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Date: December 30, 2022

Jared Clark, Standards Division, National Organic Program
USDA-AMS-NOP
1400 Independence Ave. SW, Room 2642-S., Ag Stop 0268
Washington, DC 20250-0268

Submitted via: regulations.gov

Docket Number: AMS-NOP-21-0008
Regulatory Information Number (RIN): 0581-AE02
Re: Advance Notice of Proposed Rulemaking: Inert Ingredients in Pesticides for Organic Production

Dear Mr. Clark,

Thank you for the opportunity to comment on the advance notice of proposed rulemaking for assessing inert ingredients in pesticides in organic production. MOSA certifies nearly 2000 operations in the midwest and throughout the United States. Almost all of MOSA's certified organic operations use inputs. We review inputs with inerts used in various pesticide applications for crops, livestock, and processing/handling including pesticides, insecticides, fungicides, herbicides, internal and external parasiticides and parasite control, facility pest management, and post-harvest handling. Such inputs are almost always restricted for use. MOSA has over 1100 pesticide inputs in our database. Approximately 650 are in use by our clients. We have reviewed 90 inputs with an acceptable inert ingredient and approximately 50 of them are in use by clients. Most of the products we see in use are verified by a third party: 11 are EPA approved for organic use products; almost 280 are OMRI listed (in use); and another 25 are WSDA listed. Many others are used outside of production areas and have prohibited ingredients and approval is only given through review and approval of a client's specific plan for use, under NOS § 205.271. MOSA staff extend careful consideration before approving such inputs for use.
We evaluated all inert ingredients that have been disclosed to us and have no significant concerns with updating references to options discussed below.

This notice seeks feedback from stakeholders regarding how to rectify the USDA organic regulations' references to outdated EPA policy on inert ingredients used in pesticide products. The outdated references are inconsistent with current EPA requirements.

As noted in the ANPR, we agree that inert ingredients added to pesticides may function, for example, as adjuvants, solvents, diluents, stabilizers, or preservatives and that pesticide labels do not typically disclose the identity (common or chemical name) of the inert ingredients in the product. We usually must request additional information from manufacturers of inputs. We also agree that the inert ingredients we have reviewed are a relatively small subset of the inerts found on the EPA lists.

This ANPR identifies five options as potential solutions:

1. **Option A. Allow Inert Ingredients Permitted by EPA in Minimum Risk Pesticides**
    - This option allows only materials on §152.25 Table 2 - Inert Ingredients Permitted in Minimum Risk Pesticide Products. This includes pesticides that are exempt from regulation under FIFRA because they pose little or no risk.

This option is clear and simple, though alone would not provide for thorough coverage of all of the ingredients included in materials we've reviewed. MOSA supports this option as part of the solution.

2. **Option B. Allow Specific Inert Ingredients Permitted by EPA**
    - This option allows only materials on listed at 40 CFR part 180 subpart D (§§ 180.900-180.1381).

This option is less clear and more complicated. The separate lists within 40 CFR part 180 subpart D reference different types of production to which the exemptions apply. In addition, specific materials within the different lists have limitations or specific uses included. These lists also lack material identification details (such as CAS#) which we likely would need in order to effectively look up materials. During a review, we would easily be able to determine *presence* in this section, but it would be much more cumbersome to verify appropriate category and use for each material. EPA does have the InertFinder database which would allow for easy lookup of materials, to determine if they are present at 40 CFR part 180 subpart D (§§ 180.900-180.1381). NOP clarification regarding use is required.

We agree that this reference should only apply to inert ingredients: *"Active ingredients in these sections that are exempt from the requirements of a tolerance that do not have an allowed use as an inert would not be permitted."*

MOSA tentatively supports this option as part of the solution. We request clarification regarding use of this reference.

In preparation to provide comments on Option A and Option B, we evaluated all of the inert ingredients in materials which we have reviewed and approved for use and found that all of them were covered by one of these two options. We did make a few assumptions about the correct category for a few materials and would need additional information from a these manufacturers to ensure that we used the correct terminology in our review. We appreciate the ANPR stating, *"A robust alternative to the existing regulations may require implementing more than one option."* We support the solution referencing multiple sources. If a material is not on one reference, it could be on another.

3. **Option C. Replace EPA List 3 With EPA-Allowed Inert Ingredients of Semiochemical Dispensers**
    - This option focuses on List 3 inerts for use in passive pheromone dispensers only and would replace the current review criteria with reference to EPA regulations for semiochemical dispensers found at § 180.1122: Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.

Semiochemicals are chemicals that are emitted by plants or animals and modify the behavior of the receiving species (i.e. pheromone dispensers). A semiochemical dispenser is a single, enclosed or semi-enclosed unit that releases semiochemical(s) into the surrounding atmosphere via volatilization and is applied in a discrete manner to the environment. Inerts are exempt from review when used as carriers in such dispenser products (with approved active ingredients) for use in growing crops. We understand that we would verify the special conditions specified at § 180.1122 including:

1) that exposure is limited to inadvertent exposure only. The design of the dispenser must be such as to preclude contamination of crops, either by proximity or size; and
2) that the dispenser is used discreetly, meaning in a dispenser and not broadcast or applied to plants or fields. This equates to a pheromone dispenser hanging in an fruit tree but not in contact with the fruit.

This option would simplify our review of formulated passive pheromone dispenser products yet still enable practical decision making due to the nature of use for these products. MOSA wholeheartedly supports this option.

4. **Option D. List Inert Ingredients Individually on the National List**
    - This option would require rulemaking action to list each necessary inert ingredient on the National List.

We would prefer to reference adequate lists maintained by other regulatory authorities and not have the NOSB and rulemaking process hindered by the review and evaluation of potentially hundreds of materials that would result from such a decision. We agree that the increased workload may be beyond the administrative capacity of stakeholders. MOSA does not support this option. That said, the presence of all materials on the National List would provide certifiers with a single source of easily referenced information.

5. **Option E. Take No Action (Status Quo)**
    - This option maintains reference to unsupported lists.

MOSA supports continued relisting until viable alternatives are reached. However, we agree that the reference lists the NOS uses need to be updated to other third party, regulated, and maintained alternatives.

6. **Other ideas**
    - We currently allow products approved under the *EPA for organic production or for organic gardening* program and would encourage more robust use of that system.
    - Inert ingredients used in pesticide products sold in the United States are reviewed and approved by the EPA, therefore if a product carries an EPA

registration number, we can be assured that EPA has verified that all inert ingredients in the product are allowed under a 40 CFR 180 subpart D citation. However, not all products used in organic production bear an EPA registration number, so this could only be part of a solution.

Additional Comments:
AMS noted that any reference to a third party list poses regulatory challenges including necessary oversight and management of the third party list, a process which may not be as transparent as the regulatory process we follow in our work and, for citations outside the Code of Federal Regulations (CFR) approval by the Director of the Federal Register, which is outside of the AMS's control. AMS additionally noted that the National List would need to be updated every time the referenced list is updated, creating additional steps for AMS. While there are disadvantages to referencing third party lists and review criteria, we encourage evaluation of the impact to stakeholders for *any* decision that is made and that inert ingredients review not become so arduous that it entirely reshapes our material review processes.
Additionally and notably, the standards *already* include many references to other regulations, both included and not included in the CFR, as required resources including the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), 21 CFR part 530 of the FDA for ExtraLabel Drug Use in Animals, 21 CFR 104.20 for Nutritional Quality Guidelines for Foods, Civil penalties as referenced in §3.91, Section 1001 of Title 18, United States Code for Crimes and Criminal Procedures, ASTM, and likely most notable and similar to inert review, is the rule for excipient review. However, with this inert rule, specific lists are intended as reference whereas with excipients review, certifiers are left to their own interpretation of the appropriate lists to use. ACA best practices for review of excipients point to almost twenty different resources to use for review. We encourage more specificity for inert review, though we also encourage listing references in a way that is *not so specific* that results in standards updates being necessary for every minor change that is made. For example, civil penalties previously referenced the specific citation (xxxvi) within §3.91 and through an update in recent years the specific reference was dropped since it can change when that regulation is updated. It seems like a workable plan could be reached.

In summary, MOSA is in support of updating references for the review of inert ingredients in pesticide products to current and maintained information. We will look forward to the publication of a proposed rule seeking additional comments. Thank you for your work on this topic.

Sincerely,

The MOSA Certification Team