



April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Crops & Livestock Subcommittees – EPA List 4 Inerts of Minimal Concern (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop and Livestock Subcommittee’s Sunset Review of EPA List 4 Inerts of Minimal Concern.

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

Summary

- ✓ Inert ingredients are necessary for the manufacturing of pesticide products used by organic crop and livestock producers for pest control when preventive management practices have failed.
- ✓ To resolve longstanding outdated regulatory references, OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and modernize the system for review of inert ingredients in organic approved pesticide products.
- ✓ Pesticide product development and innovation is being stifled by the outdated regulatory references for inert ingredients.

We offer the following more detailed comments:

I. Background

Inert ingredients are defined in the National Organic Program (NOP) regulations 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.**” The NOP regulations provide for certain synthetic inert ingredients to be used in organic approved pesticide products. EPA List 4 Inerts are permitted for use as inactive ingredients formulated with allowed active pesticide ingredients for both crop and livestock production. EPA List 3 Inerts have a more limited allowance only in passive pheromone dispensers in crop production.

The current listings on the NOP National List read,

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

(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.

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

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic 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

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 system of classification at the time, in which EPA organized individual substances in to List 1-4 according to toxicology (List 1 being most toxic to List 4 being least toxic). Shortly after listings for EPA List 3 and 4 were formalized in the NOP regulations, EPA began implementing a change to replace Lists 1-4 with a new system of tolerance assessments to be codified in 40 CFR Part 180. EPA completed its transition to the new system in 2006. As of then, EPA no longer uses or maintains Lists 1-4.

According to information contained in a [NOP Policy](#) for reviewing inert ingredients (emphasis added), **“EPA has informed USDA that the “Inerts List” system may no longer be effective or available for the NOP to reference in the Regulations.** Also impacted is the EPA review and labeling program for determining the compatibility of pesticides with the Regulations. As a result, **the NOP regulations must be amended to acknowledge the inert tolerance reassessments conducted by EPA.** NOP will collaborate with EPA and the National Organic Standards Board (NOSB) to determine the most effective and efficient way to amend the regulations.”

The collaboration between NOP, NOSB and EPA was very active between 2011 and 2015. The **NOP-NOSB-EPA Inerts Working Group** was established in December 2010 with the goal of submitting a proposal to NOSB, through which NOSB would then develop a formal recommendation to NOP. The working group met frequently and reported regularly to the public at NOSB meetings. The Working Group evaluated several different options for resolving the outdated reference for inerts, and ultimately proposed that NOP work with the EPA’s new **Safer Choice Program** (Formerly the Design for the Environment Program). The Safer Choice Program is a voluntary program for verifying and labeling products that meet EPA Safer Choice Standards for human health and environmental safety. Ingredients must comply with the EPA’s **Safer Chemical Ingredient List (SCIL)**. The NOSB Crop and Livestock Subcommittees agreed with this approach and included a reference to the Safer Chemical Ingredient List (SCIL) in a proposal that was passed by NOSB in fall 2015.

The [2015 NOSB Recommendation](#) would revise the listing for inert ingredients at §205.601(m) and §205.603(e) to remove the outdated and obsolete references to EPA Lists 3 and 4, and replace with

EPA's current mechanisms for approving the least-toxic inert ingredients. The recommended annotation reads:

§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]

The listing for EPA List 3 and List 4 inerts have been renewed at each of the three previous Sunset Reviews that have occurred over the past twenty years. The renewals of these listing have been critical to allow NOSB and NOP to continue their effort to resolve outdated reference for inerts with minimal disruptions. As cited by NOSB during the last Sunset Review of EPA List 4 Inerts in fall 2015, "To allow these materials to sunset at this point would be too disruptive to the industry." At that meeting, NOSB also presented a minority opinion that stressed the importance of resolving the inerts issue, citing concerns with the regulation's "current reliance on a now non-existent review process."

This year (2020), NOSB is conducting its fourth Sunset Review of the EPA List 4 Inerts to determine its continued eligibility for inclusion on the National List as an allowed synthetic substance in accordance with criteria established in the Organic Foods Production Act (OFPA): 1) The input must not be harmful to human health or the environment; 2) The input is necessary for production and processing of organic products because of the unavailability of natural or organic alternatives; and 3) The input is consistent with organic farming and a system of sustainable agriculture. At the spring 2020 NOSB Meeting, the Crops Subcommittee presents its [Sunset Summary and Request for Comments on EPA List 4 Inerts \(starts on Page 34 for crops and Page 99 for livestock\)](#). NOSB will collect public comments at the spring 2020 meeting to inform its proposal and vote at the fall 2020 meeting.

II. Necessity for Production

Inert ingredients are necessary for the manufacturing of many various forms of pesticide products. Inert ingredients are used in conjunction with active ingredients to facilitate functionality and efficacy of the active ingredient. (Note: Active ingredients are subject to individual review and approval in accordance with NOP regulations.)

Pest control products formulated with inert ingredients are widely used in organic crop and livestock production. Hundreds of organic-approved pest control products are formulated with synthetic inert ingredients. These products are part of a limited restricted toolbox that farmers can access only when their preventive pest, weed, and disease management practices have failed.

Continued availability of effective and familiar pest control products for both crop and livestock producers is necessary for organic farmers to reliably bring their organic products to market. It is critical that the availability of these products continue throughout NOSB and NOP's ongoing efforts to update the listings of inert ingredients on the National List.

III. Implementing the 2015 NOSB Recommendation

A plan for implementing the 2015 NOSB Recommendation was proposed by the Crop and Livestock Subcommittee at the fall 2015 meeting. After the NOSB's vote to proceed with the annotation change, the following items were expected to take place:

- NOP will publish a *Federal Register* Notice to notify stakeholders of the intended revision, and to outline the procedure and timeline for implementation. 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 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.
- NOP will establish a Memorandum of Understanding with EPA to formalize their relationship and allow NOP to rely on EPA's Safer Chemical Ingredient List.
- NOSB will establish a procedure for addressing 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).

In NOP's response to the 2015 NOSB Recommendation, NOP stated "The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at §205.601(m) and §205.603(e)." For a short time after the 2015 NOSB Recommendation was passed, NOP made some effort to provide verbal updates at NOSB meetings to the organic community on its progress of implementing the recommendation, although this has not occurred since 2016. It has now been five years since NOP committed to implementing the NOSB recommendation; ten years since EPA directly requested NOP to remove the reference in its regulations; and about 15 years since EPA Lists became obsolete. Yet the NOP regulations still refer to EPA Lists that were last updated in August 2004.

OTA urges NOP to prioritize the implementation of the 2015 NOSB Recommendation and resolve the longstanding discrepancy in the organic regulations with regard to inert ingredients.

Modernizing the system for review of inert ingredients is a priority of the organic industry. Stakeholders need a current and reliable framework for identifying allowable ingredients for use in organic approved pesticide products. It is critical that NOP regulations have a valid system for identifying allowable ingredients that comply with OFPA criteria for the National List. OTA continues to support the 2015 NOSB Recommendation that utilizes EPA's current mechanisms for approving the least-toxic inert ingredients: FIFRA 25(b) pesticide program inerts, Safer Choice Program's Safer Chemical Ingredient List (SCIL), and inerts exempt from tolerance at 40 CFR Part 180 (for passive pheromone dispensers only). Incorporating these oversight and approval mechanisms aligns with USDA organic regulations,

which focus on human and environmental hazards, and provides product manufacturers clarity around how to reformulate their products as the organic standards become more current with the overall evaluation of pesticide products under EPA. We encourage NOP to continue working with EPA, NOSB, organic pest-control material manufacturers, and the organic sector at large to develop and implement a program that will both ensure continued safety of organic pest-control materials and minimize disruptions to the tools farmers rely upon when their preventive pest, weed, and disease management practices have failed.

IV. Questions from the Crops Subcommittee

1. *Can you provide examples of product development that have been stifled by the lack of clarity on the regulation and approval of inert ingredients in organically approved pesticide formulations?*

Pesticide product manufacturers have indicated to OTA that they will not invest research and development resources in new products when there is uncertainty about what ingredients will be allowed. The outdated regulatory reference for inert ingredients is stifling innovation in pesticide product development and organic agriculture.

2. *Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?*

We support NOP and NOSB efforts to implement a new system of review that would apply rigorous environmental and human health safety criteria to all inert ingredients. Under the 2015 NOSB Recommendation, inert ingredients would be approved under EPA's current mechanisms for approving the least-toxic inert ingredients. This new system of review would result in prohibition of some currently approved inert ingredients such as NPEs, a class of substances that has raised concerns at past NOSB meetings. We caution against using resources to pursue separate recommendations and rulemaking on individual inert ingredients when the broader solution would accomplish the same end goal and would cover more substances. Stakeholders always also have the option of submitting a petition to prohibit certain substances.

3. *Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?*

OTA supports implementation of the 2015 NOSB Recommendation. This recommendation is the result of years of collaborative work between NOP, NOSB, and EPA, and allows for multiple avenues of identifying allowed inert ingredients without the burden of NOSB having to individually review or list inert ingredients. See **Part III** for more information on implementing the 2015 NOSB Recommendation. If there are insurmountable obstacles to implementing the 2015 NOSB Recommendation, then we would support NOSB exploring alternative approaches. NOP should be transparent with NOSB and the organic community if such obstacles exist.

4. *What would be the consequences of an NOSB recommendation to delist List 4 Inerts?*

There would be significant disruption to organic production if EPA List 4 Inerts were delisted without a valid replacement system for reviewing and approving inert ingredients. Organic producers would lose critical tools for controlling pests when preventive practices fail. See **Part II** for more information.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association