International Organic Inspectors Association
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Sept 28, 2023

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP 1400 Independence Ave. SW
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

Re: Docket #: AMS-NOP-23-0026

Re: Work Agenda Request: Inert Ingredients in Pesticide Products

Dear Ms. Arsenault:

IOIA is the leading worldwide training and networking organization for organic inspectors. Though a United-States based nonprofit 501(c)(3), IOIA operates globally with nearly 250 inspector members in over a dozen countries. Our members are the "boots on the ground" at the annual inspections of certified operators. The inspector is often the first representative in-person at the operation and sometimes the only one. We see first-hand successes and failures of the many administrative and technical innovations which are implemented in the name of ensuring organic integrity.

IOIA wishes to acknowledge and respond to the June 23, 2023 memo that the NOP sent to the NOSB titled "Work Agenda Request: Inert Ingredients in Pesticide Products". This memo summarized public comments to the USDA's Advanced Notice of Public Rulemaking (ANPR) (87 FR 54173). IOIA calls on the NOSB to consider the comments that we submitted to the NOP in response to the ANPR. These comments are attached. In response to the NOSB questions to the public regarding capacity, authority, and flexibility, IOIA offers a brief response.

> ***1. Capacity*** *– The NOSB asks, "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?"*

IOIA position: We appreciate the work of the NOSB and how much you can do as volunteers. IOIA does not want to see inert ingredient review overwhelm the NOSB's current or future workload. However, we believe that preserving the NOSB's statutory authority to review and recommend synthetic substances on the National List is essential to protecting organic integrity, the public, and those of us in the field who work as the guardians of the organic label. The NOSB has a responsibility to ensure that inert ingredients approved for use in USDA organic production meet OFPA criteria. It is not possible for the NOSB to make an informed recommendation to the Secretary of Agriculture or even know what the current and future workload is without full public

disclosure of those inert ingredients that are questionable in their compliance with the OFPA criteria. Before proceeding with a work plan, the NOSB should request and be provided a comprehensive list of inert ingredients that are not on any of the consensus lists noted in the NOP's June 23, 2023 memo to you that most commenters on the ANPR agreed to comply with the OFPA criteria.

***2. Authority** – The NOSB asks, "When should NOSB rely on EPA's evaluations of safety, necessity, and efficacy in evaluating inert ingredients used in pesticide products?"*

IOIA position: EPA's assessment and determinations on inert ingredients does not necessarily mean that those inerts meet the OFPA criteria or should be allowed for use by USDA Certified Organic operations. The NOSB has the sole statutory authority to recommend synthetic substances—including inert ingredients in pesticides—to the USDA. The USDA cannot add synthetic substances to the National List without an NOSB recommendation by a supermajority vote. The NOSB has historically used a more precautionary approach than the risk modeling of the EPA when considering other pesticide ingredients that have been petitioned. EPA can be a valuable resource for the NOSB and partner with USDA, but it is unlikely that all inerts contained in formulations with active ingredients used in organic production will meet all the OFPA criteria. Again, as above, without access to information on all those ingredients (inerts and active), it will be impossible to know whether they are compliant under OFPA.

***3. Flexibility** – The NOSB asks "How rigid or flexible should the approved list of inert ingredients be to balance competing concerns?"*

IOIA position: We are an international organization with many members that play a guardian role for the entire organic community. Our members inspect many different organic systems on all arable continents to many different standards. We ask the NOSB to understand that not all operations certified to the USDA Organic standards use pesticides that are subject to the regulatory oversight of the US EPA and the respective state pesticide enforcement programs in the US. Inspectors can only collect information at the operational level. Some of our inspectors work for Materials Review Organizations. The NOSB should be aware that fraud is not just a problem with the production and handling of food and fiber labeled as organic. Input fraud—specifically the presence of prohibited substances in pesticide products claimed to meet the USDA Organic standards—is a known issue. Implementation of any regulation will require additional verification that products comply. Our members need clear standards as to what complies. Ambiguity of what ingredients are allowed, and those which are prohibited makes the job of an inspector difficult.

While we want to see innovation move forward in a thriving organic sector, we also believe that our members have a right to know the chemicals to which they are exposed when they conduct inspections. Several of our members chose to work as organic inspectors rather than in occupations that involved greater risk exposures to pesticides,

such as pest control advisors or farm supply dealers. It is an occupational hazard that our members would prefer to choose based on accurate and complete information of the risks. Our members understand and respect the necessity of confidential business information for innovation. However, once an innovation is made, we also firmly believe such confidentiality needs to be balanced with inspectors' right-to-know about their exposure when chemical risks are involved. While most inert ingredients pose risks that are acceptable, the priority is for transparency and full disclosure of all ingredients to interested parties over an NOSB process that evaluates the risks of exposure to specific ingredients on a case-by-case basis.

Thank you again for your vision and your work on this issue.

Sincerely,

Margaret Scoles, on behalf of the IOIA Board of Directors
Executive Director

Below, please see IOIA's December 2022 submission in response to Docket number: AMS-NOP-21-0008

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Docket number: AMS-NOP-21-0008
Regulatory Information Number (RIN): 0581-AE02

Subject: Inert Ingredients in Pesticides for Organic Production

Dear Jared Clark,

Please consider these comments regarding the Advanced Notice of Proposed Rulemaking (ANPR) for Inert Ingredients in Pesticides for Organic Production on behalf of the International Organic Inspectors Association (IOIA). We are the professional organization of organic inspectors and offer training and networking world-wide for crop, livestock, and processing inspectors. IOIA collaborates within the organic sector with governmental agencies including the USDA National Organic Program, certification agencies, and other nonprofit educational entities, to ensure quality inspections, quality inspectors, and organic integrity.

We offer the perspective of almost 400 members that inspect organic operations for all scopes under several different sets of national, regional, and private standards in about a dozen countries. Our members are most often the face and the voice of the certifier and the certification program. IOIA trains reviewers as well as inspectors. While inspectors do not determine what inputs are allowed or prohibited, we need to know the status of inputs. Our members inspect input suppliers, including pesticide manufacturers. Our members inspect both within and outside the U.S. We have an interest to see that the standards are clear, verifiable, enforceable, and based on the rule of law.

Summary

- OFPA applies to all ingredients of all inputs, including those that are prohibited for use in organic production when found on an organic operation. The standard for non-active ingredients or other undeclared ingredients should apply to all categories of inputs, not just to EPA registered pesticides.
- Transparency is necessary for inspectors. Inspectors of organic operations must be able to tell from looking at a product label whether a given input appears on the Organic System Plan.
- Inspectors have a right to know what chemicals they may be exposed to on the job.

- Because our members inspect split operations with both allowed and prohibited substances, inspectors are exposed to non-organic inputs and need to be able to distinguish between similar looking brand name products that may be allowed or prohibited based on different formulations.
- The NOP regulation does not address the contamination, adulteration, and fraud caused by undeclared prohibited ingredients found in pesticides and other inputs. EPA registered pesticides with active ingredients allowed for organic production have been linked to contamination of organic crops with prohibited substances, such as EPA registered pesticides that declared neem as the active ingredient, but was found with detectable levels of malathion, chlorpyrifos, and permethrin that resulted in organic product contamination.
- Contamination, adulteration, and fraud is not limited to EPA registered pesticides. There is evidence that pesticides claiming exemption from EPA registration in the US and their adjuvants may contain prohibited “inerts”, such as an adjuvant sold as a package with an exempt herbicide that contained glyphosate and diquat.
- Many producers certified under the USDA Organic program operate in countries and other jurisdictions where pesticides are not subject to US EPA regulations or enforcement. The USDA will need to address the regulation of pesticides used by USDA Organic certified operations in jurisdictions not subject to US pesticide regulations and not covered under an equivalency arrangement with the USDA.
- Among the various other organic standards our members are required to inspect and verify compliance are the Canadian Organic Regime (CAN/CGSB 32.310 and 32.311, hereafter referred to as the COR); the Mexican Organic Law (DOF 29.10.13, further referred to as the LPO), and the European Organic Legislation (EC 2018/848, or EU standard). Our members also inspect to private standards, such as the IFOAM–Organics International standard.
- IOIA is aligned with the Accredited Certifiers Association’s (ACA) comments regarding the need for clarity and verification of compliance. Our members will need to work closely with them to implement any amendment to the NOP rule.

General

- *Should AMS replace the references in the USDA organic regulations to the outdated EPA List 3 and List 4? What problems are caused by the current references to EPA List 3 and List 4?*

  Yes. The lists are not updated or maintained by the US EPA and are obsolete. Innovation and the development of safer alternatives to currently used inert ingredients has been stymied. The ecological and human health impacts of some of the ingredients on List 4. One example is nonylphenol ethoxylate’s properties as an endocrine disruptor.

- *How do various options align (or not align) with the statute (OFPA) and with AMS's authority, as provided under the statute, to regulate inert ingredients?*

  We respectfully request that the USDA work closely with and support the National Organic Standards Board (NOSB) in carrying out their statutory authority and mandates on synthetic inert ingredients contained in the Organic

Foods Production Act (OFPA) [Title XXI of the 1990 Farm Bill]. The NOSB is charged with recommending to the Secretary what synthetic substances may be used in organic production. Specifically, the OFPA states that "[t]he Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List" [7 USC 6518(d)(2)]. Based upon the foregoing language we understand that only inert ingredients that have been explicitly recommended for inclusion on the National List may be added. Any deviation from this raises concerns of ambiguity that prevent clarity in observation regarding eligibility of materials for use under NOP.

The OFPA also directs the NOSB to work with the US EPA and the National Institute of Environmental Health Studies (NIEHS) to prepare the National List. More importantly, the OFPA requires the NOSB work with manufacturers of substances to determine which synthetic inert ingredients should be considered for inclusion in the National List [7 USC 6518(l)(2)]. Inerts that were classified by US EPA as being of toxicological concern are not eligible for inclusion on the National List [7 USC 6517(c)(1)(B)(ii)].

Several of our members have served or are currently serving as volunteers on the NOSB. While they have informed us that the work can be daunting, the NOSB serves a necessary purpose to fulfill the statutory mandate and preserve organic integrity. We urge the USDA to provide the NOSB the access to information and technical support that it needs to make informed decisions.

- *What other options might be available that AMS and NOSB have not considered?*

  Inspectors need to be sure that they are looking at the product formulations approved on the OSP when they are on the farm looking at stored inputs and auditing the records. US EPA allows for a registered pesticide to have alternate formulations on file with the same name and registration number providing that the percentage of active ingredient is consistent. That means a given registered pesticide may have one formulation with a prohibited non-active or inert ingredient and one with an allowed inert ingredient. This has been a headache for OMRI, and the organic formulation may have just one letter's difference in the name from the non-organic formulation. Canada calls such ingredients "co-formulants, which is scientifically more accurate. Inspectors need to verify that the formulations are compliant. .

Third-Party (Non-Codified) Lists

- *Should AMS rely on third-party list(s) as a means of evaluating inert ingredients permitted in organic production? If so, which third-party list(s) would be appropriate, and why?*

The nature of such a list is not clearly explained in the ANPR. IOIA is open to all workable options that are inspectable and verifiable. However, it is important for inspectors to cite the appropriate regulatory text and explain the concern to the inspected party when they find possible non-compliances.

- *To what degree should the National List include individual substances allowed as synthetic inert ingredients versus referencing third-party lists established outside of AMS?*

  All synthetic substances, including inert ingredients, are prohibited unless they appear on the National List as allowed. The NOSB has the authority to recommend that synthetics be added to the National List. If the NOSB recommends such a list and the USDA adds it to the National List, that list needs to be verifiable and inspectable. The ability to verify compliance depends on the lists and the authority to obtain disclosure. In order for IOIA to comment, we require more specific information about what third-party lists are being used, who has access to them, how the substances on those lists are identified in pesticides used in all jurisdictions where organic food is being grown, and how organic inspectors are to verify that the ingredients used comply with the third party lists. IOIA requests that the options be presented with greater clarity if the USDA wishes to proceed with this option.

- *How feasible or acceptable is it for AMS to reference third-party lists (lists that exist outside of Federal regulations that are not published in the CFR) to update current references on the National List to EPA List 3 and List 4?*

  More information is needed before IOIA can form an opinion on an answer to this question.

- *How does the approval and update process (via incorporation by reference) affect the feasibility of referencing a third-party list(s) for inert ingredients on the National List? For example, if a third-party list of inerts is not published in editions, it is ineligible for incorporation by reference. Conversely, if a third-party list were published in editions, AMS would need to take rulemaking action to update the reference to a newer edition.*

  Given that the USDA organic program is being implemented throughout the world, a third-party list would require international recognition and all formulants and ingredients would need to be fully disclosed to certifying agents or their contracted materials review organizations for inspectors to verify that they comply.

Administrative Capacity

- *AMS recognizes that it takes time and effort for the NOSB to perform a sunset review for each item on the National List, and there are likely hundreds of substances used as inert ingredients under current USDA organic regulations. How could AMS and the NOSB complete the necessary sunset reviews if substances were listed individually on the National List?*

IOIA recognizes that this is a valid concern for the NOSB. Manufacturers need to provide the NOSB all specific substances used in formulations that are approved on Organic System Plans and under what specific uses these synthetic substances are necessary for organic production before IOIA can comment further.

- *How should the time constraints influence the approach that AMS should take regarding inert ingredients?*

  The National List is subject to a statutorily mandated sunset review. That should be sufficient.

- *The referenced Safer Choice program framework includes accreditation of third-party organizations, evaluation of substances against published standards by those accredited organizations, agency review of the evaluation, and publication of a list of approved substances. If AMS adopted a similar framework to that of the Safer Choice program, what would this look like, and would it address the regulatory challenges and capacity constraints outlined in this ANPR? What additional AMS staff resources would be required to accomplish this?*

  It is not clear how AMS can implement such a program or who would implement it. The pesticide registrants or inert manufacturers would be responsible for covering the cost and providing the data. The OFPA does not give the USDA statutory authority to regulate pesticide manufacturers directly. Any regulation of pesticide manufacturers would be indirect through the regulation of producers and handlers that use pesticides.

- *If inert ingredients are individually listed, which set of substances from EPA List 3 and List 4 should be initially migrated to the National List, and how would those substances be identified?*

  The List 3 inerts are easily migrated by the incorporation of a reference to 40 CFR 180.1122. See our comments for a suggested procedure for the migration of List 4 to the National List.

- *AMS notes that the NOSB has received more than 15 petitions to add specific inert ingredients to the National List, yet none have been recommended for addition to the National List.[13] If the established petition process is used to amend the National List to add or remove inert ingredients [14] would this approach satisfy the needs of the organic industry?*

  The petition process offers only a partial solution. The NOSB has limited time and is being asked to perform free service. Several of our members have served on the NOSB, and the amount of work that such a process would require is beyond what should be reasonably expected from volunteers. The EPA has a clear role and responsibility to help the NOSB. The statute requires the NOSB to work with manufacturers.

EPA Process and References

- *How should the phrase in OFPA "not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern" be interpreted in light of the EPA's current regulations and regulatory scheme for inert ingredients (see 7 U.S.C. 6517(c))?*

  Based on the plain statutory language, only the Administrator of US EPA can answer that question.

- *If none of the inert ingredients permitted under EPA regulations are considered to be of toxicological concern to the EPA, should AMS permit all EPA allowed inert ingredients in pesticides for organic production? What are the risks and benefits associated with this option?*

  IOIA encourages interagency cooperation between USDA and EPA. However, the NOSB plays a crucial role to determine what synthetic substances are permitted for organic production and handling. We reserve the right to comment further after the NOSB has made its recommendation with information collected from the manufacturers of pesticides in all jurisdictions where producers are certified to the USDA Organic standard, including those outside of the U.S. Organic standards are not based on risk-benefit analysis. As the face and voice of the program that will be required to explain the basis of the decisions, we ask that the USDA base its decision-making on organic principles and the OFPA, rather than on EPA's pesticide regulations. .

- *If any inert ingredients that are allowed by EPA should not be permitted under USDA organic regulations, what are those substances and why should they not be permitted as inert ingredients used in organic production?*

  Even if EPA declares all inert ingredients used for organic production are not of toxicological concern, that is only a necessary and not a sufficient condition for their allowance in organic production. The IOIA asks the USDA to respect the NOSB's statutory authority to add synthetic substances to the National List, and to ensure that the National List is clear, complete, and accurate. We are in alignment with the ACA to see that formulations used by organic operations are verifiable and inspectable.

- *If inerts at 40 CFR 152.25(f)(2) were used with active ingredients in pesticide products that are not exempt from regulation (i.e., not "minimum risk pesticides") the inert ingredient would require a tolerance (or exemption from the requirements of a tolerance) at 40 CFR part 180 for use in food or feed crops. AMS understands that there is not uniformity among 40 CFR 152.25(f)(2), 40 CFR part 180, and EPA List 4 (e.g., a substance may be listed on EPA List 4 and 40 CFR 152.25(f)(2) but not be present at 40 CFR part 180). What combination of these EPA regulatory citations, if any, would be acceptable and provide the least disruption to industry?*

  IOIA requires more information on the formulations used in organic production and how those are verified to be compliant before answering this question. We also ask the USDA to understand and appreciate that our members inspect operations that are certified to other organic standards, including Canada's COR,

the Mexican LPO, and the European organic legislation. The COR and LPO approach is modeled on the NOP, with some differences. The EU regulation was revised to refer to “safeners, synergists and co-formulants as components of plant protection products” as well as “adjuvants that are to be mixed with plant protection products” [EC 2018/848 Chapter III, Article 9, §3].

Thank you again for your work on this issue.

Sincerely,

Margaret Scoles, on behalf of the IOIA Board of Directors
Executive Director