



September 30, 2021

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

Docket: AMS-NOP-21-0038

RE: Crops Subcommittees – EPA List 3 Inerts (Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Crop Subcommittee's Sunset Review of EPA List 3 Inerts.

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

- ✓ OTA strongly supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review.
- ✓ OTA supports NOP's prioritization of rulemaking on inerts and our member Task Force is poised to respond to the forthcoming Advanced Notice of Proposed Rulemaking.

We provide more details comments:

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. As described in Appendix A to these comments, the current regulatory references on the National List to EPA Lists 3 & 4 are obsolete, and a modernized system for reviewing inert ingredients is not yet in place despite past NOSB Recommendations that had identified viable solutions.

OTA strongly supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review.

There is no indication that NOP would be able to complete full implementation of a system of reviewing inerts prior to the sunset date of List 3 inerts in 2023. The prohibition of List 3 inerts prior to establishment of a new system would cause significant disruption to the availability of essential pest control tools for organic production. Voting to prohibit this important class of substances is irresponsible

and risky when farmers' access to critical tools for organic production is at stake. OTA's Farmers Advisory Council¹ agrees and strongly urges caution to protect continued availability of critical pest control tools for farmers. Therefore, the continuation of the current listings of EPA List 3 inerts is critical for ensuring continued availability of effective and familiar pest control tools for organic producers.

It is important that NOSB acts in a consistent manner across the multiple listings of inerts on the National List. Last year, NOSB voted to relist EPA List 4 and we encourage NOSB to do the same for EPA List 3. This will ensure harmonized and coordinated implementation of a viable solution for both EPA List 3 and EPA List 4 inerts. The [unanimous 2020 NOSB Resolution](#) recognizes that that a viable program allowing for the review and use of inerts must be created before the current listings are removed.

OTA supports NOP's prioritization of rulemaking on inerts and our member Task Force is poised to respond to the forthcoming Advanced Notice of Proposed Rulemaking.

Modernizing the system for review of inert ingredients is a priority of the organic industry. 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. We appreciate that USDA has included Inerts on its [Unified Agenda](#), but recognize its status as a "Long-Term Action" and the Advanced Notice of Proposed Rulemaking (ANPR) has yet to be published. It is critical that NOP continues to prioritize and proceed in a timely manner to resolve this longstanding regulatory discrepancy.

OTA's Inerts Task Force is committed to identifying and advancing viable alternative solutions for evaluating inert ingredients to ensure continued safety and availability of pest control tools that organic farmers rely upon when their preventive pest, weed, and disease management practices have failed. The Task Force will inform OTA's comments in response to the forthcoming ANPR. The Task Force has been meeting regularly since March 2021 and have made progress in establishing principles and criteria for evaluating effective and viable systems for reviewing inert ingredients. We have also explored several policy options for replacing EPA List 3 & 4 listings, and are collecting data about the impacts of each option on currently allowed and in-use inert ingredients. We look forward to providing substantive and constructive comments to support the NOP rulemaking process.

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 Miranda
Farm Policy Director, OTA

cc: Laura Batcha
Executive Director/CEO, OTA

¹ The Organic Trade Association's Farmers Advisory Council (FAC) provides the Organic Trade Association Board of Directors and staff with input from small- and medium-sized organic farmers, ranchers, and growers on matters pertinent to the advancement of organic agriculture, with a specific focus on OTA's policy agenda. More at ota.com/FAC

APPENDIX A

Regulatory Background: Inert ingredients in pest control products for organic crop and livestock production

Inert ingredients are necessary for the manufacturing of many various forms of pest control products. Inert ingredients are used in conjunction with active ingredients to facilitate 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 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.

Current Regulations

Inert ingredients in pest control products are subject to individual review and approval in accordance with USDA's 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. Substance 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.

According to information contained in the [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."

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.

2015 NOSB Recommendation

Interagency efforts to resolve the regulatory discrepancy were very active between 2010 and 2015. **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 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.

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.

2020 NOSB Resolution

At the Fall 2020 NOSB Meeting, the Board narrowly voted to renew the current listing of EPA List 4 Inerts and also voted unanimously in favor of the following [resolution](#):

In voting to relist EPA List 4 Inerts of Minimal Concern, the NOSB recognizes the vital importance of the substances included in this listing to the organic industry. However, in referencing a list that is no longer maintained, using a list on which no new substances can be added, and not allowing for review of individual or groups of materials, the use of List 4 ingredients on the National List is problematic and outdated. The NOSB recognizes that a viable program allowing for the review and use of these substances must be created before this listing can be removed. Therefore, the NOSB asks that the National Organic Program do the following:

- 1) Work with the NOSB to develop a viable alternative process that allows for the review of many of the substances presently on EPA List 4 and has minimal disruption to the organic industry;
- 2) For substances that do not meet OFPA criteria for listing, work to provide a sufficient period for industry to change formulations and receive regulatory approval for the new formulations;
- 3) Coordinate regularly with the NOSB on progress to develop an alternative to the EPA List 4 Inerts of Minimal Concern that allows for stakeholder input and the removal of the reference to EPA List 4 inerts on the National List.

In response, NOP [stated](#) that this as a leading priority and plans to move forward with an Advanced Notice of Proposed Rulemaking (ANPR) to discuss the policy options for resolving the outdated EPA List 4 listing.