April 3, 2024

Via Federal eRulemaking Portal: http://www.regulations.gov

Materials Subcommittee (MS)
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: **Meeting of the National Organic Standards Board**
***Federal Register* Notice 89 FR 8398, February 7, 2024**
Follow-Up to ANPR on Inert Ingredients in Pesticides for Organic Production
Docket ID AMS–NOP–23–0075
Submission of Comments

Dear Ms. Arsenault and NOSB Materials Subcommittee Members:

Thank you for the opportunity to comment in advance of the 2024 Spring **Meeting of the National Organic Standards Board** concerning USDA-AMS-NOP-NOSB-MS's "Questions to Stakeholders" listed in the subcommittee's February 13, 2024, meeting minutes concerning the USDA organic regulations' references to the outdated EPA inert ingredient Lists 3 and 4 and how to rectify and improve the policies and procedures for establishing allowable pesticide inert ingredients for use in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, biofertilizers, 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, biofertilizers, 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 follow-up 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 sunset reviews for EPA Lists 3 and 4, as well as the Advanced Notice of Proposed Rulemaking (ANPR) and NOSB's own request for comments 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 follow-up 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. While those lists were used strictly for internal EPA prioritization of review during that Agency's re-evaluation of then current inert ingredients, they were dynamic listings that were revised and changed on a regular basis reflecting EPA's current knowledge about the risks and benefits of those ingredients. Compounds were routinely moved from one list to another based on the available information and EPA's assessment of data submitted on inert ingredients. NOSB generally accepted the movement of these inert ingredients onto and between Lists 3, 4A, and 4B and continued to allow them for use in input products for organic production as specified in the regulations at **7 CFR Part 205, Subpart G** during the period where those lists were being publicly published, the last of which was published in October 2004.

The net sum of the inert ingredient re-evaluation process was to be able to make a determination that all inert ingredients allowed for use in pesticide products, including those previously approved as well as those newly submitted and found acceptable, would meet EPA's statutorily defined safety standard ("*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. The **FOOD QUALITY PROTECTION ACT OF 1996 (FQPA)** further strengthened the statutory safety standard by requiring that pesticide ingredients, including inert ingredients, be used with "*a reasonable certainty of no harm*." While EPA stopped using Lists 3, 4A, and 4B twenty years ago, the National List continued to reference the "frozen" Lists 3, 4A, and 4B. This has dramatically restricted the inert ingredients allowed for use in organic inputs.

BPIA would like to stress the importance of being able to formulate better inputs containing innovative technologies for use by organic farmers. Formulating a finished pest control or biobased input involves processing to optimize active ingredient and formulation stability, efficacy, handling (*e.g.*, pourability and dispersion), safety, application rates, and/or on-target movement. With biological products especially, the formulation needs to protect the living microbe and/or biochemical active agents in the bottle or bag to maintain viability of the active until it is applied in the field by the grower. Needs are varied and often 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.

The current toolbox available to input manufacturers hampers innovation, producing truly suboptimal formulations. Having access to new, innovative formulation ingredients beyond what is currently allowed will expand the portfolio and quality of biopesticide products available for use in organic production. This is necessary to maintain and increase the availability of organic products to the public and for US organic growers to remain competitive in domestic and global markets.

NOSB QUESTIONS

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)?*

Appendix A highlights quite clearly the issues that input manufacturers face relative to creating inputs allowable in organic production under the current rules. **Appendix A**, as prepared by NOP staff, lists a total of 828 entries as having been included on the October 2004 List 4A or List 4B. Of those 828 inert ingredients, 300 are indicated as currently in use in pesticide products reviewed by OMRI and/or PCO. While OMRI and PCO review quite a number

of input products intended for organic production, they do not review all such products. As such, that number is of limited usefulness.

Looking again at the 828 ingredients identified in **Appendix A**, 264 (more than 30%) were noted as "on List 4 but not in 40 CFR [Part 180]" which *de facto* restricts their use to "non-food use only." Not surprisingly, only 14 of those 217 inert ingredients were noted as being in use in products as reviewed by OMRI and/or PCO likely due to the limitation to non-food crops. These nonfood use inert ingredients are important for strictly nonfood use products and need to be maintained even if they are not represented the OMRI and PCO lists.

Another issue with **Appendix A** is the quality of inert ingredient data publicly-available to NOP. EPA has several databases devoted to inert ingredients, including InertFinder, which is found on EPA's website. InertFinder allows users to search using the name and/or CAS number for ingredients of interest, with results provided listing applicable food and nonfood use approvals.[1] While InertFinder is a good resource for understanding the magnitude of the limitations imposed on inert ingredients for organic production, there are errors and omissions in the InertFinder application. For example, **Appendix A** makes reference to **40 CFR §180.1035**, which includes a purported tolerance exemption for pine oil, which was included on the October 2004 EPA Inerts List 4B. However, this section of **40 CFR Part 180** was specifically **REVOKED** in September 2012 as it was no longer being used in any pesticide product [ref. 77 FR 59120, 2012-09-26].

Similarly, the NOP-parsed listing of 117 materials under **40 CFR §180.950**, consisting of **(a) Commonly consumed food commodities**, **(b) Animal feed items**, **(c) Edible fats and oils**, and **(e) Specific chemical substances**, as found in InertFinder indicates that lecithins, soya lecithins, peanut oil, and soybean oil are included in this section. However, all of these are potential allergens under **40 CFR §180.1071** and as such are restricted to non-direct food contact, such as through seed treatment, pre-plant, at-transplant, soil incorporation, cutting and bare root, soil-directed, rangeland, in furrow, and pre-emergence applications where the product has no direct contact with the edible portions of the food crop. There are some exceptions for oils under paragraph (c) if such oils are highly refined via a solvent extraction procedure and for lecithins under paragraph (b) that are not derived from the allergens listed in **40 CFR §180.1071**, however, it is evident that these restrictions can serve to prohibit or limit the use of certain ingredients under this CFR listing.

Additionally, of the 264 ingredients that are listed as "On List 4 but not in 40 CFR," 12 of them arguably are covered by the exemption(s) at **40 CFR §180.950** and/or **40 CFR §180.1071** as commonly consumed food or feed items (including the specified allergens), such as oils, apricot (**40 CFR §180.950(c)**); oils, basil (**40 CFR §180.950(c)**); oils, macadamia (**40 CFR §180.950(c)**/**40 CFR §180.1071(a)**); oils, orange-juice (**40 CFR §180.950(c)**); oils, orange-juice, citrus sinensis (**40 CFR §180.950(c)**); oils, sage (**40 CFR §180.950(c)**); oils, tangerine (**40 CFR §180.950(c)**); orange oil (**40 CFR §180.950(c)**); orange, sweet, Valencia, ext. (**40 CFR §180.950(c)**); paprika (**40 CFR §180.950(a)**); peanut meal (**40 CFR §180.1071(a)**); and D-xylose (**40 CFR §180.950(a)**)[2] even though InertFinder brings them up as "nonfood only." These characterizations as "nonfood" are likely due to old entries in the system that were not updated when **40 CFR §180.950** was added since specific listings of commonly consumed food commodities and edible oils was not required.

[1] InertFinder does not indicate acceptability for use in products for use in organic production so it can only be used to determine if entries on the October 2004 Lists are allowable for use in pesticide products today.

[2] This is a natural sugar derived from plants and is commonly consumed by humans, which indicates that it should be covered under **40 CFR §180.950(a)(1)(i)**; however, its only listing in InertFinder comes up as a "non-food only" ingredient, which contradicts the assumption of commonly consumed food items, including sugars, being covered by **40 CFR §180.950(a)(1)(i)**.

Further, NOP staff noted caseins, sodium complexes (**40 CFR §180.1071(b)**);[3] licorice extract (**40 CFR §180.950(e)**);[4] and Rhodamine B (**40 CFR §180.2020**);[5] as "not in 40 CFR" in **Appendix A** when in fact all are present in the tolerance exemption sections under 40 CFR Part 180.

However, probably the most important consideration is the other ingredients, many of which were previously on the October 2004 List 3, and the subsequently added inert ingredients that were approved by EPA after the last public listing of inert ingredients 20 years ago. Broader listings covering functional groups (commonly referred to as "Clusters") of compounds were added as a result of the regulatory review mandated by **FQPA**. These included some List 3, 4A, and/or 4B compounds along with new compounds. These changes confound the review of materials against the old 2004 lists as the descriptors and/or CAS numbers may not reflect the old entries but instead reflect broader characterizations of the same materials.

InertFinder, while a useful tool, has its limitations and does not account for some of the older, now out-of-date information contained therein. Additionally, while EPA does a rather good job now of including all commonly used names and applicable CAS numbers for each inert ingredient entry, earlier entries for individual inerts as well as groups of inerts often did not include all relevant CAS numbers (oftentimes did not include any) and ingredient names applicable to the compound(s) listed. Nomenclature for chemicals can be quite confusing and frequently there are multiple names that may be assigned to a compound based on IUPAC, ANSI, ISO, or other standards organization naming conventions, or it may simply use the colloquial common name, such as "water." Searching by name and/or CAS number may not return the desired information if the correct search term is not entered. While it is desirable that EPA revise its existing listings to include, at a minimum, all relevant CAS numbers, this effort would take quite a bit of time and effort and likely is not a priority for the Agency. Although the publicly-available inert ingredient lists have their limitations, EPA maintains up to date records of allowed inert ingredients and their restrictions, and pesticide manufacturers, state regulators, and others routinely reach out to the Inert Branch when clarifications are necessary.

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?*

BPIA suggests that NOSB-MS consider inviting EPA Registration Division inert ingredient review staff from the Chemistry, Inerts and Toxicology Assessment Branch to discuss the inert ingredient review process, including the types of data reviewed, the endpoints of concern, and the human and environmental risk assessment conducted to determine which ingredients meet EPA's risk standard. Other suggested speakers could include inert ingredient producers, pesticide input manufacturers and distributors, and grower groups. These groups can explain the review process and standards inert ingredients must meet to be allowed for use in pesticides and how inputs currently allowed for organic production are meeting (or not) current organic grower needs.

3. *Please provide feedback on whether the list of inert ingredients currently in use (see Appendix A) is accurate.*

Please refer to BPIA's comments to Question #1 for a discussion on the accuracy of the list provided.

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?*

As mentioned in previous BPIA comments, we strongly recommend that the NOSB utilize EPA's core list of inert ingredients as a starting point, similar to what is done now with the references to List 3 and List 4 in the regulations.

---

[3] This is actually included by name and CAS number and the name and CAS number do match what is listed in the October 2004 Inerts List 4B.

[4] Listing differs from the List 4B entry in that it doesn't include the parenthetical "(licorice and licorice derivates)" and the CAS number listed is 97676-23-8.

[5] Rhodamine B is used only a dye for discoloring seeds that have been treated with pesticides and its use itself is considered to be "nonfood" since the seed is not part of the edible food crop.

The shear number of inert ingredients, even the roughly 800 from the last published List 4, is a big lift for any organization to review, especially a volunteer cadre not all of whom have the required scientific expertise (chemistry, toxicology, environmental fate). Coupling this with the need to review that list of ingredients every 5 years makes the option to cite to EPA's approved inert ingredients, to which all ingredients in pesticide input materials are bound, a much more reasonable task to take on, keeping in mind that NOSB would retain the authority to exclude any inert ingredients for use in organic production by adding them as prohibited substances in the National List.

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. Adding hundreds of individual listings of inert ingredients 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. It is for these reasons that BPIA recommends that NOSB and NOP rely on EPA's approved inert ingredients as a baseline. 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 expertise and clearly meet the OFPA requirement that synthetic inert ingredients be "*not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern*."

It is critical that the external list be a flexible, living list. The lists referenced in the response to question 5 would allow NOSB to refer to external lists maintained and reviewed by the experts at EPA without the inflexibility that a static list would impose.

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?*

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, new lists have replaced them. The most comprehensive solution, within the requirements of OFPA, would be to allow all inert ingredients approved for food and nonfood use by the EPA in organic inputs. The reference in the **National List** would be to the inert ingredients allowed by the EPA, rather than specific lists. Alternatively, 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. Similarly, **40 CFR §152.25(f)** could be referenced for minimum risk inert ingredients. These lists 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 rulemaking. These codified regulations are updated continually as new inert ingredients are approved by EPA and older inert ingredient approvals are revoked making them a true "living" list. They also cannot simply be deleted or disused without a public process and formal rulemaking, so that these codified regulations make for a more "*permanent*" and reliable reference. Should this alternative solution be implemented, the nonfood use ingredients categorized as, "on List 4 but not in 40 CFR [Part 180]" in Appendix A could be referenced as a new and separate group in the **National List**.

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 step towards identifying viable options and developing a new paradigm to address inert ingredients at this critical time.

BPIA reiterates its support for allowing all EPA-approved inert ingredients as the "PREFERRED OPTION" for grouping inert ingredients. We strongly believe that this is the best option from a resource, expertise, and science-based 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. 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. Continuing to reference the EPA Lists 3 and 4 or a subset of those lists maintains the *status quo,* effectively baring new, innovative, and potentially safer inert ingredient technologies from being used in organic agriculture and limiting access to innovative pesticide active ingredients that rely on these technologies for formulation stability and effectiveness.

The inert ingredients approved since October 2004 reflect the innovation that has occurred to develop better and safer inert ingredients in the last 20 years, which have been incorporated into conventional pesticides, but have not been allowed in inputs for organic production. State of the art inert ingredients are especially important for developing stable and effective biopesticide and biostimulant products. US organic farmers are limited to old technology and subpar products as a result of the references to Lists 3 and 4 in the National List. This puts them at a disadvantage not only versus conventional growers, who ironically have access to better "green" inert technology, but also versus international organic growers in Europe and elsewhere that operate under organic trade agreements allowing them to freely export "USDA Organic"-labeled produce to the United States with inert ingredients that are currently not allowed in "home-grown" organic production.

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