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Materials Subcommittee
National Organic Standards Board (NOSB)
National Organic Program (NOP)
Agricultural Marketing Service (AMS)
US Department of Agriculture
1400 Independence Avenue SW
Room 2646-S, Mail Stop 0268
Washington DC 20250-0268

ATTN: Michelle Arsenault, Advisory Committee Specialist, NOSB

SUBJECT: **Meetings: National Organic Standards Board**
***Federal Register* Notice 88 FR 54173, June 8, 2023**
Follow-Up to ANPR on Inert Ingredients in Pesticides for Organic Production
Docket ID AMS–NOP–23–0026
Submission of Comments

Dear Ms. Arsenault and NOSB Materials Subcommittee Members:

Thank you for the opportunity to comment on the subject *Federal Register* **Meeting of the National Organic Standards Board** concerning USDA-AMS-NOP-NOSB's request for feedback on preliminary questions to help inform a discussion document on how to rectify the USDA organic regulations' references to the outdated EPA inert ingredient Lists 3 and 4 and improve the policies and procedures for establishing allowable pesticide inert ingredients for use in organic crop and livestock production. The Biological Products Industry Alliance (BPIA) submits herewith these comments.

By way of introduction, BPIA promotes the responsible development of safe and effective biological products including biopesticides and biostimulants. These beneficial tools are used in a variety of settings, including commercial agriculture, forestry, golf courses, home gardens, horticulture, and ornamentals. BPIA also supports public health through education, outreach, and advocacy activities at the state, federal and international levels. BPIA's membership includes both large and small manufacturers of biological pest control products and biostimulants used extensively by conventional and organic growers in the USA and globally, as well as manufacturers of pesticide inert ingredients.

EXECUTIVE SUMMARY

BPIA appreciates the opportunity to respond and comment on NOSB's preliminary questions concerning how best to include and maintain inert ingredients for organic crop and livestock production on the **NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES ("NATIONAL LIST")** under **7 CFR Part 205, Subpart G**. BPIA has provided comments to the NOSB and NOP concerning the most recent sunset reviews for EPA Lists 3 and 4, as well as the Advanced Notice of Proposed Rulemaking (ANPR) concerning inert ingredients and agrees wholeheartedly with both NOSB and NOP that the current system, referencing the outdated EPA lists, is broken and needs to be fixed. Starting this process now is critical to ensure that a new, better system is developed and in place prior to the next round of sunset reviews scheduled for 2027. In the present document, BPIA has responded to the preliminary questions posed by NOSB and addressed the various benefits as well as constraints related thereto.

The importance of having effective pesticides for use in organic production to manage crop loss, combined with the lack of effective non-synthetic inert ingredient options, is a key reason why EPA List 3 and 4 inert synthetic ingredients have historically been allowed. This need has not changed. BPIA would additionally like to stress the importance of being able to formulate inputs with the latest active and inert ingredient technologies for use by

organic farmers. Formulating involves processing to optimize an active ingredient's storage, stability, handling, safety, application, and/or effectiveness. Needs are varied and will depend on the active ingredient itself. For example:

- To uniformly spread a small amount of an active ingredient over a large area, a carrier that can dissolve the material may be needed.
- Organic active ingredients are often easily biodegraded and thus need to be protected from microbial contamination until use, and sunlight and oxidation during use.
- Adjuvants, such as stickers and spreaders, ensure that the product stays on the plant surfaces where it was applied and needs to remain to be effective.

Having access to new, innovative formulation ingredients beyond what has been allowed to date will expand the portfolio and quality of biopesticide products available for use in organic production. Recognizing the importance of and supporting the protection of food crops and food availability to consumers through the prevention of crop loss is, we believe, highly necessary and can be done safely. As the amount of organic acreage in the country grows, this need will only increase.

NOSB QUESTIONS

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?

BPIA understands and appreciates the resource requirements and constraints incumbent in the task to ensure that inert ingredients used in pesticides for organic production are consistent with OFPA. As part-time volunteers, NOSB members are sharing their time between their important Board service and their full-time jobs. Adding individual listings of inert ingredients (currently numbering at around 900 distinct listings for what was previously included on List 4) to the sunset review workload would pose an incredible burden on NOSB, certainly affecting NOSB's ability to accomplish its mission to ensure compliance with OFPA standards. A review of the comments submitted in response to the ANPR shows nearly universal agreement that individual listing of inert ingredients (**OPTION D** in the ANPR) is unworkable and not a viable alternative for inert ingredient approval due to the immense amount of work required. Seeking other options, including relying on other qualified experts, such as EPA, and grouping inert ingredients, in whole or in part, would help alleviate this burden.

Utilizing EPA's comprehensive scientific and regulatory review of individual inert ingredients to determine their acceptability for use in pesticide products, including those that may be used in organic production, would allow NOSB to rely on EPA's scientific expertise, thus providing NOSB more time to focus on the overarching issue of organic compliance throughout the food production process rather than diverting resources to inert ingredient review.

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?

BPIA fully supports NOP and NOSB coordinating with other regulatory agencies, such as EPA, and drawing on their scientific expertise to evaluate the human and environmental safety of ingredients used in pesticide inputs intended for organic production under OFPA. Regulation of pesticide products, including the inert ingredients necessary for

their effective use, is a complex process. In the United States, EPA, as the lead agency for chemical and pesticide regulation, is responsible for ensuring that all pesticide products, including those for use in organic production, are safe for humans and the environment. Reviewing and approving inert ingredients is an integral part of that process.

EPA is responsible for the safety assessment of all chemical substances used in the USA under TSCA (Toxic Substances Control Act). EPA's review under TSCA is overarching and encompasses all uses of chemicals, including those that are not related to agriculture, such as ingredients used in cleaners, lubricants, and other industrial and residential applications. EPA's work under TSCA thoroughly assesses the impact to humans and the environment of all chemicals produced, imported, and/or used in the US. TSCA was expanded and strengthened in 2016 under the Lautenberg Act [1] amendment, prioritizing review of existing chemicals based on an updated standard for determining "*unreasonable risk*."

As with all other chemicals, pesticide inert ingredients are subjected to review under TSCA. TSCA requires chemical reporting of use, manufacture, and any adverse incidents, and includes continuing obligations for data generation under programs such as the High Production Volume (HPV) program, as well as by direct "test rule" orders under TSCA §4. Only after a chemical has been vetted through TSCA, can it be considered for use in pesticide products.

In addition to TSCA oversight, inert ingredients for use in pesticides go through a second EPA assessment to meet the requirements of FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and, in the case of pesticides that may lead to residues in food, also FFDCA (Federal Food, Drug, and Cosmetic Act). The data submitted and developed under TSCA are an integral part of the pesticide inert review process, where they are supplemented with proposed use information (e.g., use sites/crops) and additional data to evaluate direct and indirect human health and environmental impacts from their use in pesticides.

As discussed in BPIA's comments on the ANPR, EPA's comprehensive reassessment of inert ingredients in pesticide products started back in 1987, when EPA instituted a policy[2] by which all old and new inert ingredients would be evaluated under FIFRA. That policy required EPA to ensure that all inert ingredients met defined safety standards ("*not of toxicological concern*") and established the set of data required to support existing and new inert ingredient approvals for both food and nonfood uses in pesticide products. This baseline dataset included physical/chemical properties, human health, environmental fate, and ecotoxicity data, as well as data on biodegradation and persistence. FQPA[3] further strengthened the standard by requiring that pesticide ingredients, including inert ingredients, be used with "*a reasonable certainty of no harm*." The current data requirements that must be addressed for pesticide inert ingredients[4] are presented below.

- ☐ Physical/chemical properties
- ☐ Toxicity Data
  - Acute toxicity (oral, dermal, and inhalation toxicity; eye and skin irritation; skin sensitization)
  - Chronic/repeat dose toxicity
  - Reproduction/developmental toxicity
  - Mutagenicity
  - Carcinogenicity
  - Neurotoxicity
  - Endocrine disruption
  - Immunotoxicity

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[1] Frank R. Lautenberg Chemical Safety for the 21st Century Act, PL 114-182, 130 Stat 448, June 22, 2016.

[2] The original "**Inert Ingredients in Pesticide Product; Policy Statement**" (52 FR 13305, 1987-04-22) was republished/revised several times in the intervening years between its establishment and the promulgation of FQPA. See PR Notice 87-6 (1987-05-12); 54 FR 48314 (1989-11-22); PR Notice 90-1 (1990-05-01); 55 FR 26753 (1990-06-29).

[3] *Food Quality Protection Act of 1996 (FQPA)* (PL 104-170, 110 Stat. 1489, 1996-08-03)

[4] See EPA's updated requirements under PRIA 5 found at https://www.epa.gov/system/files/documents/2023-05/food-use-inert-2023.pdf

- Human/animal metabolism
  - Is the chemical absorbed by the body?
  - How much of the chemical is excreted and how is it excreted (*e.g.*, urine, feces)?
  - Will it bioaccumulate? Are the degradates/metabolites of the chemical more toxic than the parent chemical? If no metabolism data are available, registrants are asked to provide potential metabolic/degradation products based on currently available scientific information.
- Exposure: Identify all anticipated exposure pathways (*e.g.*, dietary, residential, and occupational) for both pesticidal and non-pesticidal uses of the chemical.
  - Dietary exposure (includes exposure through food and drinking water)
  - Residential exposure (dermal, inhalation, and incidental oral from all residential uses as well as non-pesticidal residential uses)
  - Occupational exposure (anticipated exposure to workers mixing, loading, and applying the inert ingredient to the treatment area; also includes post-application exposure)
- Environmental Fate and Effects
  - Biodegradation/persistence in the environment
  - Expected fate of the chemical
- Ecotoxicity
  - Aquatic
  - Avian
  - Invertebrate

Since pesticide inert ingredients also have non-pesticidal uses and are generally used throughout the world, these data are often developed for multiple regulatory agency approvals, with detailed conclusions published and available for the public and EPA in peer-reviewed assessments, journals, and databases, such as WHO, OECD SIDS, IUCLID, ECHA, EPA/TSCA HPV, CIR,[5] and others. As you can see, the required data points are quite extensive and inert ingredients are subjected to a thorough assessment. All currently approved inert ingredients, having been subjected to this rigorous review process, meet the "*not of toxicological concern*" standard, which was the requirement set by OFPA for the purposes of the NOP implementing regulations.

Another important consideration is that EPA's inert ingredient review process is open and transparent, with risk assessment evaluations and safety determinations announced in the *Federal Register* and posted in the www.Regulations.gov docket repository. Interested parties, stakeholders, and the general public can review and comment on those assessments prior to EPA taking regulatory action. The lists of approved ingredients are codified and publicly available in the **CODE OF FEDERAL REGULATIONS (CFR)**. These lists are subject to ongoing review, including addition, revision, and deletion of ingredients ("living" lists), as compared to the now "frozen" and obsolete EPA Lists 3 and 4.

Moreover, EPA is continually receiving information about the production, use, and effects of inert ingredients through mandatory reporting obligations under both TSCA and FIFRA, assessing and reassessing the risks and benefits of the compounds individually as well as on a group basis, and taking action to reduce or eliminate uses as warranted to meet the safety standards imposed by the regulations discussed above. EPA's recent action on the PFAS (per- and polyfluoroalkyl substances) compounds is one such instance.

Most importantly, although EPA reviews and approves chemicals and pesticide inert ingredients, NOSB maintains ultimate oversight of inert ingredients used in organic production. NOSB has taken action on its own initiative to prohibit one or more individual ingredients or classes of chemicals in the past and will continue to have the authority

[5] WHO = World Health Organization; OECD SIDS = Organisation for Economic Co-operation and Development Screening Information Dataset; IUCLID = International Uniform Chemical Information Database; ECHA = European Chemicals Agency Information on Chemicals database; EPA/TSCA HPV = EPA/TSCA High Production Volume Challenge Program; CIR = Cosmetic Ingredient Review.

to make similar decisions should it deem them necessary to ensure organic integrity under OFPA and its implementing regulations. Ingredients prohibited by NOP can be viewed as a "Negative List" under **7 CFR Part 205, Subpart G**. Other organic programs, such as those in Europe, utilize "Negative Lists" of particular ingredients or components that are deemed inconsistent with organic production. "Negative Lists" are much smaller and more manageable than the "Positive Lists" used today in the US and Canada, and the administration and use of such "Negative" lists is clearer and easier to understand by certifiers, industry, and the general public. BPIA strongly believes that moving to a "Negative List" system is an optimal solution. A "Negative List" leverages the scientific expertise of EPA's pesticide inert ingredient review team and minimizes the time and financial resources needed to ensure that the ingredients used in pesticide formulations applied to organic crops and livestock meet the OFPA safety standard, while allowing NOP and NOSB to focus on addressing other issues affecting organic production.

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?

BPIA strongly supports grouping inert ingredients to reduce the workload required in the sunset review of materials allowed on the **National List**. The use of inert ingredient groupings is consistent with the advent of organic crop and livestock production rules and regulations, where NOSB, in February 1999, recommended the inclusion and exclusion of inert ingredients based on their EPA Inert List placement, which was then in use by EPA to prioritize re-evaluation of existing inert ingredients. As EPA added, deleted, and revised those inert ingredient listings, the status of individual ingredients was also changed under the organic production rules. This system worked quite well until EPA stopped maintaining those lists.

While those old "lists" are no longer in use by the EPA, the listings of allowable inert ingredients for food use that are codified in **40 CFR Part 180, Subpart D** can be referenced in the **National List** and serve as a starting point to indicate formulants allowable under OFPA. These listings in **Part 180** indicate the pesticide ingredients that have met EPA's safety standard for "food use" ingredients according to FIFRA, FQPA, and FFDCA regulations and policies, and are not merely internal EPA documents, like the old "inert lists" were, but rather are subjected to open review by the public through formal notice and comment. The lists cannot simply be deleted or disused without a public process and formal rulemaking, so that **40 CFR Part 180, Subpart D** makes for a more "*permanent*" and reliable reference. The codified regulations in **40 CFR Part 180, Subpart D** are updated continually as new inert ingredients are approved by EPA and older inert ingredient approvals are revoked making it a true "living" list.

As to innovation, BPIA members are hopeful that new technologies to help formulate novel, safe, and reliable products will be made available for use in organic production. New inerts that go through the EPA review and approval process undergo the same evaluation and meet the same safety standards applied to the old "List 4." The current system of relying on lists frozen in time over 20 years ago stifles innovation. While new biopesticides continue to be developed, the lack of suitable, compatible, and effective inert ingredients often results in products that cannot capitalize on the great potential of biopesticide active ingredients and result in subpar and sometimes unusable products. Just as novel and cutting-edge control agents are being developed, so too are new, unique, and effective formulating agents. However, these innovations are currently limited to use in conventional agriculture and cannot be used in organic production. This irony is not lost on BPIA.

CONCLUSIONS AND NEXT STEPS

BPIA applauds AMS and NOSB for tackling the vexing issues surrounding inert ingredients in pesticide products intended for organic crop and livestock production. This is an important first step towards identifying viable options and developing a new paradigm to address inert ingredients.

BPIA reiterates its support for allowing all EPA-approved inert ingredients as the "PREFERRED OPTION" for grouping inert ingredients. We believe that this is the best option from a resource, expertise, and regulatory perspective. Integrating the extensive materials review conducted by EPA under its chemical and pesticide programs affords NOSB a solid and scientifically-reliable base upon which to make organic policy decisions. EPA reviews all inert ingredients to the "*not of toxicological concern*" / "*reasonable certainty of no harm*" safety standard and only EPA-approved inert ingredients can be used in pesticide products. Furthermore, should any particular ingredient(s) cause concern for the organic community, OFPA and its implementing regulations provide a mechanism whereby the NOSB can propose and AMS can promulgate specific prohibitions for any compound that it deems incongruous with the organic regulations. Coupling EPA-approved inert ingredients with the "Negative List" already maintained and codified by NOP will provide clear, science-based guidance for maintaining compliance with OFPA. Maintaining the *status quo* effectively bars new, innovative, and potentially safer inert ingredient technologies from being used in organic agriculture and can limit innovative pesticide active ingredients that rely on these technologies for formulation stability and effectiveness.

We appreciate the opportunity to comment and offer support to NOSB, AMS, and EPA to work towards a solution that supports growers with the biological tools they rely on, without interruption, while also opening the door to innovation.

Thank you again for the opportunity to comment on this proposal. Should you have any questions about this response, please feel free to contact me.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director