April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Materials Subcommittee
Discussion Document: Inert Ingredients in Organic Pesticide Products

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Inert Ingredients Discussion Document.

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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

We appreciate the continuing work of the National Organic Program (NOP) and NOSB to modernize the system for reviewing inert ingredients and replace the obsolete regulatory references on the NOP National List. This has been and continues to be a complex task with much to consider. Prior to the upcoming Spring meeting, OTA intended to reconvene our Inerts Task Force, a diverse group of end-users of pest control products, manufacturers and formulators of pest control products and inert ingredients, and persons with technical expertise on the composition and/or regulatory framework regarding pest control products used in organic production including certifiers, material reviewers, and former NOSB members and NOP staff.

This Task Force continues to be the best point of reference for informing our position. However, in light of the short time frame in which to convene, review, and draft comments on the Subcommittee's discussion document we were unable to assemble our Task Force before the close of comments. We have chosen instead to bring this group together in advance of the opening of the fall docket with the hope we can provide our perspective for consideration by the Subcommittee before its proposal is finalized for the fall agenda.

In the interim, we point to the comments we have made in response to the NOP's Advance Notice of Proposed Rulemaking (ANPR) on Inert Ingredients in Pesticides, as well as our response to the request for comments on the pre-discussion document posted last fall, both of which we have included in their entirety as attachments below. While these comments reflect the work of the Inerts Task Force as of its last meetings, we are cognizant that thinking may have changed or evolved in the time since these last meetings over two years ago. We offer a couple of instances where this may be the case.

In consideration of NOSB capacity, the Task Force recommended a deference to existing EPA assessments and regulatory references as a baseline "positive list" of allowances and requires NOSB to

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build a list of exceptions (prohibitions). This option presents efficiencies, especially when review can be made of a categorical listing and relies on the expertise of EPA versus placing this burden entirely on the NOSB. But we acknowledge the concern some have expressed that NOSB only has authority to create negative lists for prohibited non-synthetics. We anticipate the Task Force will still see the use of EPA's framework as a workable option, and also recognize the NOSB has the ability to prohibit any material via response to a petition by any member of the public, or the NOSB itself.

We also recognize the concern that inerts have a role in product formulations, and that in combination with other inert ingredients, may express synergistic effects found not to align with OFPA criteria. As above, should such a concern with inerts be known or discovered, any member of the public or the Board may petition for their removal. As we have stated previously in our comments, NOSB can take the necessary additional steps when considering single or categorial listings to review the unique aspects under OFPA that are not covered under EPA. For example, "inerts" as a generic category of substances are necessary for production and are consistent with organic farming.

We look forward to convening our Inerts Task Force to consider the stakeholder questions posed by the Subcommittee in its discussion document, as well as the Board's discussions, questions, and any concerns voiced at its upcoming meeting in Milwaukee, WI. When considering areas of expertise to inform the Subcommittee's review, we encourage the inclusion of speakers with experience in the complexities of material review, those with experience in crafting regulatory text and recommendations, those who can speak to the potential financial and resource burdens of each of the proposed options, as well as those with practical experience in the development and manufacture of product formulations for use by organic producers. Listening to such diversity will aid in drafting a recommendation that is rooted in the regulation and practical in execution. We invite the Subcommittee to reach out to us if we can be of assistance in connecting with any of our Inerts Task Force members, who represent this diversity of expertise.

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,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

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Attachments:

OTA Comments Submitted RE: Inert Ingredients Pre-Discussion Document, September 28, 2023
OTA Comments Submitted RE: Advanced Notice of Proposed Rulemaking, December 23, 2022

September 28, 2023

National Organic Standards Board
Materials Subcommittee
USDA–AMS–NOP

Docket: AMS-NOP-23-0026

RE: Request for Comments on Inert Ingredients Pre-discussion Document

Dear NOSB Materials Subcommittee:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials Subcommittee's request for input on an inert ingredients pre-discussion document the Subcommittee intends to prepare for the Spring 2024 NOSB meeting.

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. Our members include growers, shippers, processors, consumer brands, 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.

We appreciate the continuing work of the National Organic Program (NOP) and NOSB to modernize the system for reviewing inert ingredients and replace the obsolete regulatory references on the NOP National List. OTA's comments submitted here mirror those submitted in response to the NOP's Advance Notice of Proposed Rulemaking (ANPR) on Inert Ingredients in Pesticides, which we've included in their entirety as an attachment below. These comments were informed by OTA's Inerts Task Force, a diverse group of end-users of pest control products, manufacturers and formulators of pest control products and inert ingredients, and persons with technical expertise on the composition and/or regulatory framework regarding pest control products used in organic production including certifiers, material reviewers, and former NOSB members and NOP staff. Our position has not changed since submitting that response.

1. **Capacity** - NOSB members devote a considerable amount of time and energy in the sunset review of the materials that make up the National List. Adding significant numbers of individual listings for inert ingredients would increase this work-load. To what extent should NOSB consider current and potential future work-load when evaluating the options for modernizing the approval of inert ingredients in pesticide products?

In comments submitted in response to the ANPR, OTA assessed the options presented as well as additional approaches and/or modifications to ANPR options. Each option was assessed against criteria

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for viable solutions including legal alignment, transparency/clarity, adaptability, efficiency, and ensuring the continued availability of effective and familiar pest control tools for organic producers.

In consideration of NOSB capacity, OTA's recommended concept will defer to existing EPA assessments and regulatory references as baseline "positive list" of allowances and requires NOSB to build a list of exceptions (prohibitions). This approach is much more efficient than alternative options presented in the ANPR, namely Option D for individual listing. Under our concept, NOSB defers to EPA for baseline allowances and focuses its resources and attention on the exceptions. This approach builds on top of EPA's technical review and regulatory references instead of throwing it all out and expecting NOSB to start reviews from scratch for hundreds of substances. By focusing on the exceptions, we anticipate a smaller and more manageable workload for NOSB review and NOP rulemaking efforts.

We anticipate that the Prohibited List (of exceptions to EPA allowances) would be relatively small; we have compiled a starter list in *Appendix 4* of the attached ANPR comments that contains about two dozen candidates, which is far less than the total number of inerts that are currently in use that would need individual review and listing under Option D. Also, a majority of the substance we identify in *Appendix 4* as candidates for the Prohibited List already have a petition, and many also already have a Technical Report.

By deferring to and building on top of EPA's framework, our concept will remove redundancy in NOSB's review of substances that will be allowed. It also avoids any need for NOP to establish an interagency Memorandum of Understanding with EPA. The goal of establishing an MOU with EPA following the 2015 NOSB Recommendation proved to be too ambitious and too challenging to complete. Therefore, it is unwise to implement a solution that requires formal interagency partnership with EPA because it has failed in the past.

2. **Authority** - Congress granted the Environmental Protection Agency the authority to determine efficacy and safety of pesticide products, and Congress granted the NOP and NOSB the authority to determine which pesticide products align with the Organic Foods Production Act and National List Criteria (7 U.S.C. 6517 – 6518). When should NOSB rely on EPA's evaluations of safety, necessity, and efficacy in evaluating inert ingredients used in pesticide products? And when should NOP and NOSB assert its additional statutory constraints and regulatory criteria in the evaluation of inert ingredients in pesticide products?

As noted above, several criteria were used to assess viable options for replacing EPA Lists 3 & 4, including legal alignment. When evaluating legal alignment with EPA's and OFPA's framework for assessing inerts, we note the following in regard to our recommended concept for reviewing inerts:

- **Legal Alignment with EPA's Framework**
  The concept directly aligns with EPA's framework for assessing inerts. It refers to EPA's assessments and regulatory reference in the CFR, while still allowing a pathway for NOP to carve-out exceptions for organic.

- **Legal Alignment with OFPA's Framework**
  The concept directly aligns with OFPA §6517(c)(1)(B)(ii) because EPA-approved inerts satisfy the criterion for "not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern" (see discussion in *Section 4* of our ANPR comments below).

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Regarding the other OFPA criteria at § 6517(c)(1)(A) and § 6518, our concept requires NOSB to conduct a categorical review of EPA-approved inerts against the other criteria. This has been a legally acceptable approach taken in a number of examples where NOSB has conducted a single review of a categorical listing that covers many individual substances. Across the National List are examples of this practice of grouping substances together into a categorical list; some categories are smaller groups of materials (e.g. fixed copper; micronutrients), and some are larger (e.g. excipients). We recommend that NOSB continue this approach for inerts.

The procedure for the categorical review of the entire combined listing of EPA-approved inerts may be discussed further to ensure clarity of processes and criteria, and to incorporate any lessons learned from previous examples of categorical reviews. In short, the evaluation should compare and identify similarities in the high-level approaches of EPA's review process/criteria and NOSB's criteria/ responsibilities under OFPA. NOSB can take the necessary additional steps to review the unique aspects under OFPA that are not covered under EPA. For example, "inerts" as a generic category of substances are necessary for production and are consistent with organic farming.

The added element of our concept (in addition to the past examples of categorical allowances), is that we also recommend creating the opportunity to carve out exceptions that are prohibited. This would involve the development of criteria and an expedited process for submitting and evaluating petitions to prohibit specific inerts that would appear on a Prohibited List as exceptions to the categorical allowance of EPA-approved inerts. Our recommendation for developing a new petition process for inerts is supported by comments at the October 2010 NOSB Meeting, when "NOSB acknowledged that the current petition process may not be appropriately suited to review of individual inert ingredients (NOP Notice 11-6)." Further discussion of our thinking on this process is provided below in our ANPR comments.

3. **Flexibility** - A stable list of approved inert ingredients can provide assurance to manufacturers and producers that the tools they need to control pests and disease will be there when preventive measures have failed. These manufacturers will continue to innovate and develop tools, and scientific advancements may require additions to or removals from the list of approved inert ingredients. How rigid or flexible should the approved list of inert ingredients be to balance competing concerns? What mechanisms provide stakeholders the ability to simultaneously raise concerns, advance innovation, and maintain confidentiality in amending the approved list of inert ingredients used in pesticide products?

OTA believes the concept we presented in response to the ANPR provides the flexibility the industry requires to innovate and develop tools, while also incorporating opportunity for stakeholder input. In establishing a categorial review of EPA-approved synthetic inerts with the options we present in our concept, there is a structured approach that also allows some flexibility. The NOSB can develop and recommend a list of initial exceptions to EPA approval and use this to establish a list of prohibited inerts. This prohibited list can be updated through the established petition process, albeit with incorporation of an expedited process for inerts. The review of the categorical listing can be reviewed when it comes up for sunset review.

The OTA's recommended concept allows for public comment opportunities. EPA regulatory changes are subject to public comment, NOSB recommendations to prohibit inerts are subject to public comment, and

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the NOSB recommendation to list and sunset review the categorical allowance listing is subject to public comment.

The OTA concept is a win-win that will resolve the regulatory discrepancy regarding inert ingredients while satisfying criteria regarding legal alignment, transparency/clarity, adaptability, efficiency, and ensuring continued availability of effective and familiar pest control tools for organic producers.

Thank you for your consideration.

Sincerely,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman
CEO
Organic Trade Association

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December 23, 2022

Jared Clark
USDA–AMS–NOP
Room 2646-So., Ag Stop 0268
1400 Independence Ave. SW
Washington, DC 20250–0268

Docket: AMS–NOP–21–0008

RE: Inert Ingredients in Pesticides for Organic Production

Dear Mr. Clark

Thank you for this opportunity to provide comment on the Advanced Notice of Proposed Rulemaking (ANPR) on Inert Ingredients in Pesticides for Organic Production.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, consumer brands, 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.

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1. EXECUTIVE SUMMARY

Inert ingredients are used in conjunction with active ingredients for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed. The Advance Notice of Proposed Rulemaking (ANPR) on Inert Ingredients in Pesticides is an important step forward in a multi-year effort to modernize the system for reviewing inert ingredients and replace the obsolete regulatory references on the NOP National List.

OTA assessed the options presented in the ANPR as well as additional approaches and/or modifications to ANPR options. Each option was assessed against criteria for viable solutions including legal alignment, transparency/clarity, adaptability, efficiency, and ensuring the continued availability of effective and familiar pest control tools for organic producers.

The overall concept that OTA recommends is to: **Permit certain EPA-approved inert ingredients as a categorical listing of allowed synthetics and create a Prohibited List for individual exceptions.** OTA supports the following combination of options:

- **Option A:** Permit inert ingredients in 40 CFR 152.25(f) Table 2 - Inert Ingredients Permitted in Minimum Risk Pesticide Products.
- **Option B with Modifications:** Permit inert ingredients in 40 CFR 180 Subpart D Exempt from Tolerance, **and** limit only to substances with an allowance as an inert used only in accordance with the conditions of EPA's approval as an inert, **and** develop a list of exceptions to EPA's approval that are published on a Prohibited List in the NOP regulations.
- **Option C:** Permit inert ingredients in 40 CFR 180.1122 Inert ingredients of Semiochemical Dispensers only for use in passive pheromone dispensers.

OTA's concept is a **win-win** that will get the known inert ingredients of concern out of organic, without over-burdening the NOSB or requiring excessive time and resources. It leverages EPA's technical evaluations and regulatory references, while still allowing a pathway for exceptions. It minimizes disruption to growers' access to currently allowed pesticide products, while successfully transitioning away from obsolete EPA lists to the current EPA framework for assessing the toxicological concerns of inert ingredients. This approach will avoid the most difficult challenges that exist with other alternative options, namely: no interagency partnerships with EPA need to be negotiated or maintained, and we are not asking NOSB to individually review and build a positive list of inert ingredients from scratch.

We acknowledge there is not a perfect or easy solution, and additional considerations will need to be explored to successfully implement a new system for regulating inert ingredients in organic production. We urge USDA to keep up the momentum to advance viable solutions for inert ingredients in pesticides. This is a complex yet critical issue that demands sustained effort and collaboration. Modernizing the system for the review of inert ingredients is a priority of the organic industry. Pesticide product development and innovation are being stifled by outdated regulatory references for inert ingredients. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products.

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2. INTRODUCTION

Inert ingredients (a.k.a. "inerts") are necessary for the manufacturing of many various forms of pest control products. Inert ingredients are used in conjunction with active ingredients (a.k.a. "actives") to facilitate the 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 organic farmers can access only when their preventive pest, weed, and disease management practices have failed. The 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 for Organic Production

Inert ingredients in pest control products are subject to individual review and approval in accordance with USDA National Organic Program (NOP) National List of Allowed and Prohibited Substances. The NOP regulations define inert ingredients as "**any substance** (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) **other than an active ingredient which is intentionally included in any pesticide product**." 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. *See Section 3 for more info on EPA's current framework for evaluating inert ingredients.*

According to the information contained in the NOP Policy for reviewing inert ingredients, "**EPA has informed USDA that the 'Inerts List' system may no longer be effective or available for the NOP to reference in the Regulations... As a result, the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA**."

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

Interagency Efforts to Resolve Discrepancy

The NOP-NOSB-EPA Inerts Working Group was established in December 2010 and remained active through 2015. 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 recommendation was passed by the NOSB in the fall 2015 but was never implemented. At the Fall 2020 meeting, NOSB unanimously passed a resolution urging NOP to make progress on developing a viable alternative to EPA List 3 and 4. Refer to *Appendix 1* for a summary of the timeline and quick links.

2022 ANPR Overview

On September 2, 2022, the USDA National Organic Program published an Advance Notice of Proposed Rulemaking (ANPR) regarding the organic regulations on inert ingredients in pesticides used in organic production. The 2022 ANPR is a step forward in the multi-year effort to resolve the regulatory issue regarding inerts. The ANPR presents five options to replace current references to EPA List 3 and/or 4, and acknowledges that a robust alternative may require more than one option. USDA asks for stakeholder feedback that will be used to inform future rulemaking.

OTA Engagement & Task Force Overview

OTA has long supported NOP's prioritization of rulemaking on inerts in comments to the NOSB throughout every sunset review of EPA Lists 3 & 4, and in comments responding to NOP's Rulemaking Priorities. OTA established an Inerts Task Force in 2021 committed to identifying and advancing viable alternative solutions to resolve the longstanding discrepancy on the National List with respect to inerts. The Task Force met regularly during this comment period to discuss this ANPR and inform OTA's comments. Members of the Task Force included end-users of pest control products, manufacturers and formulators of pest control products and inert ingredients, and persons with technical expertise on the composition and/or regulatory framework regarding pest control products used in organic production including certifiers, material reviewers, and former NOSB members and NOP staff.

3. EPA FRAMEWORK

The Federal Food Drug and Cosmetic Act (FFDCA) requires that all inert ingredients used in pesticide products applied to food sites must have an applicable tolerance or tolerance exemption in the Code of Federal Regulations (CFR) established by EPA. EPA-approved inert ingredients for use in pesticide products applied to food are those that have either tolerances or tolerance exemptions in the 40 CFR part 180 (the majority are found in sections 180.910 – 960). All food use inert ingredients are also permitted

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for nonfood use. EPA also identifies inert ingredients that are approved for use in minimal risk pesticide products under 40 CFR 152.25, implementing FIFRA Section 25(b).

EPA References for further information:

- https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance
- https://www.epa.gov/sites/default/files/2015-12/documents/faqs.pdf
- https://www.epa.gov/sites/default/files/2021-03/documents/minrisk_inert_ingredients_w_tolerances_2016-11-16.pdf

4. OFPA FRAMEWORK

The Organic Foods Production Act (OFPA) contains the legal framework for establishing the National List of Allowed and Prohibited Substances, and the role of the National Organic Standards Board (NOSB) in evaluating substances and developing recommendations for amendments to the National List. See *Appendix 2* for key excerpts.

The National List Guidelines at §6517(c) state that synthetic substances may be permitted only if their use would not be harmful to human health or the environment, is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products, and is consistent with organic farming and handling. The guidelines also provide for specific allowance of inert ingredients that are not classified by EPA as inerts of toxicological concern. The NOSB must develop recommendations to amend the National List using the procedures and evaluation criteria specified in §6518.

Criterion at §6517(c)(1)(B)(ii)

NOP asks: "How should the phrase in OFPA '*not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern'* be interpreted in light of the EPA's current regulations and regulatory scheme for inert ingredients? (ANPR p. 54177)

OTA recognizes that the OFPA language is linked to EPA's old system for categorizing inerts by toxicological concern. As required by FQPA, EPA has reassessed all inerts under a new system of tolerances and tolerance exemptions codified at 40 CFR 180. OTA's interpretation of OFPA is that all current EPA-approved inerts comply with the OFPA criterion at §6517(c)(1)(B)(ii).

Other Criteria at §6517(c)(1)(A) and 6518

If an inert satisfies the criterion at §6517(c)(1)(B)(ii) (as interpreted above, includes all EPA-approved inerts), does the inert automatically also satisfy (A)(i) and/or any other elements of §6517 & §6518? NOP says (emphasis added): "Under OFPA at 7 U.S.C. 6517(c)(1)(B)(ii), the National List may provide for the use of substances in an organic farming or handling operation if the substance is used in production and

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contains synthetic inert ingredients that are not classified as inerts of toxicological concern by the EPA, in addition to the general considerations for National List substances at 7 U.S.C. 6517(c)(1)(A) and 6518(m). (ANPR p. 54173)

OTA agrees with NOP's statement above that even EPA-approved inerts also need to be reviewed against other criteria at §6517(c)(1)(A) and 6518. There are other examples from §6517(c)(1)(B) in sub-paragraph (i) (such as copper and sulfur compounds; soaps; horticultural oils; fish emulsions) that have been reviewed and continue to be reviewed against §6517(c)(1)(A) and §6518(m). This indicates that generic substances listed in §6517(c)(1)(B) are not exempt from other criteria. In many examples, NOSB has conducted "categorical" reviews of groups of substances, rather than individual substances.

5. CRITERIA FOR VIABLE SOLUTIONS

The following criteria were developed by the OTA Inerts Task Force for the purpose of evaluating the viability of potential solutions for replacing EPA Lists 3 & 4.

Legal Alignment
- Aligns with OFPA framework
- Aligns with EPA framework / Reflects current EPA reassessments
- Be aware of international harmonization; harmonize as appropriate, if possible

Transparency/Clarity
- Clear list of substances that are allowed (easy for formulators and certifiers to verify compliant ingredients; transparent, easily accessible, publicly available)
- Easy to understand and explain

Adaptable
- Ability for substances to be added, removed and re-reviewed (with an opportunity for public comments)
- Adaptable to new information and changes in cross-referenced standards (like EPA)

Efficient
- Uses resources wisely, including NOSB time and NOP rulemaking efforts (e.g., not reviewing and listing every single allowed inert on the National List; same goes for a negative list)
- Build on other agencies' existing work on inerts (layered approach; don't start from scratch or duplicate efforts already being done by other agencies)

Industry Impact
- Does not disrupt growers' access to critical pest control tools
- Must allow a range of substances sufficient to formulate variety of forms of products (e.g., wettable powders, etc.)

Other Considerations
- All stakeholders need to be willing to make practical compromise
- Need buy-in from pesticide formulators and inert manufacturers

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- Transition to new system must provide ample phase-in time for affected stakeholders

6. OTA RECOMMENDATION

CONCEPT

The overall concept that OTA recommends is to: **Permit certain EPA-approved inerts as a categorical listing of allowed synthetics and create a Prohibited List for individual exceptions.** The categorical listing would serve as a positive list and baseline allowance for EPA-approved inerts as presented in the ANPR Options A, B (with modifications), and C. The exceptions on the Prohibited List are curated and reviewed by NOSB through an expedited petition process and NOSB-initiated proposals. This concept leans on the existing listing of Excipients (non-active ingredients in livestock medications) on the National List as a model for how to structure the categorical allowance as a positive list of allowed synthetics that refers to other federal agencies, with the added opportunity to carve-out prohibited exceptions *(See Figure 2)*.

OTA presents this concept as a **win-win** approach. It will get the inert ingredients of known concern out of organic, without over-burdening NOSB's time or requiring excessive resources. It leverages EPA's technical evaluations and regulatory references, while still allowing a pathway for exceptions. It minimizes disruption to growers' access to currently allowed pesticide products, while successfully transitioning away from obsolete EPA lists to EPA's current framework for assessing the toxicological concerns of inerts. We acknowledge there is not a perfect or easy solution, but also believe that our concept will avoid the most difficult challenges that exist with other alternative options, namely: no interagency partnerships with EPA need to be negotiated or maintained, and we are not asking NOSB to individually review and build a positive list of inerts from scratch.

Figure 2: Comparison of OTA Concept vs. Excipients Listing. On the left is OTA's recommended concept for the structure of the inerts listing on the National List at §205.601(m) and §205.603(e). On the right is the existing language that appears on the National List for excipients which demonstrates the structure of a categorical listing with sub-paragraphs that refer to applicable authoritative federal agencies.

OTA Concept for Categorical Listing of Inerts	**Existing listing for Excipients**
205.601(m) Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is: (1) Approved by EPA on 40 CFR 152.25(f); (2) Approved by EPA on 40 CFR 180 – only substances with an allowance as an inert for use only under the with conditions of EPA approval (3) Approved by EPA on 40 CFR 180.1122 – for use only in passive pheromone dispensers; (4) Except that synthetic inerts identified on the Prohibited List are prohibited: (i) Nonylphenol Ethoxylates (ii) …	*205.603(f)* Excipients – only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

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Note - 205.603(e) inerts for pesticides in livestock production would mirror this listing except without item 3 for passive pheromone dispensers (not relevant to livestock)	

Concept Details:

1. **Identify EPA-approved inerts that would comprise the categorical listing of allowed synthetics.**
   OTA supports the following combination of options:
   - **Option A:** Permit inerts in 40 CFR 152.25(f) Table 2 - Inert Ingredients Permitted in Minimum Risk Pesticide Products.
   - **Option B (with modifications):** Permit inerts in 40 CFR 180 Subpart D Exempt from Tolerance and limit only to substances with an allowance as an inert and that are used in accordance with the conditions of EPA's approval as an inert. This includes any restrictions or limits on end-uses or formulations with certain actives. If the substance is only approved as an inert in conjunction with an active ingredient that is prohibited in organic, then that inert is *de facto* prohibited; it must not be used with other actives that may be allowed in organic, because that is outside of EPA's conditions for approval. Active ingredients that do not have an allowed use as an inert are not allowed.
   - **Option C:** Permit inerts in 40 CFR 180.1122 Inert ingredients of Semiochemical Dispensers only for use in passive pheromone dispensers.

2. **NOSB conducts a categorical review to evaluate and justify categorical baseline allowance under OFPA criteria and formalizes a recommendation to add the categorical listing to National List.**
   - The category being reviewed is the entire categorical listing of approved synthetics inerts described above. The OFPA criteria being applied are the criteria not already covered by EPA's approval process. Categorical review recurs at each Sunset Review.
   - Categorical review is not a new process. Use the existing listing of Excipients (§205.603(f)) as a model for how to conduct a single review of a categorical listing that covers many individual substances, as well as other examples: pheromones (§205.601(f)), trace minerals and vitamins in livestock feed additives (§205.603(2)-(3)), and food ingredients including nutrient vitamins and minerals (§205.605(b)), microorganisms (§205.605(a)), enzymes (§205.605(a)).
   - This step is necessary because USDA cannot add new synthetics to the National List without a recommendation from NOSB. Synthetics under 40 CFR 180 have not been recommended by NOSB. Furthermore, this will satisfy NOSB's responsibility to review the category against other OFPA criteria; doing it categorically is more efficient, reserves resources, and is acceptable under OFPA as demonstrated by the examples listed above.

3. **NOSB develops and recommends a list of exceptions to EPA-approval that are published on a Prohibited List in the NOP regulations.**
   - Identify substances that should be considered for the Prohibited List based on petitions received and from NOSB-initiated proposals for known inerts of concern. These prohibitions will "narrow" the categorical allowances established above. *Refer to Appendix 4* for a starter list of candidates for the Prohibited List.
   - Develop criteria and an expedited process for submitting and evaluating petitions to prohibit specific inerts. Utilize the process for developing the initial Prohibited List and for ongoing future petitions as needed.
   - Publish the final rule with the initial Prohibited List at the same time as the categorical allowances, so that there is no gap between publishing the categorical allowance and specific prohibitions.

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DISCUSSION: *Assessing the Concept against Criteria for Viable Solutions*

Below is an assessment of OTA's Recommended Concept against the Criteria for Viable Solution (identified above in *Section 5).*

- **Legal Alignment with EPA's Framework**

  The concept directly aligns with EPA's framework for assessing inerts. It refers to EPA's assessments and regulatory reference in the CFR, while still allowing a pathway for NOP to carve-out exceptions for organic.

- **Legal Alignment with OFPA's Framework**

  The concept directly aligns with OFPA §6517(c)(1)(B)(ii) because EPA-approved inerts satisfy the criterion for "not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern" (see discussion above in *Section 4*).

  Regarding the other OFPA criteria at § 6517(c)(1)(A) and § 6518, our concept requires NOSB to conduct a categorical review of EPA-approved inerts against the other criteria. This has been a legally acceptable approach taken in a number of examples where NOSB has conducted a single review of a categorical listing that covers many individual substances. Across the National List are examples of this practice of grouping substances together into a categorical list; some categories are smaller groups of materials (e.g. fixed copper; micronutrients), and some are larger (e.g. excipients). We recommend that NOSB continue this approach for inerts.

  The procedure for the categorical review of the entire combined listing of EPA-approved inerts may be discussed further to ensure clarity of processes and criteria, and to incorporate any lessons learned from previous examples of categorical reviews. In short, the evaluation should compare and identify similarities in the high-level approaches of EPA's review process/criteria and NOSB's criteria/ responsibilities under OFPA. NOSB can take the necessary additional steps to review the unique aspects under OFPA that are not covered under EPA. For example, "inerts" as a generic category of substances are necessary for production and are consistent with organic farming.

  The added element of our concept (in addition to the past examples of categorical allowances), is that we also recommend creating the opportunity to carve-out exceptions that are prohibited. This would involve the development of criteria and an expedited process for submitting and evaluating petitions to prohibit specific inerts that would appear on a Prohibited List as exceptions to the categorical allowance of EPA-approved inerts. Our recommendation for developing a new petition

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process for inerts is supported by comments at the October 2010 NOSB Meeting, when "NOSB acknowledged that the current petition process may not be appropriately suited to review of individual inert ingredients (NOP Notice 11-6)." Further discussion of our current thinking on this process is provided below.

- T**ransparency/Clarity**

  The CFR sections cited in the categorical listing comprise the "positive list" of allowed synthetics. These CFR sections and list of substances are publicly available and readily accessible. The prohibited exceptions would be published in the NOP regulations; also publicly available and readily accessible. This framework ensures that all stakeholders, including formulators and certifiers, have clear and transparent information to verify compliant ingredients in pesticide products for organic crop and livestock production. Simply check if the inert in question is listed in the relevant sections of the CFR, and then check that it is not on the prohibited list. The same approach is used right now, e.g., check to see if an inert is on EPA List 4, and then check to see that it is not on the NOP Memo 5088 as a revoked (prohibited) inert.

  This solution is also easy to understand and explain: EPA-approved inerts are on the positive list, and there are exceptions that are prohibited. For the past 22 years, the organic regulations have utilized an indirect positive list for inerts; our recommendation improves that structure by providing an opportunity to carve-out exceptions that are prohibited.

- **Adaptability**

  This concept is highly adaptable. The CFR lists can change, new substances can be added or removed, without needing to amend the NOP regulations. NOP rulemaking is an arduous process and as such, the NOP regulations are not able to change very often. This concept accommodates the ability for inerts to be assessed against new information without needing to go through the NOP rulemaking process.

  This concept does allow for public comment opportunities. EPA regulatory changes are subject to public comment, NOSB recommendations to prohibit inerts are subject to public comment, and the NOSB recommendation to list and sunset review the categorical allowance listing is subject to public comment.

- **Efficiency**

  OTA's recommended concept will defer to existing EPA assessments and regulatory references as baseline "positive list" of allowances and requires NOSB to build a list of exceptions (prohibitions). This approach is much more efficient than alternative options presented in the ANPR, namely Option D for individual listing. Under our concept, NOSB defers to EPA for baseline allowances and focuses its resources and attention on the exceptions. This approach builds on top of EPA's technical review and regulatory references instead of throwing it all out and expecting NOSB to start reviews from scratch for hundreds of substances. By focusing on the

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exceptions, we anticipate a smaller and more manageable workload for NOSB review and NOP rulemaking efforts.

We anticipate that the Prohibited List (of exceptions to EPA allowances) would be relatively small; we have compiled a starter list in *Appendix 4* that contains about two dozen candidates, which is far less than the total number of inerts that are currently in-use (~300) that would need individual review and listing under Option D. Also, a majority of the substance we identify in *Appendix 4* as candidates for the Prohibited List already have a petition, and many also already have a Technical Report.

By deferring to and building on top of EPA's framework, our concept will remove redundancy in NOSB's review of substances that will be allowed. It also avoids any need for NOP to establish an interagency Memorandum of Understanding with EPA. The goal of establishing an MOU with EPA following the 2015 NOSB Recommendation proved to be too ambitious and too challenging to complete. Therefore, it is unwise to implement a solution that requires formal interagency partnership with EPA because it has failed in the past.

- **Industry Impact**

  This concept is the most effective in minimizing industry impact, and avoiding disruption to growers' access to critical pest control tools, while successfully transitioning away from obsolete EPA lists to EPA's current framework for assessing the toxicological concerns of inerts. Substances that are currently in-use and legally permitted under EPA's current framework will continue to be allowed. This concept also opens space for formulators to innovate with inerts that have not previously been allowed due to the static nature of the old obsolete EPA List 4. It will ensure that the list of allowed substances is sufficient to formulate various forms of products (e.g. wettable powders, etc.).

PROCESS: *Implementing the Concept*

OTA recognizes that there are many important aspects of implementing our recommended concept that will need to be further developed. It is especially important that the process is clearly defined to support an efficient transition to the new system and to ensure ongoing maintenance of the system for decades after the system has been implemented. An outline of our current thinking is presented below.

Steps

1. NOSB spends 1-2 years developing a package of recommendations that address the Categorical Allowance & the initial Prohibited List. Public comment opportunities for each recommendation.
2. NOP Proposed Rule and public comment opportunity.
3. NOP Final Rule and implementation timeframes.

Developing the Prohibited List

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As described above, OTA's recommended concept would involve the development of criteria and an expedited process for submitting and evaluating petitions to prohibited specific inerts that would appear on a Prohibited List as exceptions to the categorical allowance of EPA-approved inerts.

The expedited **process** for submitting and evaluating petitions should be used to develop an initial Prohibited List that would be published in tandem with the categorical listing allowing EPA-approved inerts. The process should also be utilized for ongoing future petitions as needed. The process should provide clear instruction to petitioners and the NOSB regarding the information that is needed to accompany a petition, so that there is efficiency and consistency across petitioned substances. The process should align with and build on the information and evaluation that would have already been conducted by the EPA for inclusion in the CFR. The process could identify key targeted aspects of additional review where petitioners and NOSB should focus its efforts.

The **criteria** against which a petitioned inert is reviewed by NOSB should also be targeted to critical additional aspects that align and build on evaluation that would have already been conducted by the EPA. The criteria will help inform petitioners when and under what circumstances should a petition/prohibition be considered.

Where to publish the Prohibited List?

If the Prohibited List is positioned as a sub-paragraph of the categorical listing, it would result in having to duplicate listings in §205.601(m) and §205.603(f) for inerts that are prohibited in both crops and livestock production.

USDA should explore an **alternative location** in "§§ 205.608-205.619 [Reserved]" to maintain a list of prohibited synthetic inerts. In this section (which is currently vacant), the regulations could house one single list of prohibited synthetic inerts that would be applicable for both crops and livestock. The alternative location could also house the details relevant to the petition process and evaluation criteria, as appropriate. This approach could also be used as a model for Excipients if there ever are petitions to prohibit certain individual excipients.

Figure 3: Comparison of the Location of the Prohibited List in the Concept vs. Alternative Location

Concept listing for Inerts	**Concept with an <u>alternative location</u> for the Prohibited List**
205.601(m) Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is: (1) Approved by EPA on 40 CFR 152.25(f); (2) Approved by EPA on 40 CFR 180 – only substances with an allowance as an inert for use only under the with conditions of EPA approval (3) Approved by EPA on 40 CFR 180.1122 – for use only in passive pheromone dispensers; (4) Except that synthetic inerts identified on the Prohibited List are prohibited: (i) Nonylphenol Ethoxylates (ii) …	*205.601(m)* Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is: (1) Approved by EPA on 40 CFR 152.25(f); (2) Approved by EPA on 40 CFR 180 – only substances with an allowance as an inert for use only under the with conditions of EPA approval (3) Approved by EPA on 40 CFR 180.1122 – for use only in passive pheromone dispensers; (4) Except that synthetic inerts identified on the Prohibited List <u>at 205.608</u> are prohibited. <u>*205.608* Prohibited Synthetic Inerts and Excipients</u>

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	(a) Process for petitions and evaluation criteria (b) Prohibited List of Inerts (1) Nonylphenol Ethoxylates (2) …. (c) Prohibited List of Excipients

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ADDITIONAL CONSIDERATIONS

OTA acknowledges the following additional considerations that need to be explored to successfully implement a new system for regulating inert ingredients in pesticides for organic production.

- Develop approach for addressing inerts used exclusively in **non-food** use products, e.g., seed treatments, ornamentals, turf. Such items are not covered by 40 CFR 180. Some items may be nonsynthetic or permitted at 40 CFR 152.25(f).
- Develop approach for addressing inerts used in pesticides manufactured and used **outside of the U.S.** since these products won't be EPA-registered and may contain less common inert ingredients that are on List 4 (potentially currently in use) but not on 40 CFR 180.
- Develop an approach to addressing the **synthetic** inert ingredients that are currently in use but are not listed in 40 CFR (identified in *Appendix 3*).
- **Don't lose momentum!** Following the close of this ANPR comment period, NOP should keep up sustained efforts to advance viable solutions on inerts, and provide regular updates on progress to the public. Maintain regular communication with EPA to support positive interagency relationships.
- **Renew Lists 3 & 4** at upcoming sunset reviews until new system is implemented. Any solution – even resource-efficient solutions – will take multiple years and will inevitably overlap with the next sunset review. Renewal of these listing is 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. List 3 & 4 should only be removed once a new system has been implemented with the appropriate phase-in time.
- **Synthetic active** ingredients in pesticides still require individual listing. As actives are petitioned and reviewed at sunset, NOSB should have visibility on possible inerts used in combination with the generic active (in a manner that protects confidential information in accordance with applicable laws and regulations such as FIFRA Sec 10(d) and 40 CFR Part 2), technical information regarding the interactions between the inerts and the active, and develop proposals to annotate limitations on inerts as needed to comply with OFPA Criteria. NOP should develop instructions to support NOSB review of synthetic actives, and provide instruction and guidance to NOSB to support NOSB and material reviewers in distinguishing between active and inert functionality.
- Coordinate with **international trading partners** to support ongoing equivalency arrangements as appropriate and minimize disruption in international trade.

7. OTHER OPTIONS CONSIDERED

This section is an inventory of options for replacing EPA Lists 3 & 4 that were considered by OTA in developing our recommendation. The inventory includes all 5 options presented in the ANPR as well as additional approaches and/or modifications to ANPR options.

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ANPR Option A (25f)

ANPR Option A would replace the reference to EPA List 4, in part, with an allowance for inert ingredients allowed by EPA regulations in "minimum risk pesticides." Minimum risk pesticides are pesticides that are exempt from regulation under FIFRA because they pose little to no risk to human health or the environment. These inerts are listed in Table 2 at 40 CFR 152.25(f).

Reference: 152.25(f) Table 2 Inert Ingredients Permitted in Minimum Risk Pesticide Products

OTA supports this option in combination with other options as described in the OTA Recommendation (*Section 6)*. NOSB recommended the allowance of these substances in the 2015 Final Recommendation.

ANPR Option B (40 CFR 180)

ANPR Option B would replace reference to EPA List 4 with an allowance for an inert ingredient that is exempt from the requirement of a tolerance in 40 CFR part 180 subpart D and specifically cites sub-sections §§ 180.900–180.1381. Active ingredients in these sections that are exempt from the requirements of a tolerance which does not have an allowed use as an inert would not be permitted.

Reference: 40 CFR part 180 subpart D - Exemptions From Tolerances

OTA explored two modifications to this option from how it was presented by the NOP in the ANPR. The 1st modification is to *narrow* the cited sub-sections (to only a few certain sub-sections), and the 2nd modification is to *expand* the cited sub-sections to encompass the entirety of Subpart D. OTA supports Modification 2 in combination with other options as described in the OTA Recommendation (*Section 6)*.

Option B Modification 1 (Narrow): Limit CFR to 180.910-960

This option would permit inerts only if listed in certain sub-sections of 180 CFR §§ 180.910-180.960. These sub-sections contain the majority of the inerts already in use.

This option would prohibit synthetic inerts that are listed in §§180.960 – 180.1395, which includes only 6 inerts that could potentially be used in organic pesticide products (See *Figure 1* below). Although this option narrows the sub-sections, it does not significantly narrow the total number of substances compared to Option B as presented in the ANPR.

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Option B Modification 2 (Expand): Broadly cite 40 CFR Subpart D

This option would modify Option B to broadly cite the entirety of 40 CFR 180 Subpart D and not limit or exclude any sub-sections: "40 CFR part 180 subpart D ~~(§§ 180.900–180.1381)".~~ It would retain limits that only substances with specific allowance as inerts would be permitted. Active ingredients in these sections that are exempt from the requirements of a tolerance that do not have an allowed use as an inert would not be permitted.

Reference: 40 CFR part 180 subpart D - Exemptions From Tolerances

OTA supports this option in combination with other options as described in the OTA Recommendation (*Section 6)* with an opportunity to carve-out exceptions that are prohibited in organic.

This is a simple modification to Option B as presented in the ANPR that simply accounts for the full spectrum of 40 CFR 180 Subpart D, which is likely what NOP intended. In Option B, NOP's references ended at §180.1381, when in fact subpart D extends to § 180.1395, which is an additional 14 listings. It is more accurate and adaptable to cite the entirety of Subpart D.

It is also important to recognize that a broad citing of 40 CFR 180 Subpart D is not a "free-for-all" to use any substance listed as an inert in any organic pesticide. This option is limited only to substances with an allowance as an inert, including any restrictions or limits on which end-uses or formulations with certain actives. If the substance is only approved as an inert in conjunction with an active ingredient that is prohibited in organic, then that inert is *de facto* prohibited; it must not be used with other actives that may be allowed in organic, because that is outside of EPA's conditions for approval. Active ingredients that do not have an allowed use as an inert are not allowed.

When these limits are taken into account, this "expanded" modification actually *does not add any additional allowed inerts.* The substances in the additional 14 listings are either nonsynthetic or don't have allowance as an inert. In the future, additional listings may be added as new inerts are reviewed and approved by EPA. Even so, the allowance is limited only to substances that EPA has specifically allowed as inert only in combination with certain active ingredients, etc. Some would never be allowed because they are only allowed in formulations with actives that are prohibited in organic.

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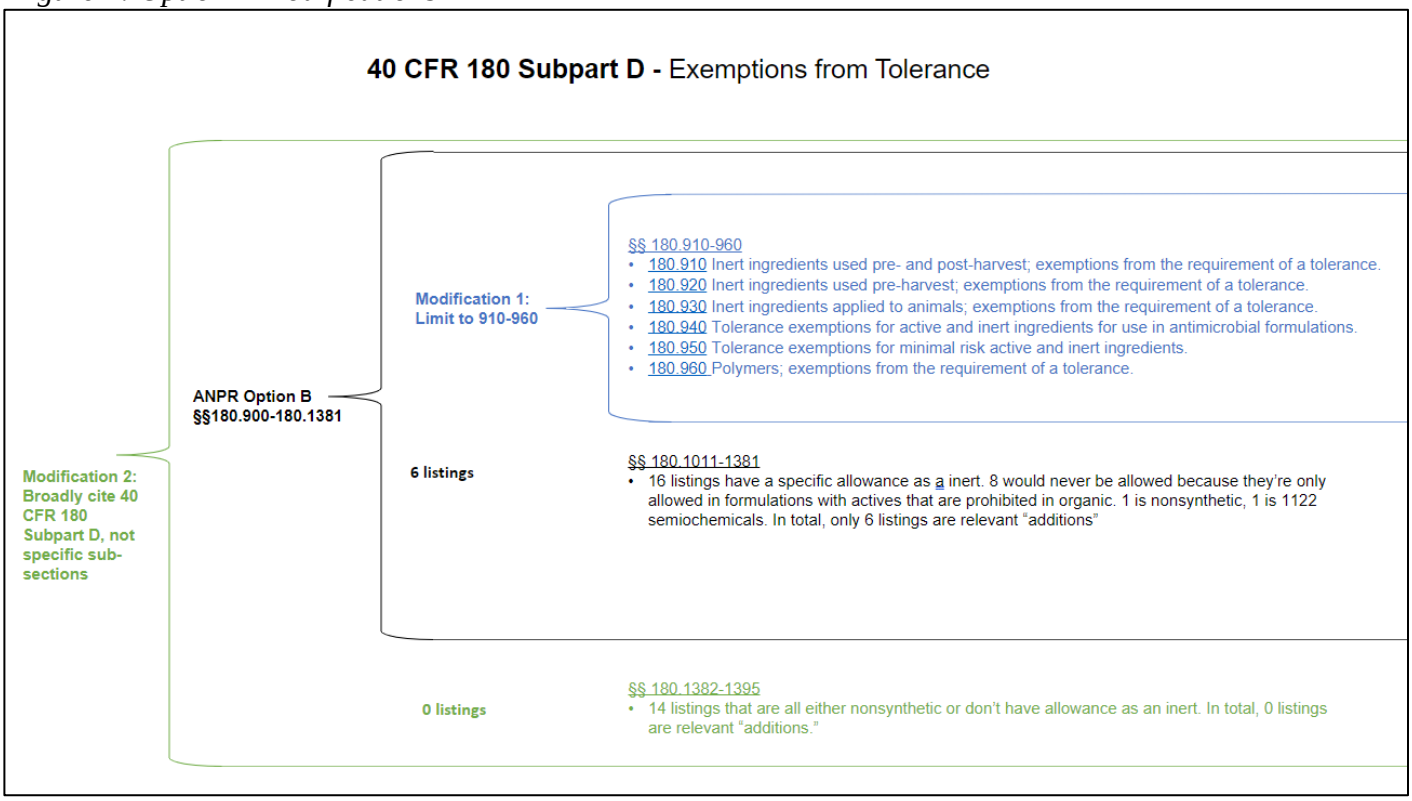
Figure 1: Option B modifications



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ANPR Option C (List 3)

This option would replace the current reference to EPA List 3 (for inert ingredients used in passive pheromone dispensers) with reference to the current EPA framework for inert ingredients in semiochemical dispensers.

Reference: 40 CFR 180.1122 Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.

OTA supports this option in combination with other options as described in the OTA Recommendation (*Section 6)*. NOSB recommended the allowance of these substances in the 2015 Final Recommendation.

ANPR Option D (Individual Listings)

Under this option as presented in the ANPR, inert ingredients would be migrated to the USDA organic regulations at 7 CFR part 205 as individual itemized or grouped listings. This would result in a codified list of inert ingredients, contained within the National List. Individual substances would be reviewed by the NOSB, and, if recommended, inert ingredients could be added to the National List by AMS through the rulemaking process.

OTA does not support this option because it is overly burdensome, costly, and redundant. There are approximately 274 List 4 inerts that are currently in use (not including the likely nonsynthetic substances) that would need to be reviewed by NOSB, be added to the National List through a proposed rule and final rule, and then undergo Sunset Review every 5 years beyond that. Not to mention any additional substances that are not on List 4 that have undergone EPA's reassessment that may be of interest to formulators and end-uses. That level of workload is untenable for the organic sector that is already strained by the stagnant rulemaking process. We estimate it will take at least 10 years and likely more to complete reviews and listings of all relevant inerts.

ANPR Option E (Status Quo)

This option would maintain the status quo and continue to rely on historical EPA List 3 and List 4. Any person may submit a petition to add an inert ingredient to the National List according to 7 CFR 205.607 and the procedures in NOP 3011.

OTA does not support this option. It fails to reflect the current EPA framework for assessing inerts. 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

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for use in organic approved pesticide products. Also, relying on petitions to add/remove from EPA Lists 3 & 4 is overly burdensome and costly, similar to the concerns identified for Option D individual listings.

SCIL (Safer Chemical Ingredient List under EPA Safer Choice Program)

This option would implement the 2015 NOSB Recommendation that would replace EPA List 3 & 4 with reference to the EPA's Safer Chemical Ingredient List (SCIL).

The EPA 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 **NOP-NOSB-EPA Inerts Working Group** recommended an approach that would build a program within the Safer Choice Program for reviewing inerts in pesticides. 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 Fall 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.

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- 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.

OTA does not support this option because it would take an incredibly large effort to implement this solution, primarily due to the inter-agency cooperation needed with EPA and the effort to complete other steps to set up program (pesticide criteria, OFPA criteria). We estimate it would be at least a 10-year timeline to establish the program. Furthermore, it is unlikely that inert manufacturers will be willing to apply (and pay) for their inerts to be added to the SCIL, which would significantly limit the allowed ingredients, and in turn, limit available tools for growers. It presents major uncertainty about what inerts would end up being allowed.

OTA agrees with the concerns identified by NOP in the ANPR regarding the challenges of referencing third-party lists (that live outside of federal regulations) on the National List. If the Safer Choice Program was ever eliminated, we would be in the same position as EPA List 4 referencing an obsolete program.

8. CONCLUSION

For the foregoing reasons, OTA recommends a solution that will: **Permit certain EPA-approved inert ingredients as a categorical listing of allowed synthetics and create a Prohibited List for individual exceptions.** This concept is a win-win that will resolve the regulatory discrepancy regarding inert ingredients while satisfying criteria regarding legal alignment, transparency/clarity, adaptability, efficiency, and ensuring continued availability of effective and familiar pest control tools for organic producers.

Thank you for the opportunity to comment.

Respectfully submitted,

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cc: Tom Chapman
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Appendix 1: History and Quick Links

2000 NOP Final Rule

The original NOP Final Rule on December 21, 2000 (65 FR 80547) allowed inerts on Lists 4A and 4B as inerts in pesticides for crop and livestock

2003 NOP Final Rule

NOP Final Rule published on November 3, 2003 (68 FR 61987) added allowance of EPA List 3 as inerts in passive pheromone dispensers

2010-4 **NOSB Recommendation: Guidance on Inerts in Pesticides**
Recommendation that NOP establish MOU with EPA and determine how to evaluate List 3 and 4 materials and new inert materials for inclusion on the National List.

2010-9 **NOP Guidance 5008: Reassessed Inert Ingredients**
NOP requires use of EPA's August 2004 list, minus the revoked inert ingredients, to verify compliant inert ingredients.

2011-2 NOP Notice 11-6: Petitions for Inert Ingredients

Options for petitioners to withdraw petitions pending the outcome of the EPA/NOP process

2011-7 NOP Guidance 5008: Reassessed Inerts Ingredients

Update to 2010 version.

2012-1 **NOSB Recommendation: Policy and Procedure on other "Inert" Ingredients**
Recommendation to proceed with reviewing individual inert ingredients

2015-10 **NOSB Recommendation: Annotation Change - EPA List 4**
Recommendation to collaborate with EPA Safer Choice Program

2020-10 **NOSB Resolution: Resolution on EPA List 4 Inerts**
Resolution urging NOP to take action to resolve the listing for the EPA List 4 inerts

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Appendix 2: OFPA Excerpts

Excerpts from the Organic Foods Production Act relevant to the framework for synthetic inerts in used in organic pesticide products. Not meant to be exhaustive.

6517. National List.

(c) Guidelines for prohibitions or exemptions. (1) Exemption for prohibited substances in organic production and handling operations

The National List may provide for the use of substances isn an organic farming or handling operation that are otherwise prohibited under this chapter only if—

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—

- (i) would not be harmful to human health or the environment;
- (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and
- (iii) is consistent with organic farming and handling;

(B) the substance—

- (i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or
- (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as **inerts** of toxicological concern; and

(C) the specific exemption is developed using the procedures described in subsection (d).

6518. National Organic Standards Board.

(l) Requirements

In establishing the proposed National List or proposed amendments to the National List, the Board shall—

- (1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;
- (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain **inert** materials that are synthetically produced; and

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- (3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

(m) Evaluation

In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board 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.

Appendix 3: Data Analysis

Methodology: Members of OTA's Inerts Task Force compiled an inventory of in-use inerts across OMRI, PCO, and WSDA Listed pesticide products, and cross-referenced each inerts to Title 40 of the Code of Federal Regulations.

Reference: Inerts Comparison Sheet 2022 (submitted to the comment docket: https://www.regulations.gov/comment/AMS-NOP-21-0008-0052)

OTA Findings:

- **301** inerts on EPA List 4 are currently in use.
  - **264** are listed or are likely listed in 40 CFR 152.25(f) and/or 40 CFR 180 Subpart D, and all would continue to be allowed under OTA's recommended concept
  - **27** are likely nonsynthetic (including water) and would continue to be allowed under OTA's recommended concept and any of the alternative options
  - **10** are synthetic and not listed in 40 CFR. *(8 Y's in Column G red highlight + 2 Y's in Column G no comment)*; need to develop an approach to address these items:

1309-42-8	Magnesium hydroxide
68071-54-5	Castor oil, dehydrated, polymer with p-tertbutylbenzoic acid, glycerol and phthalic anhydride

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6381-92-6	Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate
7803-63-6	Ammonium bisulfate
68514-61-4	Milk, hydrolyzed
68187-76-8	Castor oil, sulfated, sodium salt
860-22-0	FD&C Blue No. 2
134-03-2	Sodium ascorbate
1312-76-1	Silicic acid, potassium salt
84775-78-0	Ascophyllum nodosum, ext

Appendix 4: Candidates for Prohibited List

OTA's recommended concept would involve the development of criteria and an expedited process for submitting and evaluating petitions to prohibited specific inerts that would appear on a Prohibited List as exceptions to the categorical allowance of EPA-approved inerts. The following substances are potential candidates that could be identified on the Prohibited List because they have either been previously petitioned or have been identified by OTA members as inerts of concern and may warrant further evaluation by NOSB. This list is provided as an example only. Further research is needed to confirm whether these substances would be appropriate or necessarily to list as exceptions (prohibitions) to EPA-approval as inerts.; i.e. some may already be prohibited by EPA.

Inerts identified in the NOP Petitioned Substances Database

1. Propylene Carbonate
3. Tetrahydrofufuryl Alcohol (THFA) - revoked by EPA on 2006-08-09 (71 FR 45411)
4. Distilled Tall Oil
5. Ethylene Glycol
6. Ethylenediaminedisuccinic Acid (Ethylene DDS)
7. Hydroxyethylidene Diphosphonic Acid (HEDP)
8. Isoparaffinic Hydrocarbon
9. Manganese Sulfate Monohydrate
10. Polyglyceryl Phthalate Ester of Coconut Oil Fatty Acid
12. 2,4,7,9-Tetramethyl-5-Decyne-4,7-Diol
13. 2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole (Sumisorb 300)
13. 2-hydroxy-4-n-octoxybenzo-phenone (Sumisorb 130)
14. Butylated Hydroxytoluene (BHT)
15. Chitosan
16. Difluoroethane (DFE)

Other inerts of concern

17. Nonylphenol ethoxylates (NPEs)
    - Note the NOSB Discussion Document (Fall 2016) on prohibiting NPEs
18. Per- and poly-fluoroalkyl substances (PFAS)
    - Note the EPA notice on 12/14/2022 removing 12 PFAS chemicals from the current list of inert ingredients approved for use in pesticide products

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- Note the EPA strategic roadmap to address PFAS

19. Polyoxyethylene tallow amine (POEA; POE-T; CAS No. 61791-26-2)
20. Benzene – revoked by EPA on 2002-04-04 (67 FR 16027)
21. Toluene – revoked by EPA on 2006-03-22 (71 FR 14411)
22. Xylene
23. Bisphenol A

Other observations
- Piperonyl butoxide (PBO) – Listed at 40 CFR 180.905 but does not have allowance as an inert; would already be prohibited under OTA's Recommendation

Appendix 5: Response to ANPR Questions

General

1. *Should AMS replace the references in the USDA organic regulations to the outdated EPA List 3 and List 4? What problems are caused by the current references to EPA List 3 and List 4?*

   Yes, AMS should replace the outdated EPA List 3 and List 4 references. See Section 7: ANPR Option E (Status Quo).

2. *How do various options align (or not align) with the statute (OFPA) and with AMS's authority, as provided under the statute, to regulate inert ingredients?*

   See OTA's recommended concept in Section 6 and other options considered in Section 7.

3. *What other options might be available that AMS and NOSB have not considered?*

   See OTA's recommended concept in Section 6 and other options considered in Section 7.

Third-Party (Non-Codified) Lists

4. *Should AMS rely on third-party list(s) as a means of evaluating inert ingredients permitted in organic production? If so, which third-party list(s) would be appropriate, and why?*

   See OTA's recommended concept in Section 6 that refers to EPA Lists in 40 CFR.

5. *To what degree should the National List include individual substances allowed as synthetic inert ingredients versus referencing third-party lists established outside of AMS?*

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See OTA's recommended concept in Section 6 that utilizes a combination of EPA Lists and individual exceptions.

6. *How feasible or acceptable is it for AMS to reference third-party lists (lists that exist outside of Federal regulations that are not published in the CFR) to update current references on the National List to EPA List 3 and List 4?*

   See Section 7: SCIL for discussion of non-CFR lists.

7. *How does the approval and update process (via incorporation by reference) affect the feasibility of referencing a third-party list(s) for inert ingredients on the National List? For example, if a third-party list of inerts is not published in editions, it is ineligible for incorporation by reference. Conversely, if a third-party list were published in editions, AMS would need to take rulemaking action to update the reference to a newer edition.*

   No comment.

Administrative Capacity

8. *AMS recognizes that it takes time and effort for the NOSB to perform a sunset review for each item on the National List, and there are likely hundreds of substances used as inert ingredients under current USDA organic regulations. How could AMS and the NOSB complete the necessary sunset reviews if substances were listed individually on the National List?*

   See OTA's recommended concept in Section 6 and other options considered in Section 7.

9. *How should the time constraints influence the approach that AMS should take regarding inert ingredients?*

   See OTA's comments regarding efficiency in Sections 5-7.

10. *The referenced Safer Choice program framework includes accreditation of third-party organizations, evaluation of substances against published standards by those accredited organizations, agency review of the evaluation, and publication of a list of approved substances. If AMS adopted a similar framework to that of the Safer Choice program, what would this look like, and would it address the regulatory challenges and capacity constraints outlined in this ANPR? What additional AMS staff resources would be required to accomplish this?*

    No comment.

11. *If inert ingredients are individually listed, which set of substances from EPA List 3 and List 4 should be initially migrated to the National List, and how would those substances be identified?*

    No comment.

12. *AMS notes that the NOSB has received more than 15 petitions to add specific inert ingredients to the National List, yet none have been recommended for addition to the National List. If the established petition*

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process is used to amend the National List to add or remove inert ingredients would this approach satisfy the needs of the organic industry?

See OTA's recommended concept in Section 6.

EPA Process and References

13. *How should the phrase in OFPA ''not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern'' be interpreted in light of the EPA's current regulations and regulatory scheme for inert ingredients (see 7 U.S.C. 6517(c))?*

    See Section 4: OFPA Framework.

14. *If none of the inert ingredients permitted under EPA regulations are considered to be of toxicological concern to the EPA, should AMS permit all EPA allowed inert ingredients in pesticides for organic production? What are the risks and benefits associated with this option?*

    See OTA's recommended concept in Section 6.

15. *If any inert ingredients that are allowed by EPA should not be permitted under USDA organic regulations, what are those substances and why should they not be permitted as inert ingredients used in organic production?*

    See OTA's recommended concept in Section 6 and substances in Appendix 4: Candidates for Prohibited List.

16. *Can inert ingredients currently allowed by EPA regulations (i.e., in the Code of Federal Regulations) be sorted or classified according to toxicological concern? If some substances are of more concern, should AMS prohibit specific substances, or groups of substances, while allowing all other substances allowed as inert ingredients by the EPA? What criteria, specifically, would be appropriate for AMS to consider when assessing ''toxicological concern''?*

    See OTA's recommended concept in Section 6 and substances in Appendix 4: Candidates for Prohibited List.

17. *If inerts at 40 CFR 152.25(f)(2) were used with active ingredients in pesticide products that are not exempt from regulation (i.e., not ''minimum risk pesticides'') the inert ingredient would require a tolerance (or exemption from the requirements of a tolerance) at 40 CFR part 180 for use in food or feed crops. AMS understands that there is not uniformity among 40 CFR 152.25(f)(2), 40 CFR part 180, and EPA List 4 (e.g., a substance may be listed on EPA List 4 and 40 CFR 152.25(f)(2) but not be present at 40 CFR part 180). What combination of these EPA regulatory citations, if any, would be acceptable and provide the least disruption to industry?*

    See OTA's recommended concept in Section 6.

18. *Would the scope of allowed inert ingredients be clear if AMS adopted a reference to 40 CFR part 180 subpart D (or a subsection therein)? Is there a subsection of Subpart D that would be preferable to a*

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reference to the entire Subpart D? Are there inert ingredients listed on EPA List 4 that are being used in organic-compliant herbicides for farmstead maintenance (roadways, ditches, right of ways, etc.) and ornamental crops, which do not appear in 40 CFR part 180 subpart D? Are there alternatives within Subpart D that could substitute for inerts in currently formulated products?

See OTA's recommended concept in Section 6.

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Livestock Subcommittee – 2026 DL-Methionine Sunset Review

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2026 Sunset review of DL-Methionine.

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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow 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 2026 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 and stakeholders in the organic community on whether these inputs are consistent with and necessary for organic production, or whether there are other effective natural or organic alternatives available.

Using our online sunset surveys (see Appendix A) and direct outreach, OTA solicited feedback from certified operations to determine the continued need for DL-Methionine, as well as to address specific questions posed by the Board. OTA posts online sunset surveys for each input under review as part of the 2026 Sunset Review cycle. These surveys are open to any NOP certified organic operation and include questions addressing the necessity of each input, as well as any questions posed by the Board. The names of the companies submitting the information remain confidential and are not disclosed to OTA unless there is interest in providing contact details for follow up information.

Results of OTA Outreach
Below is a summary of the feedback OTA has received to date on DL-Methionine. OTA will open our online surveys again when the comment period opens for the fall meeting and share any further comment received at that time.

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

Substance	Summary of Responses
DL-methionine	Responses received from certified organic livestock operations raising poultry and poultry feed producers **Use** - As a feed additive **Have you tried alternative substances or management practices?** - There are no known alternatives available in sufficient form, quantity or quality - No other alternatives exist - Fish meal is the most common substitute, but there are sustainability concerns with the availability of marine ingredients. Also, too much fish meal can alter the taste of the feed. - There are limited alternative feedstuffs as noted above **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** 1. **Given supply disruptions of soybeans and soy products experienced by the organic livestock sector since February 2022, what organic crops other than soy could be incorporated into poultry rations to supply methionine?** - There is nothing commercially available to help replace the limited and unbalanced methionine soy adds. The disruption was short lived and we are well past this. - There are limited organic crop sources that are high in methionine. Fish meal is the most common substitute, but fish is outside the scope of organic and there are sustainability concerns with the availability of marine ingredients. Also too much fish meal can alter the taste of the feed. - There are feed alternatives to supply methionine, but none are economically viable or nutritionally equivalent. There are research projects looking at alternatives, but none are scalable as of yet. Some of these alternatives include black soldier fly larvae, flax, canola, and sunflower. We strongly support additional research in this field. 2. **Is there a need for changes to the USDA organic regulations to align with either Canadian (unrestricted amino acid are allowed in organic feed) and/or EU (non-organic feeds containing methionine are allowed) organic regulations? If so, what changes to the USDA organic regulatory text should be made?** - No change is needed - It would be helpful to remove the restriction on methionine. We do not average the inclusion rate over the life of the flock due to the massive recordkeeping and auditing requirements.

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	- Alignment with EU and Canada organic standards would create more consistent expectations for poultry feed. - The EU and Canadian standards are easier or more liberal which in theory creates a competitive disadvantage for the US. Our current stance is to stick with the regulation as is. At this time our producers do well with this allowance amount. 3. **What other nutritional barriers to organic poultry production do producers face when formulating well balanced rations for all poultry in the organic sector?** - The average still causes some imbalance but much better than a hard cap. - Methionine is a limiting amino acid so when the diet includes amounts below the birds' requirement it brings the nutritional value of the overall diet down to the inclusion rate of the methionine. - Methionine is an essential nutrient for poultry feed. - The change to averaging the 2 lbs/ton of synthetic methionine across the lifetime of the bird helps to alleviate these as it can be shifted from times of lower need to higher need. That said restricting synthetic methionine in rations could result in the feeding of more protein overall as the limited methionine is driving the volume. This could result in higher ammonia levels in housing negatively affecting welfare. Alternatively limiting methionine can suppress production. Our producers don't feel that this is a problem currently. Additionally, lysine is the most limiting amino acid in poultry production and goes hand in hand with methionine. 4. **Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?** - Yes, please leave in place without restrictions. - I do not think the restriction is necessary. It makes auditing harder due to the massive amount of calculations required to make sure the averaging is within the restriction. If the restriction was removed it would be beneficial to the bird so she can have a proper diet for the stage of life. - All amino acids should be allowed without restriction per the Canadian standard. - The current restriction on methionine does not align with how other essential nutrients are considered, such as vitamins and minerals. Methionine is an essential amino acid for poultry. Restricting its use could impair the health of the birds. - Previously poultry had lower production and more diverse diets. With the larger flocks and higher production modern poultry rations rely more on readily available livestock feeds and less on scavenged or diverse feed. Without synthetic methionine as a way to supplement this essential amino acid it can become a bottleneck for formulating rations. We recognize there is a 15-20% reduction in eggs with the restriction on methionine, but we feel this limit supports the organic philosophy.

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.

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Respectfully submitted,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

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Appendix A – OTA Sunset Survey on DL methionine

- What livestock product do you use this on?
- Have you tried using any alternative substances (e.g., other substances that are on the National List and/or other natural substances) or management practices?
- How necessary is this substance to your operation:
    - Not Necessary
    - Somewhat necessary
    - Essential
- Optional: Please provide any additional context and/or contact information so we can follow up with any questions.

NOSB Questions to Stakeholders

1. Given supply disruptions of soybeans and soy products experienced by the organic livestock sector since February 2022, what organic crops other than soy could be incorporated into poultry rations to supply methionine?

2. Is there a need for changes to the USDA organic regulations to align with either Canadian (unrestricted amino acid are allowed in organic feed) and/or EU (non-organic feeds containing methionine are allowed) organic regulations? If so, what changes to the USDA organic regulatory text should be made?

3. What other nutritional barriers to organic poultry production do producers face when formulating well balanced rations for all poultry in the organic sector?

4. Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Certification, Accreditation, Compliance Subcommittee (CACS)
Organic Food System Capacity and Constraints
Discussion Document

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the Certification, Accreditation, Compliance Subcommittee (CACS) on its Organic Food System Capacity and Constraints Discussion Document.

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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA circulated NOSB's questions to our stakeholder networks and received responses to the prompts regarding market constraints. OTA thanks NOSB for carefully considering stakeholder feedback on market constraints and responds to NOSB questions in turn:

1. **Are we retaining our existing organic acres and producers or are we experiencing overall loss of current organic producers?**

The 2022 USDA NASS Ag Census data reported the overall number of farms and ranches in the United States decreased seven percent from 2017. However, certified organic farms were down only four percent over the same period. Of our respondents, half reported an overall loss of organic producers while a quarter responded our existing organic acres and producers are being retained.

The retention of organic farms compared to conventional farms may speak to the resilience of organic farming models and diversification as a risk mitigation method. While we are encouraged by the UDSA investment in the Organic Transition Initiative, its impact on retaining or increasing organic producers will take more time to observe and document.

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2. **Are existing organic producers expanding or contracting acres of organic production?**

The 2022 NASS Ag Census reported the number of acres transitioning into organic was down 43% from 2017. Half of our survey respondents reported decreasing organic acres. One responded reported organic dairies are expanding production in 2023 and 2024.

The plateau in new organic farms and smaller number of transitioning acres likely reflects the diminishing premiums organic commodity crops have seen in recent years under elevated conventional corn and soybean prices. USDA must continue to invest in domestic grains supply chain infrastructure and markets to ensure a thriving domestic marketplace, and protect feedstuff growers and users from international market fluctuations. Beyond processors and markets for byproducts and rotation crops, all market participants would benefit from price and inventory reporting on a monthly or more frequent basis that would allow for proper crop planning, risk monitoring and price discovery.

3. **What additional infrastructure is needed to make organic supply chains leaner and more efficient?**

Survey respondents offered a variety of suggestions to improve organic supply chains:

- Increased processing capacity, and bulk and finished goods storage
- Consumer education and marketing
- Development of markets for byproducts and rotation crops.
- Reducing the burden for farmer record keeping – this could be financial support, or it could be right sized documentation based on the size and risk of the farming enterprise.
- Rapid, affordable and regionally located testing for unavoidable residue.
- Data on pricing and inventory on a monthly or more frequent basis.

4. **What organic processing capability do we need to establish?**

<u>Dairy</u>

The organic dairy industry has a unique supply chain and challenges. Survey respondents continue to identify market gaps in the organic dairy industry. There is a need for right sized dairy processing infrastructure for process dairy products on a small to moderate scale (cheese, whey and lactose, butter and buttermilk). The building out of organic dairy processing should be accompanied by more robust milk price and feedstuff cost data collection and reporting. A lack of milk price and feedstuff data puts both organic dairies and organic grain producers at a disadvantage compared to conventional operations who have access to regularly reported market data.

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Fiber

Organic fiber was identified as a key area for investment in the Organic Market Development Grant Program. However, fiber only received 6 of the first 103 projects awarded through the program. The organic fiber market has enormous growth potential and needs support to build out processing for hemp, cotton, and wool. Existing USDA grants rarely pay for equipment, and the industry requires strategic support for spinning and other specialized fiber equipment. Organic hemp is driving the hemp market but lacks infrastructure to reach its full potential and could benefit from:

- Support for organic cotton processing infrastructures especially at spinning stage
- Support for organic hemp production, harvest, and post-harvest processing infrastructure, and incentivize incorporation of hemp in to crop rotation

Meat and Poultry

Organic livestock farmers consistently report difficulty accessing the organic meat market for lack of local processing facilities. This problem disproportionately affects small farmers who may not be at scale to access processing plants hundreds of miles away. As a result, many organic farmers turn to other labels that are available through conventional processing, such as "all-natural" or "grass-fed," and do not receive the benefit of the USDA Organic seal. USDA's many meat processing grant programs do not have set-asides for organic meat and poultry processing facilities. To enable greater support:

- Expand access to dedicated organic meat and poultry processing facilities
- Encourage USDA to expand current meat processing support programs to include funding specifically or prioritized for organic meat and poultry

Establish a USDA certified transitional program

Certification of farms in transition can be a key aspect of encouraging increased domestic organic production by providing technical support and supply chain recognition. While various certifiers have transitional certification programs, these are not harmonized and lack consistent oversight. Transitional certification can prevent "surprises" for operations going through the certification process, because the operation has been inspected and audited during each year of its transition. Furthermore, operations enrolling in a transitional certification program will support supply chain management as transparency in future growth of organic acreage can facilitate appropriate business planning and contract development for buyers and producers. Currently it is not clear what requirements there are for supply chain partners and any requirements for segregation or marketing and therefore have greater risks in entering this marketplace. The program would also help develop transitional markets, enabling a supply-chain premium for transitional crops that can incentivize producers to move towards organic and can reduce the financial burden that a three-year transition period poses.

- OTA submitted an application to USDA Agricultural Marketing Service's Quality Systems Assessment Program to establish a USDA Certified Transitional Program. USDA made a formal announcement approving the program in early 2017 but months later withdrew the program with no explanation. USDA should reestablish this program and begin accepting applications from qualified certifiers immediately.

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Consumer Education

Consumer education must continue to be a priority in organic market programs. Respondents reported "regenerative" is taking market share from organic, a concern OTA increasingly hears from the industry.

In a recent Edelman study, 50% of the general US population indicated a high level of trust in the USDA organic seal. Additionally, the concerns consumers care about the most coincide with many of the elements of the organic standards, such as pesticide use, environmental impacts, genetically modified organisms, and animal welfare. However, there is widespread confusion about what it means to be organic, and consumers do not fully understand the label's attributes and the benefits of organic production. Only a quarter of Americans strongly believe there is enough accessible, easy to understand information about organic publicly available.[1]

- Organic market development funding must continue to be dedicated to innovative proposals to educate retailers and consumers on the benefits of organic food and fiber

Invest in organic research. As farmers experience ever-changing growing conditions under climate change, it is not the time to pull back on investments in organic research. The Organic Transition Initiative has presented significant opportunities for organic and transitioning farmers. However, the industry, NOSB, and USDA must not lose sight of the importance of organic research as markets continue to develop. Organic research benefits all of agriculture and this has been proven by the large-scale adoption of many organic practices now being labeled and tracked as climate smart. USDA investments in research should be targeted so they can have broad application and prioritizing investments in organic research allow for application by all producers.

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,

Laura R. Holm
Legislative & Farm Policy Associate
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

[1] Benchmarking Trust in Organic. Edelman. May, 2022.

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Livestock Subcommittee – 2026 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2026 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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow 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 2026 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 and stakeholders in the organic community 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 2026 Sunset Review cycle. These online surveys include questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input, as well as any questions posed by the Board. 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 remain confidential and are not disclosed to OTA unless there is interest in providing contact details for follow up information.

Results of OTA Sunset Surveys
Below is a summary of the feedback OTA has received to date on our livestock materials sunset surveys. OTA will open these surveys again when the comment period opens for the fall meeting and share any further comment received at that time.

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

Substance	Summary of Responses
Hydrogen peroxide	Responses received from certified organic livestock operations raising poultry **Use** - As a sanitizer for prevention and treatment if necessary **Have you tried alternative substances or management practices?** - Yes, but it is important to have different modes of action, to allow for a rotation of products, keeping efficacy high. **How necessary is this substance to your operation?** - Essential
Magnesium sulfate	Responses received from certified organic livestock operations **Use** - As disinfectants, sanitizer, and medical treatments as applicable **Have you tried alternative substances or management practices?** - No, there are no non-synthetic alternatives for this.
Fenbendazole	Responses received from certified organic livestock operations raising cattle **Use** - As a parasiticide **Have you tried alternative substances or management practices?** - No alternatives in a rescue situation. There are natural alternatives used preventatively. **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. How do certifiers mitigate consistent repeat use of parasiticides?** Unsure how certifiers mitigate this, but we recommend certifiers not giving this approval without a veterinarian's professional recommendation. From our perspective, we see primarily rescue treatments on severely parasitized animals. There are no organic alternatives in a rescue situation. The removal of treated animals from the organic meat market is a strong incentive to not overuse. **2. Are there suggestions to improve the annotation?** Proof of a need for treatment could include written documentation, fecal test, and/or recommendation from a vet for emergency treatment. We want to be cautious on requiring this of producers as to not add additional burdens that could lend itself to poor welfare. If treatment is required, certifiers could request an update to their plan to reduce the need for this in the future. Maybe we could provide guidance to certifiers on how to evaluate this. **3. Which age/class of animal do certifiers see their clients requesting approval for emergency parasiticide use?**

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	Intestinal parasites are seen almost exclusively in 6–18-month-old cattle. Lungworm is a growing concern and affects both youngstock and mature cattle. Unsure of which age/class of animal certifiers are getting these requests for, but that is our knowledge & experiences of parasites in cattle. **4. How often do certifiers request copies of fecal sample test results to confirm the parasite load in a herd prior to allowing an emergency treatment with parasiticides?** Unsure of this, but support certifiers confirming the use of parasiticides with these test results or other vet recommendation. We do not support additional barriers for farmers to not treat their animals. **Additional comments** - I am a veterinarian but now work for an organic milk processor so I have worked with organic farms in different relationships. I have found that often producers aren't even aware that they are able to use parasiticides. I do believe that the grazing practices many producers utilize do help prevent excessive parasite burdens but there are always animals that become overwhelmed. I think it is imperative to have compounds available to use when organic treatments and measures do not work.
Moxidectin	Responses received from certified organic livestock operations raising cattle **Use** - As a parasiticide **Have you tried alternative substances or management practices?** - NA **How necessary is this substance to your operation?** - Essential **Additional comments** - I am a veterinarian but now work for an organic milk processor so I have worked with organic farms in different relationships. I have found that often producers aren't even aware that they are able to use parasiticides. I do believe that the grazing practices many producers utilize do help prevent excessive parasite burdens but there are always animals that become overwhelmed. I think it is imperative to have compounds available to use when organic treatments and measures do not work.
Xylazine	Responses received from certified organic livestock operations raising cattle **Use** - As a sedative **Have you tried alternative substances or management practices?** - No **How necessary is this substance to your operation?** - Essential **Additional comments**

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	- Xylazine is an essential sedative when working with cattle. It can be used in larger doses to lay an animal down for surgery or other procedure. It can also be used in smaller doses to calm a fractious animal.
DL-methionine	Please see our comments on this substance, submitted separately
Trace minerals	Responses received from certified organic livestock operations **Use** - As feed additives **Have you tried alternative substances or management practices?** - No other replacements and management practices do not change nutrient absorption/enzymatic function in the animal **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. Are there effective non-synthetic alternatives to some or all synthetic trace mineral feed supplements?** - No **Additional comments** - Trace Minerals are essential for enzymatic functions in the animal. We cannot rely on the trace minerals in the commodities for consistent results.
Vitamins	Responses received from certified organic livestock operations **Use** - As feed additives **Have you tried alternative substances or management practices?** - No other alternatives exist. **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. What are common uses of vitamin B and K feed supplements? Are they necessary for good ruminant health?** - Vitamin B is essential for poultry health, providing many metabolic pathways in the animal. Deficiency would be common if these were not allowed. - Vitamin K is synthesized in the rumen and is not essential to supplement. Vitamin B is generally incorporated in mineral mixes and is essential as a coadjuvant with A, D, and E. Vitamin B is also used as a treatment for ketosis. Supplementing with synthetic Vitamins B & K is not necessary for ruminant health. **2. How common are livestock vitamin products that are produced with excluded methods?**

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	- As far as we know, this is not common. There are a series of yeast products that generate vitamins. GMO processes may or may not be involved in this across the board. **3. Are there methods to detect livestock vitamin products produced using excluded methods?** - Unsure **Additional comments** - The absence of vitamin availability in a poultry ration would lead to animal welfare and deficiency outcomes.

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,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Crops Subcommittee – 2026 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2026 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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow 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 2026 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
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Results of OTA Sunset Surveys
Below is a summary of the feedback OTA has received to date on our crop materials sunset surveys. OTA will open these surveys again when the comment period opens for the fall meeting and share any further comment received at that time.

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

Substance	Summary of Responses
Hydrogen peroxide	Responses received from certified organic specialty crop producers **Use** - In conjunction with PAA it would be used on specialty crop irrigation equipment. Limited use as crop control material **Have you tried alternative substances or management practices?** - PAA, Chlorine **How necessary is this substance to your operation?** - Somewhat necessary **NOSB questions to stakeholders** **1. Is hydrogen peroxide an alternative to other more problematic sanitizers?** - HP alone has limited impacts in growing settings due to its limited stability due to temperature, pH, light and organic matter.
Soaps, ammonium	Responses received from certified organic vegetable growers **Use** - Animal deterrents; not used by respondent **Have you tried alternative substances or management practices?** - Physical, cultural practices on ranches for large animal deterrents **How necessary is this substance to your operation?** - Not necessary **NOSB questions to stakeholders** **1. Is there still a need for ammonium soaps, considering the many alternatives for large animal deterrents?** - Limited use; there are other products and practices available. **OTA Comment** - OTA recognizes there may be perspectives or material usage not represented in the responses we receive. We are aware ammonium soaps are a valuable tool in situations when fencing or physical barriers are not a feasible alternative.
Oils, horticultural	Responses received from certified organic vegetable growers **Use** - As insecticide; not used by respondent **Have you tried alternative substances or management practices?** - Plant based oils would be used if needed **How necessary is this substance to your operation?**

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	- Not necessary **NOSB questions to stakeholders** **1. Are plant or fish oils in use that can take the place of mineral oils in organic insect or mite management programs?** - Plant based oils would be used if needed **OTA Comment** - OTA recognizes there may be perspectives or material usage not represented in the responses we receive. We are aware horticultural oils are an essential pest control material and widely used in perennial cropping systems such as tree fruit production.
Pheromones	Responses received from certified organic vegetable growers **Use** - Mating disruption; not used by respondent **Have you tried alternative substances or management practices?** - For moth related pests in vegetables we use insecticides. Would consider for disruption of plume, diamond back and other common veggie pests. **How necessary is this substance to your operation?** - Somewhat necessary **NOSB questions to stakeholders** **1. Is there an interest in knowing more about the inert ingredients that are used in formulating pheromone products?** - Yes, verification of toxicity, persistence of carriers used in active pheromone systems **OTA Comment** OTA recognizes there may be perspectives or material usage not represented in the responses we receive. We are aware pheromones are an essential pest control material and widely used in perennial cropping systems such as tree fruit production.
Ferric phosphate	Responses received from certified organic vegetable growers **Use** - As slug or snail bait; not used by respondent **Have you tried alternative substances or management practices?** - Physical practices and co-benefits with other pest control applications, e.g., Spinosad & sulfur-based applications. **How necessary is this substance to your operation?** - Somewhat necessary **Additional comments**

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	- Smaller sized operations may use based on ability to apply in areas. Not much use in large scale vegetable production
Potassium bicarbonate	Responses received from certified organic vegetable growers **Use** - As slug or snail bait; not used by respondent **Have you tried alternative substances or management practices?** - Physical practices and co-benefits with other pest control applications, e.g., Spinosad & sulfur-based applications. **How necessary is this substance to your operation?** - Somewhat necessary **Additional comments** Smaller sized operations may use based on ability to apply in areas. Not much use in large scale vegetable production
Magnesium sulfate	Responses received from certified organic specialty crop growers **Use** - As plant or soil amendment on most specialty crops though not as a direct input but in combination or as part of formulations in other materials **Have you tried alternative substances or management practices?** - No **How necessary is this substance to your operation?** - Essential
Hydrogen chloride	Responses received from certified organic cotton growers **Use** - Mating disruption; not used by respondent **Have you tried alternative substances or management practices?** - Yes **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** 1. **Are there any recent advances in alternative practices or methods for delinting cotton or planting cotton seed that hasn't been delinted?** - No **Additional Comments** - We petitioned for the listing of Hydrogen Chloride 20+ years ago and have requested it to be relisted each time it has come up under Sunset since then. However, since the last relisting, we have become aware of NOP 5029-1 issued September 5, 2018. In

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	light of NOP 5029-1, the listing is not essential, since none of the cotton planting seed being treated with HCl is certified organic seed. Due to the small volume of organic cotton in the US, I do not foresee there being any production of organic cotton planting seed, but if there was, the listing would be critical.

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,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Certification, Accreditation, Compliance Subcommittee (CACS)
Climate-Induced Farming Risk and Crop Insurance
Discussion Document

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the Certification, Accreditation, Compliance Subcommittee (CACS) on its Climate-Induced Farming Risk and Crop Insurance Discussion Document.

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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering industry feedback on crop insurance challenges.

Opportunities for Improvement:

1. **Quality Factor Consideration During Loss Adjustment**

OTA supports policy revisions that would allow coverage relevant to a farmer's organic contract price—under the contract price addendum—when an otherwise in-demand-for-food crop becomes unmarketable due to a climate event.

2. **Central Page for Organic Crop Insurance Agents**

Insurance agent education on organic crop insurance policies continues to present a barrier for organic farmers wishing to participate in risk management programs. While RMA should ramp up insurance agent education on organic policies across the board, a central resource where farmers can find knowledgeable agents would be extremely useful.

3. **Organic Adjusting Standards**

OTA agrees the adjusting standards applied to organic farms should consider the unique needs of organic management systems. Because organic management is heavily influenced by the lifecycle of weeds and other nearby plants, RMA should be mindful not to tie the hands of farmers waiting for a crop insurance adjuster during crucial points in the season. The disparate impact of adjusting standards on organic systems underscores the need for ongoing research into organic production systems.

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Other Challenges:

The other challenges CACS listed identified by producers and insurance agents reiterate the importance of several OTA priorities:

1. Research

More research is needed to determine the feasibility of compliance with required planting dates when farmers implement diverse crop rotations. Additionally, USDA should renew and increase efforts to study the risk mitigation impacts of both cultural and regionally specific crop rotations.

2. Education

There is a need for increased education on organic policies for insurance agents, and education and technical assistance for producers. Producers require more education on what options exist for them and how to access them. Producers would benefit from more guidance on the role of the Transition System Plan or Transition Producer Plan in coverage opportunities.

3. Accessibility

OTA echoes the concern of agents who report the 50+ page application for the Whole Farm Revenue Program (WFRP) creates a participation barrier. The arduous application, paired with low agent compensation for WFRP sales, disincentivizes both agents and farmers from participating in the program.

RMA programs may also be inaccessible to farmers because it may take years for the producer to establish actual production history for rotational crops, risking both insufficient crop insurance coverage and unreliable market opportunities. Market development continues to be an important element of risk management in organic.

Questions for Stakeholders:

OTA circulated NOSB's questions on transitional yields to our stakeholder network and received responses to the prompts, incorporated below.

1. **T-yields (Assigned yields when a producer doesn't have production history)**
    a. **Would organic producers be open to using transitional yield history to accelerate t-yield replacement to build organic yield history faster?**

Transitional-yields (T-yields) are county-level actuarial numbers that insurance providers will use to base a policy guarantee on when a farmer either cannot or will not provide previous production data. T-yields will be used during the four-year transition to using actual production history (APH) from a producer when they are a new farmer, transitioning to organic, or previous production data is unavailable. RMA should allow producers to utilize previous yield history, whether conventional or transitioning to organic, with appropriate discounts for known reductions in yields that may occur when employing organic production practices, when calculating Actual Production History for their organic crop insurance coverage.

    b. **Would "buy up" coverage above 85%, which is the current limit, to 120% be of**

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interest to obtain more coverage?

Respondents indicated an interest in an option for buy up's up to 120% coverage, however exercise of these options would be based on cost. It is unclear to the OTA if insuring above 100% of the projected value is actuarily sound.

c. Suppose you have a currently approved production history (APH) for organic production. Would you be interested in having a percentage of that APH carried over to your transition or organic t-yields?

Respondents indicated they would be interested in the proposed action. If a grower has a new field that was previously managed by a different producer, the grower should be able to use APH from the previous producer instead of using county t-yield data so long as the field was certified organic. OTA supports allowing organic producers to use a percentage of their APH for parcels in organic transition or with no production history.

2. What other concerns remain?

Education

As stated above, educating both insurance providers and organic farmers on the policy provisions unique to organic must be a priority at RMA. Organic policy education may not be a priority for insurance providers when those sales do not represent a large share of insurance provider income. RMA must invest in organic crop insurance education to empower organic producers to access the programs and self-advocate.

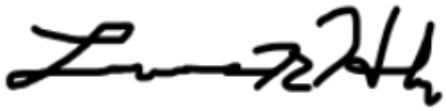
Whole Farm Revenue Cover Limit

Current RMA policies on Whole Farm Revenue Protection (WFRP) coverage limit expansion of revenue coverage to 35%. RMA should ensure that all producers, including rapidly expanding operations that have recently obtained access to premium markets like organic, can obtain coverage under this policy.

- Under the Whole-Farm Revenue Protection Program, RMA should recognize the change in farm revenue after a farm has transitioned to organic. Eliminate the 35% cap on increased production value under the expansion provision.

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,



Laura R. Holm
Legislative & Farm Policy Associate
Organic Trade Association

cc: Tom Chapman

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THE ORGANIC CENTER

April 1, 2024

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

RE: Materials Subcommittee - Research Priorities Spring 2024 (Discussion Document)

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comments on the Materials Subcommittee proposal on the Spring 2024 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 on 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 recommendations on Research Priorities. We appreciate the creation of the Research Priority Framework and the efforts to set priorities.

Summary:

- ✓ The Organic Center generally supports the subcommittee's proposed Spring 2024 Research Priorities. The proposed priorities are in line with the needs of the organic community, and will serve as an important resource to guide The Organic Center's research priority focus and project development.
- ✓ Based on feedback we have received during our own stakeholder engagement efforts, we suggest that some ongoing crop research topics (systems and nutrition research) be elevated to top research priorities. We also recommend some topics that we have identified as missing be added to the research priority list, particularly in the areas of socioeconomic impacts of organic and measurements of effectiveness of research and extension.
- ✓ While not a research topic, we suggest that the RFA administration process for federal funding programs be highlighted as an important consideration that impacts the equity and diversity of grantees, as well as the quality of proposed research.

We offer the following more detailed comments:

Research Priority Adjustments

We have reviewed the list of topics included for Spring 2024 Priorities, and while we were pleased to see the inclusion of "Whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices," and "Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons," we encourage the subcommittee to elevate these topics to a top priority. There is a general deficiency in research results for both topics and these results are of great interest to consumers and businesses attempting to meet Science Based Targets.

Whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices:

In the past two years, The Organic Center has convened Life Cycle Assessment (LCA) technicians and industry experts to discuss the limitations of LCAs in measuring the sustainability of organic farming. As a group, we have identified the following challenges that currently exist, and recommend that future sustainability metrics include whole-system measurements of organic farming outcomes:

- While Life Cycle Assessments have become a popular standard to measure the sustainability of ingredients and cropping systems, there are many challenges associated with this measurement strategy that limit the accuracy of calculations and interpretations of results. For instance, there is a lack of Life Cycle Inventory (LCI) data that are representative of organic ingredients/cropping systems and when organic data is missing, data from non-organic systems is often relied upon to fill the gaps. This prevents calculations from reflecting the true impact of organic in sustainability reporting, e.g., Scope 3 carbon accounting.
- Additionally, the quality of data that does exist is not standardized nor held to the highest standard. Many published studies on organic farms do not adequately define the organic system studied—time since organic transition, scale of operation, rotation length and composition, crop configuration (e.g. polyculture), non-crop vegetative diversity, organic soil amendments, and pest management inputs are rarely described, yet all are important factors that would impact yield and therefore the interpretation of the study and LCA outcomes. For example, research shows that as the duration of organic management increases, so does yield, closing the yield gap. Since LCAs measure the climate impacts on a per-yield basis, if an LCA includes only young organic farms, or the age is not known, then the results may be inaccurately interpreted, misrepresenting the impacts of organic management.
- Another challenge is that the current LCA frameworks/time horizons do not include key metrics that are critically important outcomes of organic systems like improved biodiversity, water and air quality, health and livelihoods of rural communities, etc. Instead, they focus almost entirely on GHG emissions-- soil organic carbon metrics are only now beginning to be integrated into carbon accounting and LCAs, which also have a bearing on an organic system's ability to mitigate climate change. This wrongfully penalizes organic ag systems in a GHG/Climate metric debate and is likely to disincentivize investment in organic programs as

2030 goals, legislation, etc. take effect. Therefore, sustainability measurements should include additional ecosystem service/disservice parameters that result in an output of multifunctionality and a truer representation of the impacts of organic management.

We believe whole farm ecosystem assessments are of top priority given the increasing popularity of LCAs as the gold standard tool to measure the sustainability of organic.

Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons:
This topic is growing in popularity amongst consumers who want to better understand the benefits of organic food to their families. While the interest in potential dietary exposure to pesticide contamination is of concern, the most recent OTA Consumer Survey shows that consumers are most willing to pay for products that they believe to be healthy and nutritious. Published research predominately shows that organic crops have more micronutrients and antioxidants, and that organic animal products like dairy and meat contain healthier fatty acid profiles, antioxidants, and increases in some vitamins and minerals, but much more research in this area is needed. Given the high consumer interest in this topic and therefore the potential for this research topic to improve the market for organic products, we recommend that this research topic be elevated to a top priority.

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. In December 2023, we also co-hosted a virtual convening with FFAR, Clif Bar, and Tuskegee to assess organic research and extension needs in the Southeastern U.S. Based on all of this engagement, we feel that the NOSB Materials Subcommittee's proposed Spring 2024 Research Priorities are largely in line with the needs of the organic industry, and appreciate the release of this report as an important resource to guide research priorities and project development.

Based on feedback we've received during our own outreach efforts, we suggest the following research topic areas be added to the currently proposed list:

All crop research questions should include a focus on minor crop varieties of high cultural importance to BIPOC communities. BIPOC farmer and consumer interviews/surveys that aim to identify preferred crops and unique research topics and resource needs should be administered to develop a more comprehensive list of crops that need additional research.

State-by-State socio-economic impacts of organic farming
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 organic farming is especially important because it can influence advocacy and policymaking, and funding support for organic research, transition and market development. Specific topics that could help increase advocacy include:

- Impacts of organic production on employment opportunities/rates/stability, household income, livelihoods/wellbeing metrics, farmer recruitment and retention.
- Impacts of federal funding investments on organic transition, farmer retention, sales/income.
- A refresh of the organic hotspots research that was based on census data from 2015 and a contrasting look at organic coldspots to see how regions with a wealth or dearth of organic impact various socioeconomic metrics.

Results from this kind of research would provide more power when talking with policymakers and congresspeople across the aisle.

Time to maturity for organic crops

Crop insurance provisions require crops to be planted between the earliest and latest planting dates to be eligible for a loss payment. 7 C.F.R. § 457.8. Coverage also ends at the end of the crop year, which is the "period within which the insured crop is normally grown." If an organic crop has different planting and harvesting timelines, it could result in a loss in coverage. It may be necessary to adjust planting dates for varieties of crops grown under organic production if the genetics or ambient conditions impact the time to maturity for organic crops compared to conventional. The data needed to assess the necessity of these adjustments is lacking, but implications could be major if organic crops do indeed have different maturity rates that do not align with current crop insurance provisions.

Measuring the effectiveness of research extension programs

Land grant institutions receive federal funding to support extension programs and specialists/agents, and current NIFA funding programs require integration of research extension into funded projects. And yet, we continue to hear from farmers that there is a disconnect between research and their access to results. This communication breakdown can occur when various audiences are not given information, or when the information delivered is not communicated in effective ways (e.g. language, cultural barriers). At our recent virtual convening, we heard from BIPOC farmers and representatives that this is a continual problem—that university extension is not meeting their needs.

These testimonies are supported by preliminary research that was recently presented at the Kentucky Black Farmers Conference in early 2024. A Master's student explored records of contact hours from two major universities in KY, one of which is a designated HBCU and found that contact hours were disproportionately spent (90%) on communication with white constituents (this group includes farmers and other stakeholders as extension programs reach rural and urban communities), including those contact hours conducted by extension specialists from the HBCU. While these results are preliminary, they highlight the need to conduct additional research that assesses the reach, quality and impact of research extension broadly, and also within the organic sector. The inclusion of end users in this research would help identify more impact strategies for future extension programs.

Considerations of funding program administration: the application process

Several USDA NIFA funding programs like OREI, ORG, AFRI, SCRI, etc. play a pivotal role in advancing organic agriculture research and extension. These funding programs help ensure that organic systems remain productive and profitable while also providing a myriad of planetary benefits. The OREI and ORG funding programs are the primary drivers of organic systems research that lead to the development of new tools and practices that help organic farmers be more competitive in a changing global market.

While these invaluable sources of funding have the potential to dramatically improve organic production, the administration of the grant programs must also be considered in their influence on the long-term success of organic research, extension, and production.

The Organic Center and the Organic Farming Research Foundation (OFRF) have years of high engagement with organic researchers and their own participation as project leads/collaborators, and together our organizations have collectively identified some opportunities and challenges with the administration process of two vital programs, OREI and ORG.

Beginning with what has helped make the application process more equitable and successful, we would like to acknowledge that publishing multi-year RFAs (requests for applications) with deadlines for more than one year in advance is very helpful. This gives all interested applicants a hard deadline to work with and under-resourced institutions more time to develop necessary collaborations, research questions and methods, and ensure their institutions have the capacity to submit proposals on their behalf. In the past, OREI has set deadlines in the summer, which aligns better with teaching schedules and avoids delays/challenges associated with winter holiday closures.

To ensure that applicants are set up for success in an inclusive and fair way to increase the submission of high-quality grant proposals with high-impact potential, we suggest three things:

1. **There should be predictability in the timing of the RFA release and the deadlines should better accommodate academic calendars.** Over the past several years the time of releasing the RFA for these two programs has been unpredictable. For OREI, it has ranged from October to March since 2014. When considering the academic calendar and the capacity constraints placed on research professors who teach (and those from less-resourced institutions tend to have high teaching loads), this inconsistency negatively impacts application rates and creates a significant barrier to less-resourced institutions. With more consistency in the timing of RFA release, we expect that applicants will be able to better fit the whole application planning and execution process into their workflow for the year. Publishing multi-year RFAs with deadlines in non-teaching months, particularly towards the end of summer so that fieldwork is already underway, will relieve the pressure that occurs when deadlines are placed in winter or spring.

2. **Consistency in available time for application with more time between release of RFA and application deadline.** Similar to the release date of the OREI and ORG RFAs, a more-consistent timeframe to draft a grant application is prudent. Since 2014, the number of days to apply ranged from 37 to 91, which reflects 5 to 13 working weeks. Many universities require an internal review process that can take up to 10 business days**.** Therefore, considering the administrative processes and requirements many institutions have to meet for grants of the scale of OREI, the actual time between RFA release and the deadline **may** severely limit potential applicants. This is especially true for applicants who have heavy teaching loads, limited administrative support, and are at institutions that have limited resources all around.

3. **Coordination of deadlines across NIFA programs is needed.** Some organizations and institutions submit multiple applications to various NIFA funding programs within a given year. For example, in 2024, The Organic Center lead or collaborated on seven grant proposals across three NIFA programs with deadlines of Feb 6, Feb 15, and March 7. The administrative burden alone to meet this cluster of deadlines put an enormous and unnecessary strain on our capacity.

   We also had an experience where one of our collaborating academic institutions, an under-resourced Hispanic Serving Institution, could not accommodate the tight turnover between program deadlines and asked us to be the lead and submit on their behalf or else they would have to pull their OREI application this year. We were not well positioned to absorb the extra work, but committed to the submission to ensure that a worthy application was not abandoned. We heard other testimonies of academic faculty and administrative support limitations due to the stacked deadlines, which was exacerbated by the timing of winter holiday closures, teaching loads, and the need to build collaborations and request letters of support at a time of year when many people were out of office and/or stretched very thin.

   And finally, The Organic Center's science staff provides review services for NIFA and other government funding programs. For two years in a row, we have had to back out of reviewing for the NIFA SCRI program because their review coincided with the due date for OREI. This limits organic representation on non-organic sources of funding.

These suggested changes will not only increase the feasibility of the application process for all researchers, but they will also increase support for organic agriculture research at institutions that have historically been underfunded and unrecognized in programs like these.

To that end, in addition to the need for increased organic research funding and refinement of the grant application program administration, we acknowledge that more infrastructure development to support applications and administration of grants across all institutions is needed, but primarily at minority-serving institutions and under-resourced institutions/organizations.

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.

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 ask the research community.

Respectfully submitted,

Dr. Amber Sciligo
Director of Science Programs
The Organic Center
asciligo@organiccenter.org

April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Celery Powder—Handling Subcommittee 2026 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the 2026 Sunset Review of celery powder listed on 205.606 of the National List (7 CFR § 205.606 - non-organically produced agricultural products allowed as ingredients in or on process products labeled as organic).

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

The Organic Trade Association supports the continued listing of celery powder on the National List due to the fact that it remains an essential ingredient used in processed organic meat products. Since the last sunset review, much work has been done to develop organic sources of celery or alternative vegetable powder. However, at this time an organic alternative is not yet commercially available. Celery powder has been in use for over a decade as a "curing" agent in certain processed meat products as an alternative to sodium and potassium nitrate and nitrite. Since 2007, conventionally grown celery powder has been allowed for use in certified organic meat products. Since 2010, the organic sausage/deli category has grown at a compound annual growth rate (CAGR) of 29.8% to an estimated $198 million in 2022. Despite this growth, the organic meat category as a whole still only represents .8% of all retail meat sales in the US and represents the least penetrated organic food category (by comparison, total food is 4.3% of the total US retail food market). As the demand for organic processed meats increases, the organic industry wants to replace the use of conventional celery powder with an organic alternative.

Work continues to build an adequate and stable supply of organic celery powder for the organic cured meat industry. Our sister organic research organization, The Organic Center, is engaged in an ongoing joint project with the University of Wisconsin-Madison and the University of Florida entitled Organic Alternatives to Conventional Celery Powder. Funded by a USDA Organic Research and Extension Initiative Grant, the project aimed to address this critical issue with four objectives:

1. Assessment of nitrogen (N) fertility, genetics, and environment on nitrate levels in organic celery, chard, and beets
2. Sensory and quality evaluation of cured meat products using organic vegetable powder
3. Economic and market assessment of organic celery powder and cured meat products
4. Extension of results.

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The long-term goal of the project aims to enhance the capacity of farmers and processors to profitably produce high quality organic processed meat products, while providing economic, agronomic, and environmental benefits to organic crop rotations. While ideally we would have seen further progress on the great work already accomplished, the COVID pandemic set back this and many research projects, losing vital field seasons and research hours. With the pandemic largely behind us, we look forward to this work continuing in earnest.

The research conducted by the University of Wisconsin-Madison and the University of Florida has demonstrated that celery and Swiss chard with adequate levels of tissue nitrate can be produced, using rates of nitrogen fertilizer greater than rates used for standard production of table celery. Higher rates of nitrogen fertilizer, to our knowledge, is also used to produce conventional curing powders. However, these higher rates can likely be managed through cover cropping in ways that minimize negative environmental impacts, although more research is required to confirm best management practices depending on soil type, crop rotation, and environment. While our research in two major production regions has generated recommendations for appropriate nitrogen fertility in these environments, we need to collect more data across working farms to validate these results across more harvest conditions as well.

While organic sources of curing powders are now available, concerns remain with respect to the feasibility of these sources meeting the needs of the entire organic meat processing industry. These concerns include the availability and consistency of supply, as well as understanding the season-to-season variability between sources, for which we need further research. Current research has also investigated the impact of organic curing powders on processed organic meat quality and food safety; this work at UW-Madison demonstrated that organic sources of curing powders produce equivalent food safety and quality parameters as compared to conventional sources. However, more work is needed in partnership with industry to optimize formulas to account for the novel organic curing powder sources.

To further scale up supply, more research is also required to understand how to optimize the fermentation of the organic juices to produce the nitrate used in curing powders. New technologies are being explored to produce the high-quality, consistent product required by industry using organically-allowed practices. In addition to fermentation research, scaling up supply also requires a continued assessment of transportation and processor/handler logistics to ensure consistent product quality. Finally, concurrent with—or in addition to—ramping up supply, processors of cured meat products will require time to trial alternatives to ensure products meet the taste and consistency consumers expect.

Results of OTA Outreach

In addition to the research noted, OTA used our online sunset surveys (see Appendix A) to solicit feedback from certified operations to determine the continued need for celery powder, as well as to address specific questions posed by the Board. OTA posts online sunset surveys for each input under review as part of the 2026 Sunset Review cycle. These surveys are open to any NOP certified organic operation and include questions addressing the necessity of each input, as well as any questions posed by the Board. The names of the companies submitting the information remain confidential and are not disclosed to OTA unless there is interest in providing contact details for follow up information.

Below is a summary of the feedback OTA has received to date on celery powder. OTA will open our online surveys again when the comment period opens for the fall meeting and share any further comment received at that time.

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Substance	Summary of Responses
Celery powder	Responses received from certified organic producers and processors of cured meat products **Use** - In a variety of processed meat products that carry the "uncured" label, as required by USDA-FSIS. This includes hot dogs (beef and turkey), meat sticks, summer sausage logs, deli ham, summer sausage, pepperoni, pork bacon and half hams. Celery powder provides additional attributes to curing, including maintaining a pink color, flavor, and stability of the finished product. **Have you tried alternative substances or management practices?** - See other comments **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?** - We are unaware of ancillary substances in celery powder. **2. Is organic supply commercially available for this material? What are the barriers to organic production?** - Wenda Ingredients (Suzhou China) offers NOP certified organic celery powder and organic celery juice powder. The celery is grown in Chile then shipped to China for production. When referencing 606, we also noticed they offer organic beet powder and organic beet juice powder. **3. Is the organic version of the same caliber as the nonorganic?** - Prosur in Spain (Prosur - Get it Natural) offers EU organic plant-based curing agents. This product works best with poultry and ham. Since less effective with other pork products, its use would be limited in our business.

As evidenced by the results of the work to date, the Organic Trade Association, The Organic Center, our research partners, and cured meat processors are committed to help the industry innovate and proactively take steps to transition to an organic form of celery or vegetable powder. However further work and investment is necessary to scale up production, diversify raw and processed suppliers, and ensure there is product consistency before removing celery powder from 205.606 of the National List.

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,

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Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

Appendix A – OTA Sunset Survey on Celery Powder

- What products do you use this on?
- Have you tried using any alternative substances (e.g., other substances that are on the National List and/or other natural substances) or management practices?
- How necessary is this substance to your operation:
    - Not Necessary
    - Somewhat necessary
    - Essential
- Optional: Please provide any additional context and/or contact information so we can follow up with any questions.

NOSB Questions to Stakeholders

1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?
2. Is organic supply commercially available for this material? What are the barriers to organic production?
3. Is the organic version of the same caliber as the nonorganic?

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Crops Subcommittee
Discussion Document: Compost

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Crops Subcommittee on its Compost Discussion Document. 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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA appreciates the Board's effort and intent to update the organic definitions and regulations regarding compost production and recognizes the significant task this presents in light of a myriad of considerations: updating the regulations to reflect the many composting processes currently in practice; the use of compost across a wide variety of cropping systems; food safety concerns regarding the use of compost from animal origin; the Biodegradable Product Institute's petition to USDA to change the definition of compost and add a definition of "compost feedstock;" and the inclusion of mushroom-specific requirements of compost production in UDA's recent proposed rule on mushroom production.

OTA looks forward to engaging our membership in earnest on this issue. In light of these complex considerations and a relatively brief period in which to comment, we were unable to convene any discussions prior to the April 3 comment deadline. In support of developing comments to inform the Board on this topic so central to organic production, we intend to tap into our diverse membership in the coming months to provide insight on the nine technical topic areas queried by the Board. We will then collate these comments for submission when the fall meeting docket opens for consideration by the Board. In the interim, we look forward to the compost panel's insights and the Board's conversations at its upcoming meeting in Milwaukee.

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,

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Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

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April 3, 2024

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

Docket: AMS-NOP-23-0075

RE: Handling Subcommittee – 2026 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2026 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. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow 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 2026 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 2026 Sunset Review cycle. These electronic surveys include questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input, as well as any questions posed by the Board. 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 remain confidential and are not disclosed to OTA unless there is interest in providing contact details for follow up information.

Results of OTA Sunset Surveys
Below is a summary of the feedback OTA has received to date on our handling materials sunset surveys. OTA will open these surveys again when the comment period opens for the fall meeting and share any further comment received at that time.

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

Substance	Summary of Responses
Acids, citric	Responses received from certified organic companies producing dairy, flavors, processing aids, and consumer packaged goods **Use** - pH adjustor - Taste/flavor - We utilize citric acid in two American cheese products. Citric acid lowers the cheese's pH to improve food safety and increases meltability and flavor. We are exploring applications for fluid milk. **Have you tried alternative substances or management practices?** - Yes, organic citric acid - No, it is critical for organic flavor creation and denaturing of organic ethanol to render ethanol as not potable in order to comply with TTB regulations - No other known sources for this use **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** 1. **There are now numerous suppliers of certified organic citric acid. Should NOSB consider recommending the addition of an annotation to citric acid requiring processors to use an organic version of citric acid when commercially available?** - We would support if organic citric acid was readily available and provided the same properties of non-organic citric acid. - I agree with the recommendation to require organic citric acids, as long as they are "commercially available." We switched to an organ version many years ago to replace hydrochloric acid. It has been no problem. - There are not numerous suppliers of organic citric acid. Organic Integrity Database search results of certified brokers, co-packers, and distributors yielded no results.
Acids, lactic	Responses received from certified organic companies producing meat & dairy, consumer packaged goods **Use** - Shelf stable meats and unsalted butter - Macaroni and cheese for pH, taste/flavor **Have you tried alternative substances or management practices?** - No **How necessary is this substance to your operation?** - Essential

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	Additional comments - Our company has used microbial fermented encapsulated lactic acid within our shelf stable meats in the past. Encapsulated lactic acid decreases fermenting time, lowers pH, and improves shelf stability. Our current copacker utilizes lactic acid starter culture in our shelf stable meats and we are glad these cultures provide similar attributes of encapsulated lactic acid. Lactic acid is also an important food safety tool for carcass washes. So that we have flexibility in choosing different copackers, we support keeping lactic acid on the National List. - Our company utilizes lactic acid for our unsalted butter. In this application, lactic acid decreases butter pH, and improves food safety and shelf life. Cultures can serve this same purpose, but our preference is to use lactic acid. Our business may have future application for cheese, specifically to lower pH, improve food safety, and shorten "make" time. We support keeping lactic acid on the National List.
Calcium chloride	Responses received from certified organic companies producing meat & dairy, consumer packaged goods **Use** - We utilize calcium chloride to improve the firmness and "make" of our Italian and feta cheeses. - Canned tomatoes, salsas, pasta sauces **Have you tried alternative substances or management practices?** - No other known alternatives for use in product **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** 1. **Is the calcium chloride that is commercially used/available produced using non-synthetic processes?** - We utilize calcium chloride that is derived from natural brines and not a synthetic product of the Solvay process. **Additional comments** - We support keeping calcium chloride on the National List.
Enzymes	Responses received from certified organic companies producing dairy, flavors, processing aids, and consumer packaged goods **Use** - Lactose-free milk products, in cheese for curd development (vegetarian rennet) - Production of cheese for use in macaroni and cheese **Have you tried alternative substances or management practices?** - None are available that perform the function required in our application. **How necessary is this substance to your operation?** - Essential / Somewhat necessary

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	NOSB questions to stakeholders 1. **For manufacturers: describe how you ensure no excluded methods are used when including enzymes into your organic formulation.** - Certifiers require that operators submit Non-Organic Ingredient Declaration forms (or similarly named forms) where the vendor attests the enzyme was not derived from GMO technology. - We have obtained a letter from the manufacturer stating that it has not been irradiated, no human sewer sludge, no pesticides and Non-GMO. - Supplier documentation is reviewed to ensure enzymes are from nontoxic plants, nonpathogenic fungi or nonpathogenic bacteria 3. **Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?** - Not that I am aware of.
L-Malic Acid	Responses received from certified organic flavor companies **Use** - Not currently used in organic flavors **Have you tried alternative substances or management practices?** - Not currently used but wish to maintain on National List for future creation **How necessary is this substance to your operation?** - Somewhat necessary **NOSB questions to stakeholders** 1. **Do any organic products contain nonsynthetic forms of L-malic acid?** - Not currently used in organic flavors 2. **Do stakeholders think L-malic acid should be reclassified as a synthetic substance and added to §205.605(b)?** - No 3. **If L-malic acid is added to §205.605(b), should its nonsynthetic listing be removed from §205.605(a)?** - Yes
Microorganisms	Responses received from certified organic companies producing meat & dairy, consumer packaged goods **Use** - Buttermilk, buttermilk powders, hard cheeses, spoonable cheeses; potential for yogurt and probiotic milk - Cultures used to increase shelf life of meat sticks and summer sausage - Functional, dietary additive - Cheese cultures in macaroni and cheese **Have you tried alternative substances or management practices?** - There are no other equivalents for probiotic microorganisms.

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	How necessary is this substance to your operation? - Essential **NOSB questions to stakeholders** **1. For manufacturers: describe how you ensure no excluded methods are used when including microorganisms in your organic formulation.** - Certifiers require that operators submit Non-Organic Ingredient Declaration forms (or similarly named forms) where the vendor attests the microorganism was not derived from GMO technology. - We rely on documentation from the supplier of the microorganism. **3. Are there any ancillary substances that should be prohibited due to the potential for excluded methods?** - Certifiers require that operators submit Non-Organic Ingredient Declaration forms (or similarly named forms) where the vendor attests the microorganism was not derived from GMO technology.

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

Substance	Summary of Responses
Ascorbic acid	Responses received from certified organic companies producing meat & dairy, flavors, and consumer packaged goods **Use** - In milk products to limit oxidation & reduce off flavors - Flavors - Fruit snacks for fortification **Have you tried alternative substances or management practices?** - No **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. Do stakeholders have any experience with natural or organic alternatives to ascorbic acid for some or all of its uses in organic handling?** - We utilize organic cherry powder, which provides ascorbic acid. Organic cherry powder is used in our bacon, pepperoni, meat sticks, and summer sausage. Organic cherry powder cannot be used in our omega milk because of off flavors.
Hydrogen peroxide	Responses received from certified organic dairy and flavor companies **Use** - As a processing aid for dried whey production to control microbes

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	Have you tried alternative substances or management practices? - Yes, evaluations for food safety effectiveness and sanitation lead to more stable and effective materials **How necessary is this substance to your operation?** - Somewhat necessary / Essential **NOSB questions to stakeholders** **1. Is hydrogen peroxide an alternative to other more problematic sanitizers?** - Hydrogen peroxide alone is not commonly used as a direct produce food contact sanitizer or for use on food contact surfaces. It is commercially found in conjunction with peracetic acid/peroxyacetic acid. It does not appear to be a viable "use alone" product for our company. - Yes, but limited in stability and effectiveness. Yes, ranges between 80 & >200 **2. Do certifiers allow it to be used in direct contact with products?** - Our experience shows that certifiers allow direct contact with organic products. **Additional comments** - We support relisting hydrogen peroxide on the National List. Hydrogen peroxide is one of the limited sanitizers for produce wash water and "no-rinse" dairy equipment sanitizers. It is often listed in conjunction with peracetic acid on commercial labels. With limited tools for sanitization, this product must remain on the National List.
Nutrient vitamins and minerals	Responses received from certified organic companies producing dairy **Use** - Vitamins A & D to supplement milk; algal sourced DHA in omega 3 milk - Potential use in food and beverage innovation **Have you tried alternative substances or management practices?** - N/A **How necessary is this substance to your operation?** - Somewhat necessary / Essential **NOSB questions to stakeholders** **1. Are you aware of nutrient vitamins and minerals being used in organic products in ways that do not conform to 21 CFR 104.20?** - No **2. Are there any remaining issues with fortification of infant formula that have not been resolved?** - No **4. Are certifiers reviewing ancillary substances for nutrient vitamins and minerals in accordance with the Spring 2016 NOSB recommendation? Are they imposing limits on ancillary substances that may be present?** - Formula disclosures are required when submitting label additions, therefore certifiers would see the use of nutrient vitamins and minerals

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	5. Are there any specific substances included in this categorical listing that pose health or environmental concerns requiring closer review? - No
Peracetic acid/Peroxyacetic acid	Responses received from certified organic dairy companies, vegetable processors **Use** - Produce wash water, shell egg rinse water, sanitizing milk equipment and tankers **Have you tried alternative substances or management practices?** - Sodium hypochlorite is the alternative. Most handlers use the peroxies, but many farms choose chlorine because of costs and their systems. **How necessary is this substance to your operation?** - Somewhat necessary / Essential **Additional comments** - Peracetic acid/peroxyacetic acid is critical for produce wash water to maintain food safety. Our produce growers use this material to mitigate microbial presence on marketed produce. It is also a food safety tool for shell egg rinse water. Peracetic acid/peroxyacetic acid is critical to the dairy industry and is used to sanitize milk equipment and tankers that handle fluid dairy products. Organic dairy tankers must also meet the Federal Pasteurized Milk Ordinance (PMO). There are limited compliant organic sanitizers that meet both the organic regulations and the PMO. We have tracked commonly used sanitizers in the organic dairy industry, and peracetic/peroxyacetic acid is used most.
Potassium citrate	Responses received from certified organic vegetable processors **Use** - Vegetable production and equipment **Have you tried alternative substances or management practices?** - Yes - sanitation and food safety effectiveness evaluated. Other allowed materials with restrictions used **How necessary is this substance to your operation?** - Somewhat necessary
Sodium citrate	Responses received from certified organic consumer packaged goods companies **Use** - pH control in fruit snacks **Have you tried alternative substances or management practices?** - No known alternatives available **How necessary is this substance to your operation?** - Essential

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Tocopherols	Responses received from certified organic companies producing meat & dairy, flavors, and consumer packaged goods **Use** - Prevents oxidation of milk - Stabilizes high fat, shelf-stable snacks - Flavors - Extends shelf life of grahams, cookies, crackers, snack mix, granola **Have you tried alternative substances or management practices?** - Yes, rosemary extract, but it imparts too much flavor at the level needed to be effective. **How necessary is this substance to your operation?** - Somewhat necessary / Essential **NOSB questions to stakeholders** **1. Are organic tocopherols commercially available?** - We are unaware of any commercial sources of organic tocopherols. We are unable to utilize rosemary extracts because this would cause an unacceptable flavor profile of our milk. - We are unaware of an organic form of tocopherols. - Integrity search for certified organic tocopherols handled by brokers, distributers, marketer/trader yielded no results **2. Is there an adequate and suitable supply of non-synthetic tocopherols to meet commercial needs?** - Yes, we currently utilize a naturally derived source of tocopherol extracted from vegetable oil. We derived this conclusion from the manufacture's Regulatory Product Documentation for Food/Dietary Supplements. This ingredient is sourced from DSM (DSM - Bright Science. Brighter Living.™). - Yes, we have been able to source adequate supply. - Thus far, yes.

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

Substance	Summary of Responses
Celery powder	Please see our comments on this substance, submitted separately
Fish oil	Responses received from certified organic companies producing dairy **Use** - We use algal based DHA oils in our omega milk products, but for redundancy and DHA availability we support continued listing of fish oil on the National List. - Potential use in organic innovation of packaged goods

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	Have you tried alternative substances or management practices? - DHA from natural algal fermentation **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. Are there any environmental concerns to be considered?** - We desire that wild caught fish used for oil are sustainably harvested. In the 2019 sunset review process, there was industry support for annotations to further address conservation concerns. The NOSB recommended an annotation to reference a third-party sustainability standard and require fish oil to be only derived from industry byproducts. We support this approach and encourage the National Organic Program to address these concerns through annotation changes.
Gelatin	Responses received from certified organic companies producing consumer packaged goods **Use** - Potential use in organic innovation of packaged goods **Have you tried alternative substances or management practices?** - No **How necessary is this substance to your operation?** - Somewhat necessary **NOSB questions to stakeholders** **1. Is there sufficient commercially available organic gelatin?** - Organic Integrity Database search of gelatin from all business types yielded no results

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,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman, co-CEO
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