

National Organic Standards Board
Materials Subcommittee
Inert Ingredients in Organic Pesticide Products Proposal
August 13, 2024

Introduction:

The National Organic Program (NOP) issued a [memo](#) to National Organic Standards Board (NOSB) on June 23, 2023 requesting the NOSB provide a recommendation related to inert ingredients used in pesticide products allowed in organic production. The memo provides a history of the inerts issue, describes four options NOP is considering for the future regulation of inert ingredients, and provides a synthesis of the public comments received on NOP's Advance Notice of Proposed Rulemaking (ANPR) published September 2, 2022. The four options as described by NOP are as follows:

- Allow inert ingredients in EPA-registered pesticides without further review. This would be the easiest to implement and an effective way to evaluate products for compliance. This option would require stakeholders to actively engage in EPA rulemaking and may delegate some control of inert ingredients in organic production to the EPA.
- Reference a subset of EPA regulations (e.g., inerts exempt from the requirement of a tolerance) for allowed inert ingredients. This could be combined with an initial list of prohibited inert ingredients. Further prohibitions or allowances may be added through the petition process. This option maintains much of the simplicity of allowing all EPA registered pesticides while allowing more control. Specifically, it allows stakeholders to submit petitions to prohibit or allow certain inert ingredients as more research is published.
- Develop a single, external list of allowed inert ingredients. The National List would reference this list for allowed inert ingredients. This would function similarly to the current system of referencing EPA List 3 and List 4. This option reduces the sunset burden but is inflexible, like the current reliance on EPA List 3 and List 4. The initial list could be developed from EPA List 3 and List 4, but it is unclear how and by whom this list would be maintained or updated, and how it would fit within the regulatory framework of the National List.
- List allowed inert ingredients individually on the National List in the organic regulations. While the NOSB may be able to initially review these inert ingredients in groups to recommend adding them to the National List, they would need individual sunset reviews every five years. This could nearly double the Board's sunset workload.

NOSB received numerous comments on the topic of inert ingredients at its Fall 2023 and Spring 2023 meetings; the general themes of the comments are summarized below:

- There are two options that garner the most support: 1. To list each inert ingredient allowed for use in organic pesticide formulations on the National List individually; and 2. To reference a subset of EPA regulations in combination with an initial list of prohibited inert ingredients.
- There is consensus that inert ingredients allowed in minimum risk (“25(b)”) pesticides and inert ingredients allowed in pheromone type pesticides should be allowed in organic production.
- There is little interest from stakeholders in allowing all inert ingredients permitted in EPA pesticides in organic pesticide formulations, as this would delegate too much of the regulatory authority away from NOSB and NOP.
- Several stakeholders pointed out that the number of inert ingredients currently in use is a relatively small subset of those permitted, and should be the starting point for handling this issue. Material Review Organizations (MRO’s) can disclose the inerts in formulations they approve, without revealing confidential information about specific products.

Subcommittee Resources:

The Materials’ Subcommittee (MS) has worked with NOP staff to provide the resources needed to continue evaluating the viability of these options, which we describe in additional detail:

- Inert substances spreadsheet - in collaboration with Board members, NOP staff have developed a spreadsheet of the three hundred inert substances currently in use in organic pesticide formulas (according to public comments from MROs), descriptions of these substances’ functions in formulas and general chemical classifications, and any current EPA inert ingredient regulations that list these substances. The spreadsheet also includes all of the substances currently allowed as inert ingredients, which have been allowed in pesticide products as part of EPA’s ongoing inert ingredient review and approval process.
- Guest speaker - The MS has had the pleasure of hosting two calls with experts in the field of pesticide formulation and registration. Evisabel Craig and Kerry Leifer from EPA provided an overview of EPA’s inert ingredient review and approval process, and Karen Warkentien and Scott Tann-Lamberti, both from companies that formulate pesticides and produce inert ingredients, provided the MS with an overview of the considerations taken into account when formulating different types of pesticides and how the pesticide industry has adapted to EPA’s current regulatory framework governing approval of inert ingredients in pesticide products.

Below is a list of viable options that the MS has identified in response to the National Organic Program’s request. It must be emphasized that the NOSB deems it extremely important to avoid the current dependence on an outdated and/or static substance list.

Two Viable Options

The MS has concluded through its own review and discussion, input from stakeholders through the public comment, and guest speakers, that there are two viable options to review inert ingredients in organic pesticide products:

1. List inert ingredients individually on the National List. Starting with the list of substances currently in use in organic pesticide formulas, NOP should move forward with rulemaking listing all of these substances individually. With the status-quo preserved in the National List with individual listings, additions and removals can be petitioned by the public as needed, and NOSB can propose additions and removals during the sunset cycle. MS acknowledges this option expands the National List substantially and adds to the sunset review burden for future boards, however, this option also focuses the individual review of inert substances used in organic pesticides away from EPA and towards NOSB and NOP, which aligns with many public commenters' opinions.
2. Allow substances defined and allowed by EPA as "inert ingredients" (40 CFR 152.3 & 7 CFR 205.2) with restrictions and prohibitions. Starting with inert ingredients that have been reviewed and approved by EPA for inclusion in pesticide formulas, MS recommends further restricting this group by only allowing those which are allowed in formulations that are exempt from the requirement of tolerance. MS also proposes an initial list of prohibitions that include alkylphenol ethoxylate substances and per- and polyfluoroalkyl substances.

Sunset Review

Both options will require sunset review every five years as mandated by the Organic Foods Production Act (OFPA). While the two options may present different sunset review burdens, future boards will benefit from NOSB providing a road map for this review. As such, the MS will continue to work on developing a sunset review process for both options, so future boards are supported in their ongoing work. We hope this work can parallel the rulemaking process at NOP so that there is a sunset review road map for whatever option NOP ultimately decides to enact.

Further Discussion:

Option 1: List Individually or individually by group

National List Criteria

Substances to be added to the national must satisfy the following criteria:

1. The input is necessary or essential because of the unavailability of natural or organic alternatives
2. The input is not harmful to human health or the environment; and
3. The input is consistent with organic principles.

Pros / Cons

This option aligns fully with National List requirements. It is not dependent on external lists that may change without notice over time, giving confidence to pesticide manufacturers. Inerts that are nonsynthetic are not part of the National List and can be used in organic pesticide formulations. Manufacturers must document their nonsynthetic status as part of the material review process.

Our current listing of inerts in use in approved organic pesticides indicates 227 synthetic substances. All of these substances will need to be reviewed on a staggered 5-year basis. We suggest they be placed into groups based on chemical types and use:

- Alkylphenols
- Polymers
- Emulsifiers and surfactants
- Solvents
- Minerals, pH adjusters, physical effects
- Preservatives
- Coloring agents
- Other

This grouping approach should not impact how a substance can be used in a pesticide formulation, but, rather, provides a framework to add efficiency to the sunset review process. For example, if a substance functions as either a surfactant or a solvent, it can be used for either purpose regardless of whether its sunset review is done within the surfactant group or the solvent group. This process is manageable and gives pesticide manufacturers the opportunity to provide input to the NOSB during the sunset review process. If a substance is voted by the NOSB to be removed from the National List, there is time during rulemaking for further input and reformulation.

This process is transparent and allows the NOSB to apply NOP standards to inerts, which go beyond the requirements of the EPA for approval. It strengthens the integrity of the process and allows for innovation since substances not on the National List can be petitioned for inclusion.

Sunset Considerations

We suggest staggering the reviews of these groups over a 5-year period, with those that may have problematic items being reviewed earlier. For instance, the alkylphenol group or some members of the emulsifiers and surfactant group may be removed from the list after initial review. We expect the first sunset review of each group to be most difficult, requiring research assistance from the NOSB food technologist. Subsequent reviews may require less work.

Option 2: EPA List with restrictions and prohibitions

National List Criteria

Substances to be added to the National List must satisfy the following criteria:

1. The input is necessary or essential because of the unavailability of natural or organic alternatives
2. The input is not harmful to human health or the environment; and
3. The input is consistent with organic principles.
 - a. Inert ingredients are necessary components of organic pesticide formulations. Depending on the chemical and physical characteristics of approved active ingredients, the target pest, and application method, synthetic inert ingredients are necessary in

order to make pesticide formulations effective. It is impossible to evaluate the necessity of each individual inert ingredient within a particular pesticide formulation, as these formulations are confidential and protected by the disclosure laws included in the Federal Insecticide, Fungicide, and Rodenticide Act.

- b. EPA currently evaluates all inert ingredients used in pesticide formulations and either determines that the individual compounds are allowed in pesticide formulations that are exempt from tolerance or establishes limits for individual compounds used in pesticide formulas. NOSB is proposing to only allow the inert ingredients that are permitted to be included in pesticide formulas exempt from the requirement of a tolerance because these are the substances that EPA has determined to be not harmful to human health or the environment. We have also proposed an exception to this general rule for alkyl-phenol ethoxylates, as new science has shown this class of compounds to have negative environmental impacts and should not be allowed in organic pesticide formulas.
- c. Consistency with organic principles is a challenging National List criteria to apply to an opaque set of compounds and formulas. However, we acknowledge that forever chemicals such as per- and polyfluoroalkyl substances (PFAS) are not consistent with organic principles and should not be included in organic pesticide formulas regardless of use pattern or potential to cause harm to human health or the environment. Therefore, we propose an additional exception to the allowance for inert ingredients to prohibit this class of substances.

The intention behind this option is to allow all inert ingredients allowed in pesticide formulas exempt from tolerance, with exceptions. The two exceptions proposed at this time are alkyl-phenol ethoxylates and PFAS for reasons explained above. We chose to use language in the recommendation around exemptions from tolerance rather than specific regulatory references in order to ensure this baseline remains evergreen should EPA update its categorization of inert ingredients again. However, currently, the inert ingredients that meet this minimum threshold are included in the following federal references:

- 40 CFR 180.910 (Crops)
- 40 CFR 180.920 (Crops)
- 40 CFR 180.930 (Livestock)
- 40 CFR 180.940 (Post-Harvest Antimicrobials)
- 40 CFR 180.950 (Minimum Risk Pesticides)
- 40 CFR 180.960 (Polymers for Passive Pheromone Dispensers)

Pros / Cons

The option to align with EPA's list of inert ingredients with exceptions will significantly reduce the burden on NOSB to conduct lengthy sunset reviews of each substance potentially used in pesticide formulas. It will allow NOSB to focus on prohibiting problematic substances as they arise during the sunset review process. This option also does not rely on MROs disclosing substances actually in use in organic pesticide formulas, which is privileged information and may not be available to NOSB in future sunset cycles. It also ensures that, at a bare minimum, only inert substances allowed in tolerance-exempt pesticides will be allowed in organic pesticide formulas. It also allows pesticide manufacturers to reformulate organic pesticides with the

industry's best and least toxic materials immediately rather than to wait for the petition and addition of individual compounds to the National List.

The efficiency gained by aligning with EPA does come with tradeoffs, however. NOSB will not evaluate and vote on each individual inert ingredient allowed in organic pesticide formulas, and some stakeholders will view this unfavorably. There is also a concern related to the potential difficulty in adding to the list of exceptions in the future as new science reveals additional substances that should not be permitted in organic pesticide formulas.

Sunset Review Considerations

Regardless of which option ultimately becomes part of the National List, NOSB will be obligated to conduct sunset reviews of the listings. Should the EPA list-with-exceptions become the regulation, NOSB will have to evaluate whether these substances continue to meet National List Criteria or if additional prohibitions should be proposed. In order to support this work, the NOSB is committed to developing an inerts sunset "roadmap" regardless of which option is adopted. For this option, a starting place for future NOSB sunset reviews could be to compare current allowances and exceptions with the European Union's banned co-formulants list ([Annex III to Regulation \(EC\) No 1107/2009](#)). Many of the substances on this list are prohibited with the proposed exceptions (APEs and PFAS) in this proposal.

Subcommittee Vote:

Motion to accept this proposal, which proposes two viable listing motion options for NOP to consider in rulemaking related to synthetic inert ingredients used in organic pesticide products.

Motion to add [individual substances identified in Appendix A] at 205.601(m)

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

~~(1) EPA List 4 Inerts of Minimal Concern~~

~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~

(1) 1,2,3-Octadecenoate (CAS 9007-48-1)

(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)

(3) ...

Motion to add [individual substances identified in Appendix A] at 205.603(e)

(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.

~~(1) EPA List 4 Inerts of Minimal Concern~~

~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~

(1) 1,2,3-Octadecenoate (CAS 9007-48-1)

(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)

(3) ...

OR

Motion to amend 205.601(m)

(m) ~~As Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance,~~ 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, except for:

- ~~(1) EPA List 4 Inerts of Minimal Concern~~
- ~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
- (1) Alkylphenol ethoxylate substances
- (2) Per- and polyfluoroalkyl substances

Motion to amend 205.603(e)

(e) ~~As Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance,~~ 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, except for:

- ~~(1) EPA List 4 Inerts of Minimal Concern~~
- ~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
- (1) Alkylphenol ethoxylate substances
- (2) Per- and polyfluoroalkyl substances

Motion by: Nate Lewis

Seconded by: Brian Caldwell

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

APPENDIX A:

See [Regulations.gov](https://www.regulations.gov) - docket # AMS-NOP-24-0023 - under "Supporting & Related Material" for Excel Spreadsheet

