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

Introduction:

NOP issued a memo to NOSB on June 23, 2023 requesting NOSB provide a recommendation related to inert ingredients used in pesticide products allowed in organic production. This 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 regarding these options in its Advanced Notice of Proposed Rulemaking published September 2, 2022. The four options as described by NOP in its memo 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 this memo without adequate time to bring forward a discussion document for the Fall 2023 meeting. However, the topic was referred to the Materials Subcommittee (MS) who formed a workgroup to focus on this agenda item. The Subcommittee submitted the following questions into the public docket for stakeholders to consider and to ensure there would be multiple opportunities for stakeholders to provide comments on the topic of inert ingredient review and approval:

- 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 will increase this workload. To what extent should NOSB consider current and potential future workload when evaluating the options for modernizing the approval of inert ingredients in pesticide products?
- 2. Authority Congress granted the Environmental Protection Agency the authority to determine efficacy and safety of pesticide products and the NOP and NOSB the authority to determine which pesticide products aligned with the Organic Foods Production Act and National List Criteria. 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?
- 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 research will emerge regarding safety and necessity that may require additions and removals from the list of inert ingredients approved for use in pesticide products. 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?

NOSB received numerous comments on the topic of inert ingredients at our Fall meeting, and the general themes of the comments are summarized below:

- There are two options which 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. MRO's can disclose the inerts in formulations they approve, without revealing confidential information about specific products.

Subcommittee Next Steps:

The Materials Subcommittee focused on ensuring the various options are fairly considered and in order to do so, requested NOP provide NOSB with a way to evaluate; which substances are currently allowed as a

List 4 or List 3 inert, which would be allowed under the various options, which are nonsynthetic and therefore categorically allowed in organic pesticide products, and which are currently in use according to Material Review Organizations who review pesticide formulas for compliance to the organic regulations. The data for this last category of substances was drawn from comments received in response to the 2022 Advance Notice of Proposed Rulemaking (ANPR). NOP staff have delivered a draft of this analysis in the form of a spreadsheet, and the MS has included it in this discussion document as Appendix A (See Regulations.gov Docket # AMS-NOP-23-0075: Supporting and Related Materials).

The MS also intends to invite experts on the topic of inert ingredients to its meetings in preparation for a proposal for the Fall 2024 meeting in Portland, OR. We hope the additional information received at the Spring 2024 meeting and through discourse with experts will lay a foundation of understanding for the entire board on this complicated topic, so that a recommendation can be reached advising the NOP on its intention to move forward with rulemaking related to inert ingredients.

Questions for Stakeholders:

The MS has the following specific questions for stakeholders and, as always, welcomes any additional perspectives, solutions, and information related to inert ingredients used in organic pesticides.

- 1. Please provide feedback on the format and analysis of Appendix A. The Board will use this to comprehend the practical impact the various options will have on the number of substances that would need to be added to the National List based on the corresponding option (e.g. if all inerts are listed individually or that would be allowed under various subsets of EPA regulations depending on the option)?
- 2. What areas of expertise should the MS consider when inviting speakers to subcommittee meetings in order to obtain the fullest and most accurate understanding of this topic?
- 3. Please provide feedback on whether the list of inert ingredients currently in use (see Appendix A), is accurate.
- 4. Does the potential reduction in the number of substances the Board must review outweigh the inflexibility associated with the option to develop a single, external list of allowed inert ingredients?
- 5. Would designation of a specific entity responsible for maintaining the single external list of allowed inert ingredients change stakeholder's opinions of this option?

Subcommittee Vote:

Motion to accept the discussion document on Inert Ingredients used in Organic Pesticide Products

Motion by: Nate Lewis Seconded by: Brian Caldwell

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Appendix A (See Regulations.gov Docket # AMS-NOP-23-0075: Supporting and Related Materials).