
<tr>
<th>Propylene glycol for treatment of ketosis §205.603(a)(27)</th>
<th><strong>5 Responses</strong> received from certified organic operations that include propylene glycol in their organic system plan for raising dairy cows.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The material is necessary because:</strong></td>
<td></td>
</tr>
<tr>
<td>- 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.</td>
<td></td>
</tr>
<tr>
<td>- Propylene glycol is another tool we can use for ketosis when other things don’t work.</td>
<td></td>
</tr>
<tr>
<td>- Used in treating ketosis in fresh cows</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of use:</strong></td>
<td></td>
</tr>
<tr>
<td>- As needed</td>
<td></td>
</tr>
<tr>
<td>- less than 15% of fresh cows</td>
<td></td>
</tr>
<tr>
<td><strong>Alternatives:</strong></td>
<td></td>
</tr>
<tr>
<td>- Dextrose - works but requires IV therapy</td>
<td></td>
</tr>
<tr>
<td>- We have used Ketonic. It is effective but sometimes not effective enough</td>
<td></td>
</tr>
<tr>
<td>- we have tried using molasses in place of with less efficacy</td>
<td></td>
</tr>
<tr>
<td>- Organic Glycerin; this is an effective treatment but availability is limited</td>
<td></td>
</tr>
<tr>
<td><strong>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?</strong></td>
<td></td>
</tr>
<tr>
<td>- For ketosis, dextrose is the only other effective option but requirement for IV therapy makes it more complicated to use</td>
<td></td>
</tr>
<tr>
<td>- Yes, These treatments are equally necessary. Electrolytes are used in conjunction with propylene glycol to help maintain the health of animals suffering from ketosis.</td>
<td></td>
</tr>
<tr>
<td><strong>If the material were prohibited:</strong></td>
<td></td>
</tr>
<tr>
<td>- Would reduce options for treatment of ketosis</td>
<td></td>
</tr>
<tr>
<td>- We would see increased risk of displaced abomasums in fresh cows</td>
<td></td>
</tr>
</tbody>
</table>
| Acidified sodium chlorite as a teat dip. §205.603(a)(28) & (b)(9) | 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 |
| Zinc sulfate as a hoof treatment. §205.603(b)(11) | 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. **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,

[Signature]

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association
Appendix A – Sample Survey for Crop and Livestock Inputs

1. 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

<table>
<thead>
<tr>
<th>Unnecessary (don’t need it at all)</th>
<th>Neutral (nice to have but could live without it)</th>
<th>Critical (would leave organic without it)</th>
</tr>
</thead>
<tbody>
<tr>
<td>★</td>
<td>★</td>
<td>★</td>
</tr>
</tbody>
</table>
September 30, 2021

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

Docket: AMS-NOP-21-0038

RE: Materials/GMO Subcommittee – Discussion Document on Excluded Methods Determinations

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\(^1\) Determinations. The Subcommittee is continuing the work of identifying emerging excluded methods technologies, and for this document is seeking feedback on the To Be Determined (TBD) list terms ‘cell fusion’ and protoplast fusion.’

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

For the sake of continuity, OTA is carrying forward many of our comments from the Spring 2021 meeting that we hold true and central to this topic. We recognize 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 and appreciative of the work being done in this area.

OTA supports the recommendations that have been made to date, and these include the clarification provided in the 2016 Recommendation that gene editing techniques such as CRISPR are currently prohibited under the NOP definition (7 CFR 205.1) of “excluded methods.” Further, we maintain that gene editing, gene silencing, synthetic biology and all of the other new and emerging techniques identified as ‘excluded

\(^1\) Excluded methods (§ 205.2 Terms defined). 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.
methods’ in the terminology chart are prohibited in organic production and handling because they meet the NOP definition of ‘excluded methods.’

As we continue this discussion, it is important that we do not lose sight of the strength of our existing definition of ‘excluded methods,’ as per § 205.2, 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 regulatory definition is important and helpful because it provides industry and certifiers with additional definitions and criteria to help guide evaluations and compliance decisions, and compiles more examples (new and emerging) that can be referred to and updated over time.

Questions for Stakeholders

1. Should the NOSB prioritize developing additional criteria for excluded methods determinations before continuing to work on the remaining TBD list techniques?

No. To ensure consistency with the determinations that have been made to date, additional criteria should not be developed. If additional criteria were developed, it would likely delay if not set the process back, because all of the methods on the list would need to be revisited. We believe the regulatory definition of ‘excluded methods’ in conjunction with the definitions and criteria previously recommended by NOSB are adequate, and NOSB should focus on completing the chart and passing a final recommendation to NOP as soon as possible.

Although we do not support developing additional criteria, we agree with the Spring 2021 comments from the Organic Seed Alliance on the need for a technical correction to the first criterion for scientific accuracy:

The genome is respected as an indivisible entity, and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g., through transmission of isolated recombinant DNA, RNA, or proteins). In vitro nucleic acid techniques are considered to be an invasion into the plant genome.

Finally, we recognize that the advances of modern agricultural biotechnology will continue, and so must the work of NOSB on this topic. Although we are not recommending additional criteria for the remaining TBD list, we expect an on-going evaluation process by NOSB to inform future updates to the guidance. We also see a need for additional information and resources that the organic certifiers

2 See Docket AMS-NOP-20-0089, Organic Seed Alliance comments (April 5, 2021), pg. 3
and inspectors can use to help determine where and when excluded methods may be applied in the production of any given input and/or in its supply chain.

To comply with the regulations and meet the promise of the organic label, it is critical that organic businesses, certifiers and other organic regulators have the necessary information to effectively inspect, certify and enforce the prohibition on excluded methods. At this point, perhaps our greatest challenge to upholding the prohibition on excluded methods is the lack of transparency around where and when the technology is being used and the shortcomings of current detection methods.

One solution is for NOSB, through the public comment process, to compile and create an electronic resource page - a one-stop shop - that the organic sector can use to find information on approved or pending GE crops, deregulated crops, GE food additives/processing aids and new and emerging technologies, etc. that are in use or in the pipeline. As a resource page, this could be updated periodically in a much simpler and more streamlined fashion than guidance and/or the regulations. 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 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 NOP webpage.

Another solution is to include an evaluation question in Technical Report that explores where and when genetic engineering may be used (generically) in the production of the National List input under review. Since accredited certifiers and Material Review Organizations (MROs) are the organizations that carry out excluded methods determinations, case-by-case at the brand-name level, the Technical Report could be a very helpful and valuable resource that certifiers and MROs could use to help inform their evaluation process.

The prohibition on genetic engineering in organic production and handling is not a choice, it’s a regulatory requirement for those choosing to be certified. It is also an expectation of consumers who choose to buy organic products. OTA strongly urges USDA to support NOSB in its effort of creating greater transparency around when and where excluded methods are being developed, commercialized and employed.

2. Is Policy Memo 13-1 complete and applied consistently in organic systems, i.e., do cell fusion and protoplast fusion need to remain on the TBD list or can they be moved to the excluded method section with the notes that allowance is made for these techniques when employed within taxonomic plant families?

OTA recommends that cell fusion and protoplast fusion employed within taxonomic plant families (consistent with PM 13-1) be moved to the list of techniques that are allowed (not Excluded Methods). The cell and protoplast fusion methods covered under this section of the list would be covered under the third sentence in the regulatory definition of ‘excluded methods’ as traditional breeding, hybridization, in vitro fertilization, and tissue culture. A recommendation by NOSB that explicitly recognizes that cell and protoplast fusion are not excluded methods when the donor cells/protoplasts fall within the same taxonomic plant family, and when donor or recipient organisms are not derived using techniques of recombinant DNA technology, will further validate long-time NOP policy and secure the historical and future use of such techniques within traditional breeding
programs. All other cell and protoplast fusion techniques would continue to be excluded methods per the NOP definition, and as further expanded upon in NOP Policy 13-1.

For the sake of greater clarity, OTA also recommends that cell and protoplast fusion involving recombinant DNA technology, techniques involving the direct introduction into the organism of hereditary materials prepared outside the organisms (such as microinjection), and use of donor cells or protoplasts that do not fall within the same taxonomic plant family be added to the list of techniques that are excluded methods – the YES list.

3. **As the NOSB makes excluded methods determinations on the remaining TBD list techniques, should this organic system include allowance for historical use and a time frame for phasing out excluded uses?**

Consistent with our Spring 2021 comments, this question should be directed specifically to each individual TBD technique and the answer will depend on the decision. Generally speaking, the purpose of the NOSB recommendation should be to clarify the regulatory definition with updated examples of new and emerging technologies, not to change the definition or its meaning or change the prohibited or allowed status of GE techniques that have been is use by the organic sector for a long time. 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 policy). The recommendation is for Guidance to support the regulation and it should help inform sound decision-making moving forward. In the case of techniques that have long been employed under traditional breeding programs, such as certain cell and protoplast fusion techniques, the guidance will further support that which is already allowed, or prohibited. If all cell fusion were to be prohibited, full stop (inconsistent with PM 13-1), then a time frame for phasing out would be necessary given its historical use according to NOP policy. For emerging technologies, such as gene editing and synthetic biology, the Guidance will affirm their prohibition - given that the techniques did not exist and therefore were not included, as examples, when the regulatory definition of excluded methods was drafted and finalized in 2002.

**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. The list of techniques covered to date and the clarification provided are incredibly important and useful, and are already assisting the organic sector with regulatory determinations. It is time to formalize this significant body of work.

We urge NOSB to complete its work on the existing terminology list and push forward with a recommendation to NOP that encompasses the ‘package’ of excluded methods terminology recommendations passed to date.

Finally, OTA continues to express the critical nature of standards development and the need for USDA to modernize the organic standards to better reflect the growth and developments of the organic market. Since the regulations were implemented in 2002, the organic practice standards have been updated just twice (pasture regulations and residue testing) and only one of those updates (pasture regulations) was the result of a NOSB recommendation. This is unacceptable for a thriving $60 billion industry that is 20 years of age.
The arrested state of the recent NOSB recommendations on organic seed usage is a perfect example and one that is very relevant to this Discussion Document. Many of the excluded methods that NOSB and the organic sector are grappling with are seed breeding techniques. As we know, seed is a fundamental input of an organic system and organic seed must be used unless an equivalent organically produced variety is commercially unavailable. The commercial availability clause developed 20 years ago, opens the door to conventional seed use in organic systems. Thankfully, organic and non-organic seed used on a certified organic farm must be produced without the use of excluded methods, and certified operations are obligated to meet those requirements. 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 compliant with the organic regulations, but this can be challenging since its production falls outside of the organic certification and oversight system. Our best option for success is to focus on and regulate ORGANIC seed, and to put our energy into the development of organic seed production and organic seed breeding. A focus on requiring and increasing organic seed usage will keep the oversight of excluded methods within the organic seed trade, ensure we have the best adapted varieties for organic growers and address the important environmental benefits of using seed produced organically rather than conventionally. All of this points to the critical importance of USDA implementing the 2018 and 2019 NOSB recommendations to update and strengthen the organic seed and planting stock regulation.

In addition to the organic seed recommendations, other NOSB proposals that are integral to this discussion but have not been acted upon by USDA include:

- Excluded Methods Prevention Strategy (2015, Guidance)
- Genetic Integrity Transparency of Seed Grown on Organic Land (2019, Instruction)
- Use of Excluded Methods Vaccines in Livestock Production (2019, Rulemaking)

OTA continues to urge NOSB and organic stakeholders to call upon USDA to prioritize standards development and address the backlog of NOSB recommendations that were developed to clarify and update the organic standards. Inaction by USDA is preventing unique segments of the organic industry from developing or advancing and lending to inconsistent certification practices and consumer confusion about the value of the organic label.

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
September 30, 2021

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

**Docket:** AMS-NOP-21-0038

**RE: Policy Subcommittee – Discussion on Oral and Written Comment Submission**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Policy Subcommittee Discussion Document on oral and written comment submissions. The subcommittee is seeking feedback from organic stakeholders on how it might modify established procedures to maximize community engagement practices that facilitate fair and equal access to NOSB members by all stakeholders.

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.

**Questions for Stakeholders:**

1. *Should the Board move to an entirely virtual format for oral comments the week before in-person meetings or maintain the pre-pandemic format of hearing oral comments, both virtually prior to the in-person meeting as well as in-person at the public NOSB meeting?*

   The Organic Trade Association supports a process that optimizes the ability for every organic stakeholder to provide comment. The virtual format for oral comments appears to be working very well and could provide NOSB with additional time at in-person meetings to hear from expert panels, extend complex topic discussions as needed, or even plan for other day-long organic education/stakeholder symposium opportunities. We have learned that public comment can be successfully accomplished through virtual means. Therefore, we encourage NOSB to think about how the in-person time can best utilize activities or functions that are not possible or ideal in a virtual setting. That said, we are not opposed to maintaining the pre-pandemic form of hearing oral comments virtually and at the in-person meeting. It is very possible that some stakeholders can only give oral comments in person. We favor equal opportunity for every organic stakeholder to give oral comments.
2. If NOSB meetings move to a model wherein all oral comments are heard virtually the week before the meeting, would it reduce the attendance of stakeholders at the Board meeting?

Perhaps for some, but not others. Oral comments (in-person), are certainly entertaining and liven up the experience of in-person attendance. There is also no doubt that the room begins to empty once the public comment session is over. None the less, we don’t believe in-person comments are, or should be, the number one driver of showing up in person.

3. Restrictions due to the pandemic aside, would the availability of a live-stream meeting discourage in-person attendance?

We support the live streaming of all NOSB meetings. The goal should not be in-person attendance, rather it should be accessibility for all organic stakeholders in a manner that works best for all.

4. Is the practice of scheduling multiple oral comments by a single organization (such as a business/company/non-profit/trade group) inherently unfair? Is there a path by which the Board can field multiple areas of expertise from a single organization, while balancing the limits of time, fairness, and the importance of receiving a wide range of stakeholder feedback?

No, we do not think it is unfair given that a single organization can represent thousands of organic stakeholders responding to an NOSB agenda of 30+ topics detailed by a 200+ page meeting packet. Our observation is that most organizations try to cover the full range of topics by utilizing staff according to areas of expertise. This approach seems perfectly fair and reasonable. The approach of an organization signing up multiple staff people to cover ONE topic may challenge the limits of time and fairness, although this may be difficult to parse out in advance (e.g. if commenters are addressing different aspects of a single topic).

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
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cc: Laura Batcha
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Organic Trade Association
September 24, 2021

Ms. Michelle Arsenault
National Organic Standards Board
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RE: Ammonia Extract Impacts Review

Dear Ms. Arsenault:

Thank you for this opportunity to provide comments on the Crops Subcommittee Proposal: 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 products 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 resulting
product from extraction.

✓ There is a lack of peer-reviewed science on environmental impacts of ammonia extract, so we must rely on
scientific publications that examine effects of analogues including synthetic nitrogen fertilizers.

✓ We offer a summary of science that shows how various forms of ammonia may impact soil health with
three main conclusions:

1) The majority of available research has not been conducted in organic systems, which should
influence outcomes of ammonia application.
2) Impacts of ammonia on soil health and soil biodiversity are variable across studies, with no
apparent trend of being beneficial.
3) Research suggests that 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 there are several manufacturing processes that capture and purify ammonia, all are early in their
commercialization with limited use, and are proprietary, there are few studies examining their impact on soil health.
However, because the final products in the extraction of ammonia (NH₃) and/or ammonium (NH₄⁺) are chemically identical, whether synthetically produced or stripped from a natural source, the final ammonia product should interact with crops and the environment similarly to synthetically produced 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:**
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. 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 stripping and ammonia concentration, reflect two main outputs: one of ammonia concentrated amongst other excising compounds including organic matter, and one of pure ammonium salt solution (ammonia + acid/base; e.g. ammonium sulfate) or dry powder. The technical report describes two manufacturing methods to extract ammonia, however, technological advances will certainly result in more extraction methods, also with various end formulations.

**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. Given that ammonia extract can be produced through a variety of methods, resulting in various formulations of ammonia and non-ammonia components, and that we expect that ammonia extract will vary in its impacts on soil health dependent on its resulting, specific formulations, we cannot lump all forms of “ammonia extract” into an overall assessment.

For instance, “ammonia stripping” generally results in specific ammonia compounds: some variation of ammonium salt depending on the acid used to trap ammonia gas at the end of the stripping process. Ammonia stripping from anaerobic digestion of animal manure, simply put, converts ammonium from organic matter (NH₄) to ammonia (NH₃) gas, which is then absorbed in an acid solution to create ammonium sulfate** or ammonium nitrate* (Baldi * et al. 2018). 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 extracts to understand their true impacts on soil health, initial hypotheses of their soil impact may be derived from studies looking at synthetic ammonia products and their impacts because their chemical structures are the same.
The majority of available research has not been conducted in organic systems:
We agree with NOSB’s position that “much more research regarding the use of these materials and of the soil health, plant health, and biological interactions is needed. There is conflicting information from studies on conventional soils and very little research conducted on organic soils.”

Two comprehensive meta-analyses that that cover nearly 200 studies combined and have been presented to support that argument that ammonia extract might benefit soil health are based on science primarily conducted in non-organic systems (Geisseler and Scow 2014; de Graff et al. 2019). This is important because there is much scientific evidence indicating that organic and conventional soils can differ in their structure, fertility, and biological activity (Wittwer et al. 2021; Mullath et al. 2020). For instance, a national assessment of soil properties of conventional versus organic farms across the U.S. shows that overall, organic soil has higher levels of soil organic matter than conventional (mean 8.33% vs 7.37% respectively; Ghabbour et al. 2017). Because the impact of ammonia products on soil properties is affected by the initial soil properties before use, and because there are differences in baseline soil properties between organic and conventional soils, it is important that ammonia products are tested in organic farming systems to get an accurate understanding of their impacts.

Effects of ammonia on soil health and soil biodiversity are variable:
Several large scale meta-analyses that consider nitrogen cycling and impacts of nitrogen on soil health exhibit much variation in their results. For instance, when comparing nitrogen losses in conventional versus organic, Noll et al. (2020) found no difference between organic and conventional (suggesting that leaching is no greater in one type of system), however the authors also suggest that the high variability and high uncertainty in both systems doesn’t allow them to make solid conclusions ‘on the statistical significance of these potential differences’. Similarly, the meta-analysis by de Graff et al. (2019) also seems plagued by large variation in the data included in their analysis. For example, the study concludes that using nitrogen fertilizers do not have a significantly negative impact on soil health including biodiversity, yet the authors make several statements throughout the paper highlighting the variation in their data:

“Despite a plethora of studies showing that high rates of synthetic N inputs negatively impact soil bacterial communities …our meta-analysis showed that high N fertilization rates had no significant negative effect on bacterial biodiversity.”

“While the significant reduction in diversity with higher relative to lower N inputs confirms that fertilizer inputs can negatively affect bacterial diversity…our data underscore that responses are highly variable.”

“This variability can often be explained by among-study differences in site conditions…where fertilization may differentially affect other factors that mediate soil biodiversity such as soil synthetic properties, plant productivity, plant diversity, and soil organic matter content.”

This variation means that, while there may be benefits to applying ammonia fertilizers to the soil, there are also enough detriments to wash out any strong signal of benefits, and blanket conclusions cannot be made about the positive or negative impacts of ammonia fertilizer on soil health. It is important to consider the scientific literature that shows there are negative impacts.

Some science that shows negative impacts:
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 2019).

However, de Graff et al. (2019) argues that nitrogen fertilizer application on farms with high levels of soil organic matter (SOM) will have less of a deleterious impact. This suggests that organic farms will be less impacted by the application of ammonia extract. We argue that this assumption cannot be made because, while research shows that organic farms tend to have more SOM than conventional, there is also variation within the organic system (e.g. 0.5% to 88.9% SOM in organic soil samples; Ghabbour et al. 2017).

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 nitrate and ammonium sulfate.

Urea can be found in raw-manure-based organic soil amendments, particularly in wet forms, and can have negative environmental impacts depending on how it is applied. 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.”

It should be noted that support for the use of ammonium extract is often paired with the comparison against excess manure use in organic, suggesting the use of AE would reduce the presence of urea and potential build-up of phosphorus. We agree with points by the NOSB that suggest the systems-based approach that organic farmers must employ does not solely rely on animal manure for fertilizer and that the diversity of practices can balance soil nutrients like phosphorus over time. We offer additional references to strengthen this argument. For instance, Pires et al. 2018 conducted a national survey of organic farmers to learn about the use of biological soil amendments of animal origin (BSAAOs- including raw, untreated and treated manure, and compost) and found that manure-based soil amendments were not solely relied upon to manage soil fertility. Only 41.3% of organic farmers applied these soil amendments to forage or grain crops, 50% applied to crops typically cooked or processed, and 60% of organic farmers applied to produce crops to be consumed fresh.

Furthermore, the scientific literature does not indicate that organic farms consistently exhibit excess soil phosphorus. There is no comprehensive study that identifies farming regions with excess phosphorus based on soil sampling, however maps of phosphorus production from animal manure (e.g. CAFOs) and phosphorus application across the U.S. have been created (Bian et al. 2021, Spiegal et al. 2020). It is noteworthy that that the locations of excess phosphorus application do not match up with current organic hotspots, but rather more so with organic coldspots (see Marasteanu and Jaenicke 2018). And proper soil fertility management with practices like implementing diverse crop rotations and diversifying organic soil amendments can help reduce the P-loading (Cavigelli et al. 2013).

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."

“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).

**Negative impacts of nitrogen fertilizers are reduced when applied with other soil amendments:**
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). This is supported by Tully and McAskill (2019) who conducted a meta-analysis with only organic studies and found that using a combination of organic amendments had a larger benefit on soil health than using only one amendment type. And de Graff et al. (2019) also found that soil “bacterial diversity increased (~ 6%) when N was applied as an organic fertilizer or as a combination of inorganic and organic N fertilizers.”

**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 (NH4)2SO4. 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 (NH4)2HPO4). 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,

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The Organic Center
### References:


September 22, 2021

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USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

RE: Materials Subcommittee – 2021 Research Priorities

Dear Ms. Arsenault:

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

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

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

- In response to the “Questions to Our Stakeholders” we support the inclusion of benefits and risks of livestock integration into crop rotations, nutritional value of organic animal products (such as dairy, meat, and eggs), comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products, and research into the effects of organic crop production on water.

- We also encourage you to include priorities focused on how to protect organic farmers from chemical contaminants and alternatives to conventional celery powder for curing organic meat.
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.

The Organic Center submitted was recently awarded a grant 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 USDA 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 and 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 technological 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.

**Answers to “Questions to Our Stakeholders”**

In response to the “Questions to Our Stakeholders” section, we would like to support the inclusion of benefits and risks of livestock integration into crop rotations, nutritional value of organic animal products (such as dairy, meat, and eggs), comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products, and research into the effects of organic crop production on water into the 2021 research priorities.

**Benefits and risks of livestock integration into crop rotations**

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 animal products (such as dairy, meat, and eggs)**

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.

**Comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products**

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

The Organic Center 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.

**Research into the effects of organic crop production on water**

Studies on the impacts of organic production on water are limited, but may have major implications for organic growers who must meet nutrient runoff restrictions (eg. in California). However, we want to emphasize that research on water quality should not be limited to nutrient losses, but must also take into account the impacts of pesticide pollution on waterways. Almost all water quality discussions that have been circulating recently focus on nutrient loss, but pesticide runoff has an equally, if not larger, impact on environmental and human health. We need to integrate research on pesticide residues into our discussion about water quality by reviewing the research on contaminated watersheds, the impacts of pesticide residues in water, and how organic can keep pesticides out of waterways.

In addition to pesticide impacts on water quality, some areas of research need include: (1) additional research examining the impacts of organic versus conventional systems on nutrient loss. Dr. Cambardella et al. were able to isolate all runoff from a farming system in Iowa, but there needs to be an examination of data from a broader regions to better understand the overarching effect that farming system has on nutrient runoff/leaching. (2) best practices on reducing nutrient runoff/leaching for organic farmers. This is a hot issue with organic farmers right now, because several states have mandated reductions in nutrient loss, but many of the recommended strategies for reduction are not developed with organic systems in mind, so might not be useful to organic farmers and/or would not have the same nutrient loss impact as they would on conventional farms.

**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 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 protection of organic farmers from chemical contaminants and conventional celery powder alternatives 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.

**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.

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
Sept. 24, 2021

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

Docket: AMS-NOP-21-0038

RE: Letter to Secretary Vilsack Regarding Climate Change and Organic Agriculture (dated July 13, 2021)

Dear Ms. Arsenault:

Thank you very much for allowing us to comment on The Compliance, Accreditation & Certification Subcommittee's (CACS) preliminary proposal: Letter to Secretary Vilsack Regarding Climate Change and Organic Agriculture.

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 Compliance, Accreditation & Certification Subcommittee for its Letter to Secretary Vilsack Regarding Climate Change and Organic Agriculture. We also acknowledge and thank the NOSB for including several scientific references that we suggested. We offer, for the record, some additional points with scientific support. We appreciate the NOSB's communication of science regarding the benefits of organic agriculture in regards to its ability to help provide climate change solutions.

Summary:

- The Organic Center supports the subcommittee's proposed letter and the proposed recommendations in response to the USDA's 90 Day Progress Report.

- We suggest minor additional points of consideration and clarification, with additional references that will emphasize the benefits of organic as supported by science that was not included in the final proposal.
We offer the following more detailed comments:

**Organic's ability to reduce greenhouse gases**

The statement presented in Paragraph 4: “Organic farming systems emit lower levels of GHG. Organic agriculture does not rely on synthetic inputs...” could include the additional point that *because* they do not rely on these synthetic inputs greenhouse gas emissions are reduced in two ways: 1) synthetic inputs like pesticides and especially ammonia nitrate fertilizer emit GHGs in their production, and 2) synthetic inputs require a lot of *energy* to manufacture and transport. Studies show that because organic farmers do not use synthetic fertilizer, they emit fewer greenhouse gases and require less energy overall than conventional farming (Seufert and Ramankutty 2017, Camargo et al. 2013, Pelletier et al. 2008, and Wood et al. 2006).

Another additional point that could be presented in Paragraph 4 to support the statement that “...others find that an overall reduction in GHG emissions, due to the widespread adoption of organic farming systems, is possible...” is that organic emits fewer GHGs on a per acre basis, particularly when crop rotations are diversified and lengthened (Hoffman et al. 2018), and organic farming can result in a reduction of N₂O emissions up to a 40.2% per hectare (Skinner et al. 2019). And see Meier et al. (2015) and van der Werf et al. (2020) who challenge the traditional Life Cycle Assessment models that compare global warming potential of organic and conventional farming and argue that GWP and costs of organic are often inaccurately overestimated.

**Organic’s ability to sequester carbon**

In paragraph 5, we encourage a stronger emphasis on the statement “…organic farms start from the vantage of having higher soil organic carbon, *suggesting that there is potential for these farms to contribute to climate change mitigation,*” as there is a lot of science that consistently shows organic farms have more soil carbon than conventional (Tully and McAskill 2019, see this report by The Organic Center that includes many statistics and references), and that the type of carbon found in soil under organic management is more stable and locked into the ground for longer periods of time (Ghabbour et al. 2017). Recent work even pinpoints which organic practices are better at building carbon in the soil (Crystal-Ornelas et al. 2021).

**The following are additional references not listed in the climate letter’s bibliography:**


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.

On behalf of The Organic Center, I would like to extend my thanks to the National Organic Standards Board for your commitment to furthering organic agriculture.

Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center