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

Mr. Jared Clark
Standards Division
National Organic Program (NOP)
Agricultural Marketing Service (AMS)
US Department of Agriculture
1400 Independence Avenue SW
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SUBJECT: **Advance Notice of Proposed Rulemaking**
Inert Ingredients in Pesticides for Organic Production
***Federal Register* Notice 87 FR 54173, September 2, 2022**
Docket ID AMS–NOP–21–0008, RIN 0581-AE02
Submission of Comments

Dear Mr. Clark:

Thank you for the opportunity to comment on the subject *Federal Register* Advance Notice of Proposed Rulemaking (ANPR) concerning USDA-AMS-NOP's request for comments on how to rectify the USDA organic regulations' references to outdated EPA policy on inert ingredients used in pesticide products and improve the policies and procedures for establishing allowable pesticide inert ingredients for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 regarding USDA-AMS-NOP's proposals outlined in the ANPR.

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 producers of biological pest control products and biostimulants used extensively by US farmers, including organic growers, as well as producers of pesticide inert ingredients.

EXECUTIVE SUMMARY

BPIA appreciates the opportunity to comment on the ANPR and respond to the various questions posed by AMS and the proposed options to address how to revise and maintain 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reviews for EPA Lists 3 and 4 and agrees wholeheartedly with both NOSB and NOP that the current system, referencing the outdated EPA lists, is broken and needs to be fixed.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 commented on the options available and has addressed the various benefits as well as constraints of each one. A summary of BPIA's position is outlined below.

PREFERRED RECOMMENDATION

BPIA's preferred recommendation is to move away from a "Positive List" of permissible ingredients. BPIA supports inclusion of all current and future EPA-approved inert ingredients. AMS itself posed the 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?*

BPIA enthusiastically supports **AMS permitting all EPA allowed inert ingredients in pesticides for organic production**.

Benefits:

This option would ensure that all ingredients that had previously been allowed under the old Lists 3 and 4 system would still be permitted to be used in organic crop and livestock production (subject to said ingredients' continued approval by EPA).

This also allows for new inert ingredients to be used after review and approval by EPA.

Organic standards in other parts of the world, such as the EU, use a "Negative List" only, rather than the "Positive List" that we currently use in the United States. With the "Negative List" approach, all ingredients are allowed in organic production unless they are specifically excluded. The "Negative List" is a much smaller and more manageable list than the "Positive Lists" used today in the US and Canada. Administration of such a list is likewise easier as is its use by certifiers, industry, and the general public. The **ORGANIC FOODS PRODUCTION ACT OF 1990 (OFPA)** and its implementing regulations provides a mechanism whereby ingredients can be specifically prohibited from use in organic crop and livestock production, making this option consistent with the mandate of the NOP.

This option leverages the scientific expertise of EPA's pesticide inert ingredient review team while allowing NOP and NOSB to focus on other issues affecting organic production and the value added by NOP and the NOSB.

This option ensures that the ingredients used in pesticide formulations used in organic crop and livestock production meet the OFPA standard of "*not of toxicological concern*" and is also the least time-intensive, requiring a minimum amount of resources from AMS-NOP and the NOSB.

This option provides clarity and predictability for certifiers and the regulated community.

This option also provides flexibility for the future. For example, if FIFRA were amended to have expanded criteria for acceptable inert ingredients, that newer standard would automatically be incorporated into the NOP acceptability criteria.

Risks:

Any risks can be mitigated by the creation of an NOP "Negative List."

ALTERNATIVE RECOMMENDATION

While BPIA clearly supports the inclusion of all EPA-approved inert ingredients for use in organic crop and livestock production, should this preferred recommendation not be adopted, BPIA asks that AMS consider a combination of the following options proposed in the ANPR:

- **OPTION A: ALLOW INERT INGREDIENTS PERMITTED BY EPA IN MINIMUM RISK PESTICIDES:** BPIA recommends utilizing the list of ingredients identified by EPA and codified at 40 CFR §152.25(f)(2): Minimum Risk Pesticides, Permitted Inert Ingredients, to support inert ingredients for organic crop production on nonfood-use sites (*e.g.*, farmstead maintenance, irrigation system cleaning systems, and ornamental crops).

- **OPTION B: ALLOW SPECIFIC INERT INGREDIENTS PERMITTED BY EPA:** BPIA recommends utilizing the list of ingredients identified by EPA and codified at 40 CFR Part 180, Subpart D: Exemptions from Tolerances[1], to support the listed ingredients when used as inert ingredients for organic crop and livestock production.
- **OPTION C: REPLACE EPA LIST 3 WITH EPA-ALLOWED INERT INGREDIENTS OF SEMIOCHEMICAL DISPENSERS:** BPIA recommends utilizing the EPA tolerance exemption codified at 40 CFR §180.1122: Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance, to support inert ingredients utilized in passive pheromone dispensers. Note that adoption of **OPTION B** also incorporates this section by reference.

OPTIONS NOT RECOMMENDED

BPIA does not recommend either of the last two options proposed in the ANPR [Option D: List Inert Ingredients Individually on the National List; and Option E: Take No Action (*Status Quo*)].

BPIA agrees with AMS that Option D would require substantial work by NOSB and AMS to perform technical review and approve at least 190 substances that are noted as "currently in use" (but could grow to include many more) every five years and would require extensive collaboration with the US EPA's Inert Ingredients Branch to validate the status of each individual ingredient.

Similarly, BPIA agrees that Option E, maintaining the *status quo,* simply continues the conflict and disconnect that has plagued the inert ingredient listings since August 2004, when the last list of categorized inert ingredients was published by EPA. Should we maintain the *status quo*, all parties will inevitably be in the same predicament when List 4 and List 3 are again on the NOSB meeting agendas for Sunset Review in 2025 and 2026, respectively. As clearly expressed by AMS in this ANPR, a new system is necessary.

IN-DEPTH DISCUSSION OF OPTIONS AND RECOMMENDATIONS

PREFERRED RECOMMENDATION: PERMIT ALL EPA ALLOWED INERT INGREDIENTS IN PESTICIDES FOR ORGANIC PRODUCTION

BPIA strongly supports allowing all EPA-approved inert ingredients in organic crop and livestock production as the "preferred" option. This option would ensure that all food and nonfood use inert ingredients currently allowed under the outdated Lists 3 and 4 system would still be permitted and allow for new ingredients to be used after approval by EPA. This option relies on EPA's scientific expertise to meet the OFPA requirement that inert ingredients are not classified as inerts of toxicological concern by the EPA, while minimizing the time and resources required of AMS-NOP and the NOSB to review and approve inert ingredients.

BPIA would like to address the points raised and questions posed by AMS in the ANPR concerning the best way to move forward and away from the outdated Lists 3 and 4 system. The first questions we will address concern whether or not to have a list. The relevant questions from the ANPR are as follows:

- *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?*
- *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?*

The first question is the crux of the issue at hand. EPA completed the inert reevaluation and tolerance reassessment process that generated the infamous EPA Lists, including List 3 and List 4, in 2006. That reassessment program, begun in 1987 and expanded in 1996, required EPA to ensure that all inert ingredients met defined safety standards. The

[1] The ANPR lists 40 CFR §§180.900-180.1381 only but BPIA proposes that all entries in Subpart D be included when the listed ingredient is used as an inert ingredient.

original "**Inert Ingredients in Pesticide Product; Policy Statement**" (52 FR 13305, 1997-04-22)[2] was established to categorize inert ingredients according to toxicity and to establish a baseline set of data required to support existing and new inert ingredients for both food and nonfood uses in pesticide products. The **FOOD QUALITY PROTECTION ACT OF 1996 (FQPA)** (PL 104-170, 110 Stat. 1489, 1996-08-03) required the reassessment of inert ingredient tolerances and tolerance exemptions for food-use inert ingredients that were in place before its enactment. FQPA requires that EPA make safety findings when setting tolerances that pesticides can be used with "*a reasonable certainty of no harm*." Only those ingredients that meet those safety requirements for exposure and toxicity remain approved for use. All ingredients, including those that are naturally derived, are subjected to EPA's safety and risk assessments. All inert ingredients on the outdated EPA lists, including those on Lists 3 and 4, as well as all new inert ingredients added during and after completion of the reassessment process, have been determined to be "*not of toxicological concern*" when used as specified. This is the standard that was once represented by EPA List 4. **As such, all EPA-approved inert ingredients meet the OFPA requirement that they are "not of toxicological concern" and qualify as "List 4" for the purposes of the NOP implementing regulations**.

As to the second question, BPIA does not believe that there are any inert ingredients that are currently approved by EPA that should be prohibited under USDA's NOP regulations. That said, OFPA and the NOP regulations provide a mechanism to prohibit ingredients that otherwise qualify for organic production and indeed, NOSB has recommended that certain compounds be prohibited. This practice is in keeping with what is done elsewhere. Organic standards in the EU use a "Negative List" only, rather than the "Positive List" that we currently use in the United States. With the "Negative List" approach, all ingredients are allowed in organic production unless they are specifically excluded. The "Negative List" is a much smaller and more manageable list than the "Positive Lists" used today in the US and Canada. Administration of such a list is likewise easier as is its use by certifiers, industry, and the general public. BPIA strongly believes that moving to a "Negative List" system is an optimal solution. It leverages the scientific expertise of EPA's pesticide inert ingredient review team while allowing NOP and NOSB to focus on other issues affecting organic production. This system minimizes the resources, both time and money, needed to ensure that the ingredients used in pesticide formulations applied to organic crops and livestock meet the OFPA standard and are not of toxicological concern.

Additional, related questions by AMS concerned how EPA and EPA's processes related to OFPA and compliance with the statute. Those questions included the following:

- *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))?*
- *Can inert ingredients currently allowed by EPA regulations (i.e., in the Code of Federal Regulations) be sorted or classified according to toxicological concern? If some substances are of more concern, should AMS prohibit specific substances, or groups of substances, while allowing all other substances allowed as inert ingredients by the EPA? What criteria, specifically, would be appropriate for AMS to consider when assessing "toxicological concern"?*

As previously stated, the purpose of EPA's inert ingredient policy is to ensure that all ingredients used in pesticide formulations are "*not of toxicological concern*." At the outset of the program, inert ingredients of "more concern" were those assigned to EPA Lists 1 and 2 with those of "unknown toxicity" assigned to List 3. After thorough evaluation, EPA kept only the inert ingredients that met the safety standard and administratively revoked the ingredients that did not comply. Accordingly, all currently-approved inert ingredients in pesticide products adhere to this standard. BPIA believes that relying on EPA's evaluation and approval of ingredients is the most appropriate way to ensure that inert ingredients of toxicological concern are not used in organic production.

[2] This policy 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).

ALTERNATIVE RECOMMENDATION: UTILIZE A COMBINATION OF OPTIONS A, B, AND C PROPOSED IN THE ANPR

While BPIA strongly recommends allowing use of all EPA-approved inert ingredients, BPIA would like to present an alternative recommendation should AMS choose not to adopt the Preferred Recommendation. This Alternative Recommendation seeks to combine three of the options proposed by AMS in the ANPR (Options A, B, and C) as a means to capture many of the inert ingredients currently allowed in organic crop and livestock production while providing a mechanism whereby the approved ingredients are thoroughly reviewed and scrutinized to meet the OFPA standard of "*not of toxicological concern*"; the lists of ingredients are codified in the Code of Federal Regulations and publicly available; and the lists are subject to ongoing review, including addition, revision, and deletion of ingredients ("living" lists).

BPIA has addressed the advantages and disadvantages of each option on its own, as well as part of an overall discussion of how the three options can work in concert to serve as a possible replacement to the references to EPA List 3 and List 4.

OPTION A: ALLOW INERT INGREDIENTS PERMITTED BY EPA IN MINIMUM RISK PESTICIDES

AMS posed the following question in its request for comments in the ANPR:

- *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?*

Minimum risk inert ingredients listed at **40 CFR §152.25(f)(2)** include both food- and nonfood-use ingredients. Any food use ingredients listed at 40 CFR §152.25(f)(2) must also have a food-use inert clearance under **40 CFR Part 180, Subpart D**, irrespective of whether or not the active ingredient in the formulation is listed as a minimum risk active ingredient under 40 CFR §152.25(f)(1). Merely being listed under 40 CFR §152.25(f)(2) does not allow use of the ingredient on food/feed, even in an exempt pesticide product. As clearly stated in §152.25(f)(2): *"All listed inert ingredients may be used in non-food use products. Under FFDCA section 408 and EPA implementing regulations at [P]art 180 of this chapter, food and animal feed in commerce can bear pesticide residues only for those ingredients that have tolerances or tolerance exemptions in [P]art 180 of this chapter."*

BPIA supports inclusion of the inert ingredients identified by EPA and codified at 40 CFR §152.25(f)(2): Minimum Risk Pesticides, Permitted Inert Ingredients, to support inert ingredients for organic crop production on nonfood-use sites (*e.g.*, farmstead maintenance, irrigation system cleaning systems, and ornamental crops).

As stated in the ANPR, this option would:

1. Satisfy the OFPA requirement that inert ingredients not be classified by the EPA as "inerts of toxicological concern," as the EPA review process for all food-use inert ingredients includes a robust evaluation of toxicity and exposure risks;
2. Be similar to current regulations, and relies on the EPA's assessment of inert ingredients; and
3. Not allow substances currently used in formulated pesticide products (in compliance with current USDA organic regulations at §205.601(m) and §205.603(e)) that are not on EPA Table 2 at 40 CFR §152.25(f). This could eliminate products currently available to organic producers and/or require manufacturers to reformulate.

Concerning Points 1 and 2, BPIA agrees that EPA's inert ingredient assessment process ensures compliance with OFPA's mandate that any inert ingredient included in products for organic crop and/or livestock production be classified as "not of toxicological concern." Importantly, just as is the case for food-use ingredients, nonfood-use ingredients must also be assessed and approved by EPA prior to use in pesticides.

Concerning Point 3, BPIA agrees that **choosing only Option A as a replacement for the current references to List 3 and List 4 would disallow many ingredients that are currently permitted in products for organic crop and livestock production**. When EPA last published the inerts lists in August 2004, List 3 had over 1,900 ingredients while List 4 had over 1,000, for a total of nearly 3,000. By comparison, the **FIFRA §25(b)** list of inert ingredients, promulgated at **40 CFR §152.25(f)(2)(iv)**, only includes 287 ingredients, 214 of which are approved for use on food crops. This listing of ingredients in 40 CFR §152.25(f)(2)(iv), while not nearly comprehensive of all inert ingredients currently used in organic crop and livestock production, is useful in concert with Options B and C, as there are ingredients included here that are limited to nonfood uses only. Options B and C refer to EPA's regulations promulgated at 40 CFR Part 180, which only includes food-use ingredients. Including the listing of inert ingredients at 40 CFR §152.25(f)(2)(iv) allows reference to a codified list of ingredients that includes nonfood-use ingredients. BPIA is reviewing the exclusively nonfood-use ingredients currently allowed in organic crop and livestock production to determine which ingredients are not included in this listing under 40 CFR §152.25(f)(2)(iv). BPIA will provide additional information about those findings in a subsequent filing with AMS.

OPTION B: ALLOW SPECIFIC INERT INGREDIENTS PERMITTED BY EPA

AMS posed the following question in its request for comments in the ANPR:

- *Would the scope of allowed inert ingredients be clear if AMS adopted a reference to 40 CFR part 180 subpart D (or a subsection therein)? Is there a subsection of Subpart D that would be preferable to a reference to the entire Subpart D? Are there inert ingredients listed on EPA List 4 that are being used in organic-compliant herbicides for farmstead maintenance (roadways, ditches, right of ways, etc.) and ornamental crops, which do not appear in 40 CFR part 180 subpart D? Are there alternatives within Subpart D that could substitute for inerts in currently formulated products?*

BPIA strongly agrees that referencing **40 CFR PART 180, SUBPART D**, would provide a clear list of approved inert ingredients for use in organic food crop and livestock production. However, **this reference does not capture inert ingredients whose approval is limited to nonfood-use applications only**, such as farmstead maintenance, irrigation system cleaning systems, and ornamental crops. Additionally, should this Option be chosen, BPIA believes that the best reference would be to Subpart D in its entirety, and not a subset of listings. This would allow for revisions, additions, and deletions to Subpart D, that will occur over time, to continue to be referenced in the NOP regulations, making this a "living" reference.

This option seeks to utilize the list of ingredients approved by EPA and codified at 40 CFR Part 180, Subpart D: Exemptions from Tolerances, as a reference of approved inert ingredients for organic crop and livestock production. This subpart includes pesticide inert ingredients for which EPA has made a safety determination under the **FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)** (21 USC §301-392). EPA sets maximum residue limits ("tolerances") or exemptions ("tolerance exemptions") specifying the safe levels of both active and inert ingredients in food products.

"Tolerance" and "Tolerance Exemption" are defined at 40 CFR §176.3:

> *Tolerance* means the maximum amount of a pesticide chemical[3] residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.
>
> *Tolerance exemption* means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C 346a(c), that no tolerance is needed for a given pesticide chemical residue in or

[3] NB: The language of FFDCA refers to any ingredient in pesticide products, including inert ingredients, as a "pesticide chemical." See 21 USC §321(q)(1)(A): "[T]he term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 *et seq*.], including all active and inert ingredients of such pesticide."

> on a particular food commodity. For purposes of this part, the term "tolerance" shall include an exemption from the requirement of a tolerance.

FFDCA §408 authorizes EPA to establish either a tolerance (§408(b)) or an exemption from the requirement of a tolerance (§408(c)) if the Agency determines that the tolerance or tolerance exemption is safe for use on food crops, feed crops, and/or livestock.[4]

EPA defines food and nonfood uses at 40 CFR §180.2003:

> (a) Food uses are the uses of a pesticide chemical that are likely to yield residues in food or feed crops, meat, milk, poultry or egg.
>
> (b) Non-food uses are those uses that are not likely to yield residues in food or feed crops, meat, milk, poultry or egg.

If EPA determines that a tolerance or tolerance exemption is not safe, EPA must modify or revoke that tolerance or exemption.[5] FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[6]

Subpart D at §180.900: Exemptions from the requirement of a tolerance explicitly defines the standard by which a tolerance exemption can be granted:

> An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.

These ingredients have been thoroughly evaluated by EPA, which has concluded that they can be used on food crops, feed crops, and/or livestock without posing a hazard to public health. The inert ingredients approved by EPA have been deemed "safe" in the context of FFDCA and have been determined to be ingredients that are not of toxicological concern.

Utilizing existing, codified listings of EPA-vetted and approved inert ingredients for use in pesticide products provides a simple reference upon which the OFPA implementing regulations at 7 CFR §205 can rely. Linking to codified regulations provides more certainty that the list of ingredients will remain published, posted, and updated, something the previous EPA-internal "policy" listings of inert ingredients failed to do.

As stated in the ANPR, this option would:

1. Satisfy the OFPA requirement that inert ingredients not be classified by the EPA as "inerts of toxicological concern," as the EPA review process for all food-use inert ingredients includes a robust evaluation of toxicity and exposure risks;
2. Be similar to current regulations, as this option relies on the EPA's assessment of inert ingredients. Inerts permitted by the EPA are codified (appear in the Code of Federal Regulations [CFR]) and could be easily cross-referenced within the USDA organic regulations. When EPA adds or removes inert ingredients, the USDA organic regulations would not require corresponding revisions. Additional engagement with EPA in their rulemaking process by AMS and stakeholders may be warranted to stay informed of changes to EPA regulations; and
3. Potentially permit the use of more inert substances compared to the number of inert substances on EPA List 4 (approximately 870 substances) and EPA List 3 (approximately 1,850 substances).

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[4] See 21 USC §§346a(b) and (c).

[5] *Op cit*. 21 USC §§346a(b) and (c).

[6] See 21 USC §§346a(b)(2)(A)(ii), and (c)(2)(A)(ii).

Concerning Points 1 and 2, BPIA agrees that the EPA assessment ensures continuing compliance with OFPA's mandate that any inert ingredient included in products for organic crop and/or livestock production be classified as "not of toxicological concern."

Concerning Point 3, BPIA agrees that this option may permit the use of more inert ingredients than are currently permitted under the references to "EPA List 4" and "EPA List 3" last published in August 2004. BPIA, however, believes that it is important and imperative that the references for inert ingredients be a "living list" that will get updated on a periodic basis based on EPA's continuing assessments of existing and new inert ingredients, just as it was up until EPA stopped publishing updated inert ingredient lists.

Moreover, it is important to note that just as EPA is permitted to add new inert ingredients to 40 CFR Part 180, Subpart D, that comply with FFDCA, likewise EPA is required under FFDCA to remove ingredients if new data leads to a determination that use of such inert ingredients no longer meets the safety standard under FFDCA. One could argue that replacing the reference to the static List 4 with a reference to 40 CFR Part 180, Subpart D, will better meet the OFPA requirement that inert ingredients classified by EPA as "inert ingredients of toxicological concern" not be used in organic production.

Additionally, BPIA notes that while the ANPR lists 40 CFR Part 180, Subpart D, it also includes a parenthetical with only the sections 180.900-180.1381 included. BPIA is concerned that limiting the listing to only these sections may inadvertently omit new inert ingredients that may be added to Subpart D under a separate listing not covered by this section range. For this reason, BPIA recommends that the regulations in **7 CFR §205.601** and **§205.603** refer to any listed ingredients under **40 CFR Part 180, Subpart D** when used as inert ingredients in organic crop and livestock production.

OPTION C: REPLACE EPA LIST 3 WITH EPA-ALLOWED INERT INGREDIENTS OF SEMIOCHEMICAL DISPENSERS:

BPIA supports referencing the EPA tolerance exemption codified at 40 CFR §180.1122: Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance, to support inert ingredients utilized in passive pheromone dispensers.

As stated in the ANPR, this option would:

1. Continue to allow passive pheromone dispensers; and
2. Simplify the review of formulated products for certifying agents and third parties who review inputs for compliance with USDA organic regulations.

BPIA agrees on both points. This tolerance exemption citation covers all inert ingredients that may be used in passive pheromone dispensers applied to growing crops. Pheromones are semiochemicals emitted by a species that modify the behavior of members of their own species. The current listing under **7 CFR §205.601(m)(2)** allows use of List 3 ingredients in "*passive pheromone dispensers*" but does not provide a definition for this term. As an increasing variety of pheromone-dispensing technologies has become available, this has made interpretation of the current regulations difficult. By contrast, as noted in the ANPR, the ingredients covered by the tolerance exemption at **40 CFR §180.1122** are only allowed in dispensers that meet certain conditions, namely: (1) the dispenser is made of polymeric matrix materials; (2) any exposure to inert ingredients must be limited to inadvertent physical contact only; and (3) the dispensers must be applied discretely (*i.e.*, as distinct physical units placed in the field to emit semiochemical(s) into the atmosphere via volatilization out of the unit). This exemption does not apply to formulations that are broadcast sprayed onto crops. There should be little to no exposure to organic crops from the use of any inert ingredient permitted under 40 CFR §180.1122. Furthermore, all inert

ingredients allowed under this exemption must also be reviewed and approved by EPA[7], which includes a thorough evaluation of toxicity and exposure risks.

Replacing the reference to List 3 with a reference to **40 CFR §180.1122** would meet the requirement of the OFPA that synthetic inert ingredients used in organic production are not classified by the EPA as "*inerts of toxicological concern*" and facilitate interpretation of the organic regulations codified at **7 CFR §205.601**. It would also allow for new inert ingredients to be approved for use in semiochemical dispensers using the existing EPA inert ingredient approval process without necessitating additional resources from the USDA NOP or NOSB. Passive pheromone dispensers currently on the market commonly contain EPA-approved nonfood use ingredients. Referencing 40 CFR §180.1122 would greatly reduce or even eliminate market disruptions that could occur if inert ingredients currently approved in these products were no longer allowed. Importantly, should AMS adopt Option B, which includes a reference to 40 CFR Part 180, Subpart D, for inert ingredients used in organic crop and livestock production, the citation at 40 CFR §180.1122 would already be included by reference. As such, an individual listing under 7 CFR §205.601 would not be necessary to support inert ingredients used in passive pheromone (semiochemical) dispensers.

OPTIONS NOT RECOMMENDED

Options D (individual listing of ingredients) and E (take no action) are not recommended for the reasons listed below.

OPTION D: LIST INERT INGREDIENTS INDIVIDUALLY ON THE NATIONAL LIST

BPIA strongly opposes and does not support listing inert ingredients individually on the National List. Doing so would be duplicative with the work already being done by EPA when it approves inert ingredients for use in pesticides.

As stated in the ANPR, this option would:

1. Require coordination or validation of these inert ingredients by the EPA to verify they are not of toxicological concern to meet the OFPA requirement that synthetic inert ingredients not be classified by the Administrator of the EPA as "inerts of toxicological concern;"
2. Require a sunset review of approximately 190 substances currently in use in organic-compliant pest control products every five years as required by OFPA at 7 U.S.C. 6517(e). This change would nearly double the number of substances currently present on the National List (approximately 230 substances) and would significantly increase the NOSB's and NOP's workload; and
3. Likely require a lengthy implementation period to minimize disruption and provide adequate time for submission of petitions, NOSB review, and AMS rulemaking.

AMS posed the following questions in its request for comments in the ANPR:

- *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?*
- *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. If the established petition process is used to amend the National List to add or remove inert ingredients would this approach satisfy the needs of the organic industry?*
- *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*

[7] Due to the nature of semiochemical/pheromone dispensers, ingredients otherwise considered "nonfood-use" inerts are allowable under this tolerance exemption but only when used in semiochemical dispensers as specifically defined in **40 CFR §180.1122**.

regulations. How could AMS and the NOSB complete the necessary sunset reviews if substances were listed individually on the National List?

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

Each of these questions underlies the issues with any proposed adoption of OPTION D. BPIA understands and appreciates the resource requirements and constraints incumbent in the task to ensure that inert ingredients used in pesticides for organic crop and livestock production are consistent with OFPA. The NOSB is comprised of many dedicated organic advocates who volunteer their time to serve on the board on a part-time basis. Some, if not most, of those individuals are not scientists trained in chemistry and toxicology. Consequently, the board members lack the expertise, knowledge, and experience to effectively review and approve every pesticide inert ingredient for its acceptability for use in organic crop and livestock production. EPA has the established process, manpower, and know-how to conduct robust safety assessments. EPA's approval of individual inert ingredients provides a solid basis upon which to rely when making decisions on the acceptability of those inert ingredients for use in organic production.

EPA's mandate to ensure that pesticide products, including inert ingredients, pose "*a reasonable certainty of no harm*" to humans and the environment meets the statutory requirements of OFPA that inert ingredients used in organic crop and livestock production not be of toxicological concern. Furthermore, any inert ingredient used in pesticide products, be they allowable for organic production or not, has already been thoroughly vetted by EPA. It would be redundant and not cost-effective to ask NOSB/NOP to conduct similar reviews on each inert ingredient used in pesticides and biological products for organic crop and livestock production. OFPA allows NOSB/NOP to take action to specifically prohibit any ingredient that it deems inappropriate and/or unacceptable for use in organic agriculture. This should provide NOSB/NOP with the latitude to address any particular ingredient individually should it deem it necessary.

OPTION E: TAKE NO ACTION (STATUS QUO)

AMS posed the following question in its request for comments in the ANPR:

- *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?*

BPIA does not support the option of "take no action" and leaving the *status quo* in place. AMS should and indeed must replace the archaic, outdated, and confusing references to EPA List 3 and List 4. This ANPR is a good first step in addressing this thorny problem and setting forth a cogent approach to regulating pesticide product inputs for organic crop and livestock production well into the 21st century.

When OFPA was enacted, EPA was in the midst of reassessing all inert ingredients and, as part of that process, had created four inert ingredient lists based on toxicity. The last list (List 4) included only compounds for which EPA had made a safety determination that the ingredients posed "minimal risk" to humans or the environment. OFPA included a reference to EPA's "List 4" and "List 3" in the regulations at **7 CFR §205.601(m): Synthetic substances allowed for use in organic crop production,** and **7 CFR §205.603(e) (1): Synthetic substances allowed for use in organic livestock production**. During the course of the reevaluation of ingredients, up until August 2004, EPA was continually updating and revising the lists, moving ingredients to different lists based on its assessment of the relevant toxicity data. In fact, many ingredients were added to List 4 (most from List 3) during that review period and that continued even after the published Lists ceased to be updated.

While reference to these lists may have been expedient at the time OFPA was enacted and its regulations were promulgated, using these uncodified, internal EPA listings was misguided. These lists were never codified in **40 CFR, Chapter I, Subchapter E**, as they were never intended for citation or reference. The lists were simply an internal tool by which EPA prioritized data review. The intention of EPA's reassessment effort was to move all inert ingredients either to List 1 (Inerts of Toxicological Concern) or List 4 (Minimal Risk Inerts). Those in List 1 would be handled through the administrative process to limit or remove them based on the findings of the reassessment process while those now reassessed as List 4 had been determined to pose only "minimal risk" to humans or the environment and could continue to be used in pesticide products.

The last publicly-posted list of inert ingredients by "List Number" dates to August 2004, two years before EPA completed its reassessment of all inert ingredients in use at that time. In the intervening 18 years, the list of acceptable ingredients for use in organic production has stood frozen in time and fails to reflect reevaluated ingredients (including many originally on EPA List 3) that were reclassifed to or removed from List 4 along with newer ingredients that also meet the same safety standards set for List 4 compounds. All inert ingredients allowed for use in pesticide products today meet the EPA safety standard under FFDCA ("reasonable certainly of no harm"). The FFDCA standard meets or exceeds the OFPA standard of "not of toxicological concern."

As stated in the ANPR, this option would:

1. Continue to conflict with current EPA regulations. EPA has revoked the use of certain List 4 inert ingredients in pesticide formulations. AMS would need an effective mechanism to identify and communicate these discrepancies between EPA tolerance assessments and List 4 inert ingredients;
2. Potentially lead to stagnation in development of alternative products for organic production, including products with potentially lower toxicity, and loss of confidence among stakeholders/industry in NOP's ability to address pressing regulatory needs; and
3. Potentially result in the removal of EPA List 3 and List 4 from the National List at the conclusion of NOSB's next sunset review. AMS would prefer not to remove List 3 and List 4 from the National List in the absence of a viable alternative.

BPIA agrees on all points that something needs to be done now to remove the conflict between EPA's antiquated "lists" referenced in **7 CFR Part 205** and the inert ingredients currently approved by EPA for use in pesticides. EPA's abandonment of the Inerts Lists causes confusion in the organic community as well as in the pesticide industry. As eloquently stated in the NOSB Crops Subcommittee October 2020 meeting proposal document: "*The current situation, where NOP policies are tied to long outdated US EPA guidance, is broken*." BPIA's Preferred Recommendation (allowing all EPA-approved inert ingredients in organic crop and livestock production) eliminates the need for any direct references to "lists" of any sort. BPIA's Alternate Recommendation (utilizing a combination of Options A, B, and C) provides more robust references, linking to codified regulations subject to notice and comment rulemaking, that cannot simply "disappear" or stagnate. BPIA applauds AMS for recognizing and addressing this issue now and we look forward to working with AMS to develop a new framework for identifying inert ingredients approved for organic crop and livestock production.

THIRD-PARTY LISTS—ADVANTAGES & DISADVANTAGES OF RELYING ON EXTERNAL SOURCES/LISTS

AMS notes that utilizing "Third-Party Lists," though advantageous from a workload/resources point of view, may cause negative consequences. As stated in the ANPR, regulatory challenges to using third party lists include:

- *Updates to third-party lists would require oversight and management by the third party, rather than AMS. For example, opportunities for public input about revisions to the list (or revisions to the standards/criteria used to assess substances) may be more limited or less transparent than provided by AMS during its notice-and-comment rulemaking.*
- *Any reference to a list that is not within the CFR—and that is required to understand or comply with the regulations—would require approval by the Director of the Federal Register, as dictated by the Federal regulations related to "incorporation by reference" (see 1 CFR part 51). The Director's decision is outside of AMS's control.*
- *AMS would be required to refer to only one publication (i.e., an edition with a specific publication date) of a list within the USDA organic regulations (see 1 CFR 51.1). Providing notice of the change in the Federal Register and updating the CFR would be some of the steps necessary to update the reference to a new edition of the list (1 CFR 51.11).*

AMS also posed the following questions for comment:

- *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?*

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

BPIA acknowledges that there are issues with referencing third-party lists. For this reason, BPIA recommends that any references to third-party lists be codified in the Code of Federal Regulations (CFR), or in a Federal statute citable under the United States Code (USC). The previous EPA Inerts Lists were "internal" lists used by EPA for its own purposes to prioritize review of inert ingredients. They were never intended for citation by other government agencies, such as USDA, or organic certification entities, like OMRI, WSDA-Organic, CCOF, Ecocert, and others.

EPA has another "third-party list" that is publicly available, the "InertFinder" database search tool. However, it too has the same issues as the "lists" that it ostensibly replaces: it is not statutory or codified, it is not always complete, and it is not mandated to be updated on any regular schedule. Furthermore, the references to ingredients currently approved for use may or may not use the same chemical name, Chemical Abstracts Service Registry Number (CAS RN) or other identifying number, or utilize any standard nomenclature by which to search. BPIA strongly suggests that any references to lists outside of the NOP program be limited to codified statutory and/or regulatory citations.

Concerning the "Safer Choice" program, BPIA has previously addressed the issues related to this EPA initiative that is only tangentially-related to pesticide products and is woefully lacking in needed ingredients to create stable, functional pesticide formulations. This two-decade old program is a voluntary "*non-regulatory initiative*"[8] directed at common household consumer products, including all-purpose cleaners, car care products, dish soaps, floor cleaners, laundry products, and tub and tile cleaners, none of which is intended for direct application to food or livestock products. As such, little thought was given to the need for tolerance exemptions (EPA) or food additive clearances (FDA) when compiling the SCIL (Safer Choice Ingredient List). Furthermore, of the 764 ingredients on the SCIL, only 148 of those were on List 4. The 148 common allowable ingredients from SCIL only accounts for 17% of the total ingredients currently allowed on List 4. As you can see, this is not a viable option.

CONCLUSIONS AND NEXT STEPS

BPIA applauds AMS for tackling the vexing issues surrounding inert ingredients in pesticide products intended for organic crop and livestock production. This ANPR is a good first step to identify viable options and develop a new paradigm to address inert ingredients.

BPIA reiterates its support for allowing all EPA-approved inert ingredients as the "Preferred Option." We believe that this is the best option from a resource, expertise, and regulatory perspective. Only EPA-approved inert ingredients can be used in pesticide products and EPA reviews all inert ingredients to the "*not of toxicological concern*" safety standard. Additionally, OFPA and its implementing regulations provide a mechanism whereby the NOSB and/or AMS

[8] https://www.epa.gov/saferchoice/history-safer-choice-and-design-environment

can propose and promulgate specific prohibitions for any compound that it deems incongruous with the organic regulations.

Should the Preferred Option not be chosen, BPIA's second choice is for AMS to consider a combination of Options A, B, and C, as proposed in the ANPR. However, as noted above, this combination of options is not entirely inclusive and likely omits untold numbers of inert ingredients not otherwise captured in any one of the Options A, B, or C. The full extent of the omission is not yet known and could cause significant disruption to product availability in the organic crop and livestock production markets.

BPIA does not support Options D or E in any way or form. Both proposals are unworkable options for the reasons presented above.

In summary, the process for any wholesale changes to the allowed ingredients in crop protection products for organic production needs to be iterative, clear, and transparent before making any changes to the **NATIONAL LIST**. Creating a new reference that meets the needs of NOP while ensuring that safe, effective, and environmentally focused crop protection products continue to be available is everyone's goal. BPIA is hopeful that these comments will be helpful as AMS determines the path forward.

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.

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