

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

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

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

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).

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



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

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.

Contents [Use PDF headings to navigate between sections]

- (1) Executive Summary
- (2) Introduction
- (3) EPA Framework
- (4) OFPA Framework
- (5) Criteria for Viable Solutions
- (6) OTA Recommendation
- (7) Other Options Considered
- (8) Conclusion

Appendix 1: History and Quick Links

Appendix 2: OFPA Excerpts

Appendix 3: Data Analysis

Appendix 4: Candidates for Prohibited List

Appendix 5: Responses to ANPR Questions

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.

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.**”

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

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

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 subparagraph (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

- 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.

<u>OTA Concept for Categorical Listing of Inerts</u>	<u>Existing listing for Excipients</u>
<p>205.601(m) Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is:</p> <ul style="list-style-type: none"> (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 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: <ul style="list-style-type: none"> (i) Nonylphenol Ethoxylates (ii) ... 	<p>205.603(f) Excipients – only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:</p> <ul style="list-style-type: none"> (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.

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.

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

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.

- **Transparency/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

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

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
<p>205.601(m) Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is:</p> <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (i) Nonylphenol Ethoxylates (ii) ... 	<p>205.601(m) Inerts – only for use in the manufacture of pesticide products used in organic crop production, when the inert is:</p> <ul style="list-style-type: none"> (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 at <u>205.608</u> are prohibited. <p><u>205.608 Prohibited Synthetic Inerts and Excipients</u></p>

(a) Process for petitions and evaluation criteria

(b) Prohibited List of Inerts

(1) Nonylphenol Ethoxylates

(2)

(c) Prohibited List of Excipients

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.

**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
Modificatio
n 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.

**Option B
Modification
n 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](#)

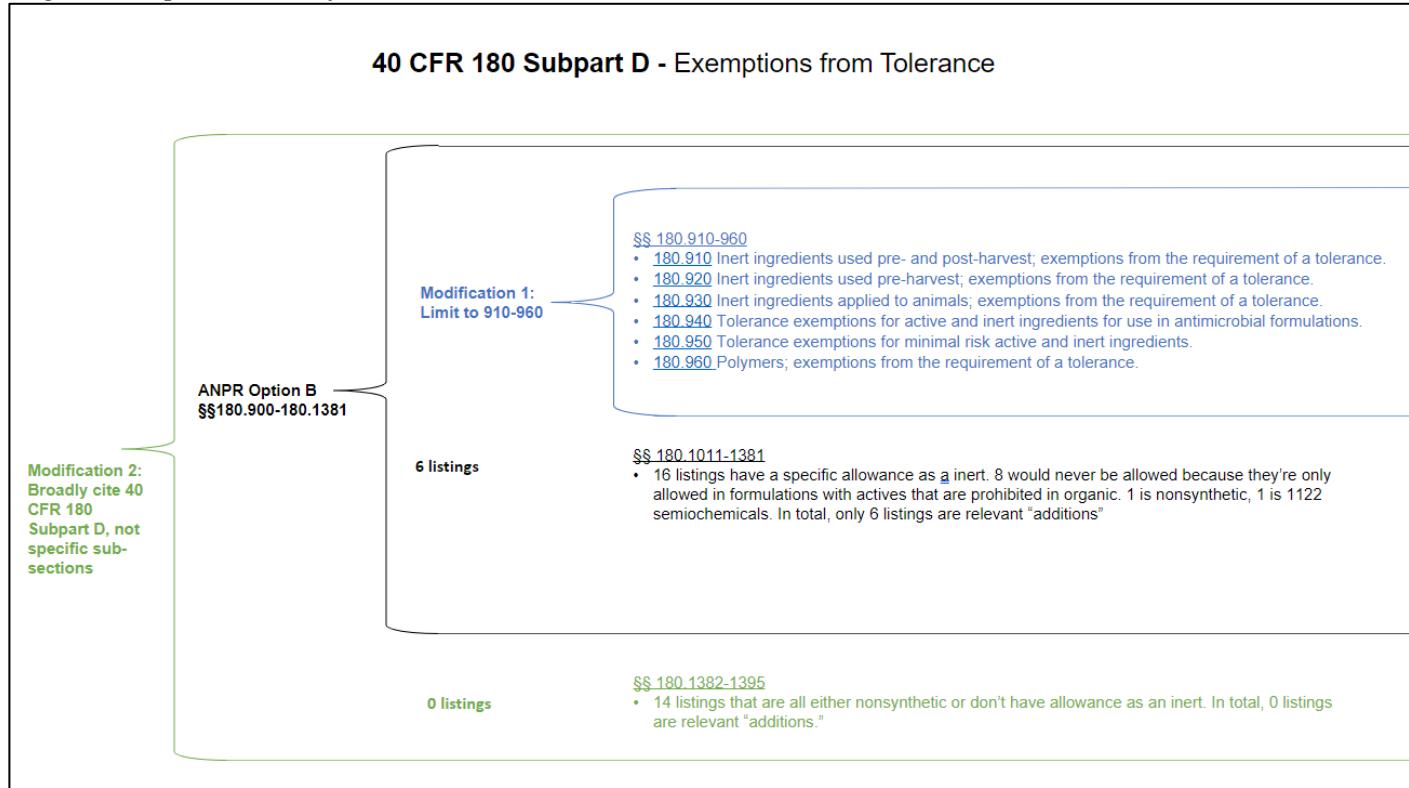
OTA supports this option in combination with other options as described in the OTA Recommendation (*Section 6*) with an opportunity to carve-out exceptions that are prohibited in organic.

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.

Figure 1: Option B modifications



**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

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.

- 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 inert 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 inert 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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Organic Trade Association

cc: Tom Chapman
CEO
Organic Trade Association



Appendix 1: History and Quick Links

2000
NOP
Final Rule

The original NOP Final Rule on December 21, 2000 (65 FR 80547) allowed inert on Lists 4A and 4B as inert 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 inert 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 Inert 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



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 in 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 cleaners; 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

- (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

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 prohibit 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 necessary 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. Tetrahydrofurfuryl 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

- [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?*

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*

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



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.