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Subject: Inert Ingredients in Pesticides for Organic Production; Docket #AMS-NOP-21-0008; Regulatory Information Number (RIN) 0581-AE02

We submit this comment in response to the Advanced Notice of Proposed Rulemaking (ANPR) for Inert Ingredients in Pesticides for Organic Production on behalf of the Heartland Health Research Alliance (HHRA) and the Swette Center for Sustainable Food Systems at Arizona State University (Swette Center). HHRA is a non-profit organization that conducts research on the impacts of farming systems and technology on public health, with focus on women during pregnancy, the health of infants, and children's development (hh-ra.org). The Swette Center conducts transdisciplinary research and education on food systems transformation for social progress, economic productivity and environmental resiliency (sustainability-innovation.asu.edu/food/).

The signatories have actively contributed since the 1980s to the laws, policies, and scientific assessment of the impacts of organic farming on pesticide use, exposures, and risk. Kathleen Merrigan is the Executive Director of the Swette Center and is Chair of the HHRA Public Policy Committee. She is a former Deputy Secretary of the USDA. Mark Lipson is Director of Policy and Regulatory Engagement for HHRA. He is a partner in Molino Creek Farm and served as the first USDA Organic and Sustainable Agriculture Policy Advisor. Brian Baker is a consultant for HHRA. He was a co-founder of the Organic Materials Review Institute. Charles Benbrook is the Executive Director of HHRA. He is a former Executive Director of the Board of Agriculture for the National Academy of Sciences / National Research Council.

Summary

Our primary concerns as commenters are the public-health consequences of National Organic Program (NOP) rulemaking for "inert ingredients" (hereafter referred to as "coformulants[1]"), and the integrity and transparency of the National List process itself.

[1] Our preference for the term *coformulant* derives from recognition that so-called "inert ingredients" are rarely inert; most coformulants are incorporated in pesticide formulations to enhance efficacy against their intended target, and international adoption of the term coformulants.

The importance of certified organic foods for reducing exposure and health risks from agricultural pesticides is a keystone principle of consumer fidelity to the organic label. In responding to the ANPR we wish to draw attention to significant public and consumer health concerns about coformulants and the need to examine their properties accordingly. A discussion of this principle and the related work of HHRA on pesticide exposure and dietary risk is included below.

The integrity of the National List process as directed by the Organic Foods Production Act (OFPA) is foundational. We do recognize the partial obsolescence of EPA list 4 in light of OFPA statutory language regarding "...synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern…" [7USC 6516 (c)(1)(B)(ii)]. Nevertheless, AMS must still adhere to the letter and spirit of OFPA. "Expedited" or "alternative" regulatory approaches which elude aspects of the National List process are not acceptable.

We recommend that the USDA require full transparency of coformulant substances and subject these substances to the standard National List review process. Of the options suggested in the ANPR for replacing the fossilized Lists 3 and 4, HHRA and the Swette Center believe the only coformulants that presumptively warrant classification as "not of toxicological concern" are those currently listed as "minimum risk" by 40 CFR 152.25(f)(2). All others may pose toxicological risks that require additional scrutiny, and possibly limitations on use.

Beyond supporting this single avenue for adoption of an existing EPA regulatory list, our responses to the ANPR's questions offer a stepwise process for dealing with other categories of coformulants within the National List petition and sunset processes. We support stakeholder efforts to inform Congress about the need for resources to effectively pursue this strategy.

We further urge USDA to seek continued consultation with EPA to elicit greater cooperation and clarity on these issues. We note below that EPA still has taken no action on its ANPR from 2009 regarding public availability of "inert" coformulant substances in pesticides. New legislation and/or rulemaking to require public disclosure of coformulants – and both their identity and concentrations -- would benefit pesticide applicators and farmworkers, the scientific community, occupational health professionals, government-funded pesticide safety educators, and the public in many ways beyond advancing EPA's statutory responsibilities under OFPA to work with the NOSB.

Structural Issues

Transparency is Essential

The integrity of and respect for the National List process is founded on its transparency. This needs to be extended to coformulants that are in the pesticides approved for use on organic farms and ranches.

The National List process should include the source of the coformulants and their concentration in ready-for-sale pesticide products. The absence of this information makes it impossible to assess the impacts of formulated pesticides on human and environmental health, as well as on the ecological and biological impacts of the pesticides used within a farming system (i.e., the criteria for National List review in OFPA).

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows pesticide manufacturers to classify the coformulants in their products as Confidential Business Information (CBI). Such classification is then relied on by manufacturers to deny the public, pesticide applicators, farmers, and the scientific community information on the identity and concentrations of coformulants in nearly all EPA registered pesticide products. ***This arcane, out-of-date provision in law creates one of the most consequential black boxes in the global laws and policies governing the risk assessment and regulation of chemical hazards.*** The many reasons FIFRA must be amended to end CBI-induced ignorance have been spelled out in multiple papers and several efforts are underway internationally to require disclosure of all ingredients in formulated pesticides (Benbrook, 2020; Benbrook, Perry, et al., 2021; Cox & Surgan, 2006; Cox & Zeiss, 2022; European Commission, 2022; Mesnage et al., 2014, 2019; Mesnage & Antoniou, 2018; Nagy et al., 2020).

Members of the organic community and the public have long sought full public disclosure of all ingredients found in pesticide formulations. In the 1994 case, *NCAP v. Browner* [941 *F. Supp.* 197. October 11, 1996], a federal district court ordered the US EPA to release the common names and chemical abstract service (CAS) numbers of inert ingredients in six pesticide formulations in response to a Freedom of Information Act (FOIA) request.

The plaintiffs were public interest groups and were supported by public health officials and state attorneys general. The case ruling established that the public has a legitimate interest that outweighs any rights to CBI claimed by pesticide registrants. The ruling also established that ingredients that could be determined by analytical chemistry or reverse engineering were not protected as CBI.

HHRA and the Swette Center strongly believe that further rulemaking by the NOP on the assessment and approval of coformulants must be predicated on full disclosure of coformulant identify, sources, and concentrations.

In December 2009, the US EPA proposed regulations regarding the public availability of inert ingredients in pesticides [74 *FR* 68215, December 22, 2009]. The US EPA received over 400 substantive public comments, as well as hundreds more mass and sign-on comments. Most supported the public availability of full information on coformulants. Several organizations working to support growth in organic farming and ranching commented in favor of full public disclosure of all inert ingredients/coformulants. The US EPA has not followed through on that proposed rulemaking and the coformulant black box remains sealed as a result.

If organic integrity is to be protected, the inputs used by organic farmers, producers, handlers, and processors need to be subject to the same scrutiny required of organic producers and handlers. Organic producers, handlers, and certifiers need full disclosure of all ingredients used in every input to be able to ensure and verify compliance and track human health and environmental impacts. In short, organic integrity depends on such disclosure.

Necessity Must be Established

To understand whether non-active, coformulant ingredients are compatible with organic principles and standards, it is essential first to know 1) what co-formulants are being used to formulate pesticide

products approved for use in organic production; 2) the functional purpose of those coformulants; and 3) the reason why they are necessary for organic production. The OFPA requires that to be allowed for organic production, a synthetic substance must be determined to be "necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products", and this assessment must benefit from consultation with the Department of Health and Human Services—which includes the FDA—and with EPA [7 USC 6517I(1)(A(ii)].

It is not possible to determine the necessity of a coformulant, or whether natural substitute products are available, unless formulators, manufacturers, and registrants clearly state: (1) what coformulants are needed, (2) which formulations they are used within, and (3) the purpose they serve. Before rulemaking can proceed, registrants should fully disclose what inert ingredients are currently used in formulated pesticides allowed for use in organic production, why they are being used, and the findings of research that purportedly shows the absence of natural alternatives. In some cases, evidence will emerge suggesting that a coformulant significantly contributes to product efficacy via some direct or indirect impact on target organisms. The NOSB needs information to determine whether and when a coformulant should be listed among the active ingredients in a formulated pesticide product. Such a change may or may not impact the outcome of EPA assessments under FIFRA or NOSB/NOP assessments under OFPA. One sometimes important consequence would arise from the more rigorous testing required of the active ingredients in pesticide products.

Overall Impacts of Coformulants Can Be Serious and Must Be Considered

It is scientifically inaccurate to call most ingredients in a pesticide formulation "inert" in the chemical or biological sense (water is one exception). The scientific literature more properly refers to most of them as "adjuvants" or "surfactants". In Canada, the European Union, and much of the world, non-active ingredients in pesticide formulations are called "coformulants". Every ingredient used in a pesticide formulation is added to improve product handling, stability, and performance. Coformulants serve many functions. Most enhance product efficacy in one or several ways that do not include a direct toxic impact on the target pest (Cox & Surgan, 2006; Cox & Zeiss, 2022; Jorge-Escudero et al., 2022; Mesnage et al., 2019; Mesnage & Antoniou, 2018).

Prior the NOP rule limiting coformulants and inert ingredients to those classified as "minimum risk", many inert ingredients used in organic pesticides were more acutely or chronically toxic than the active ingredients they were mixed with in formulations. Despite pesticide regulatory reforms since the passage of OFPA and extensive review and guidance from the NOSB, concerns remain over inappropriate classification of biologically-active compounds as purportedly "inert" coformulants.

After the passage of OFPA in 1990, Congress passed the Food Quality Protection Act (FQPA) in 1996 [PL 104-170]. Among other things, the FQPA required a reassessment of ***all*** ingredients used in pesticides, not just "active" ones. As noted in the ANPR, the US EPA stopped classifying inert ingredients using the four-list process. The lists were replaced by formal rulemaking that either established tolerances for coformulants or exempted them from the requirement to set tolerances in food. EPA limited many coformulants to incorporation only in non-food use pesticides. While this EPA reassessment process played a valuable role in gathering data on the toxicity of pesticide ingredients, it fell far short of

fulfilling the requirements necessary for addition by the NOP to the National List. EPA coformulant assessments focus on human health and ecological risks and do not take account of a core OFPA requirement – understanding how inputs will impact the ecological and biological interactions that create and sustain soil health and prevent pests from exceeding economic-damage thresholds.

Federal pesticide laws, including the FQPA, are based on risk assessment models and risk-benefit analysis. By contract, organic standards are based on the Principle of Care. The petition process requires those who want to use synthetic substances to demonstrate a need for them. The NOSB is required to consider synthetic substances using the criteria established in 7 USC 6518(m). While the EPA reassessment partially answers the requirement of the NOSB to consider human health [7 USC 6518(m)(4)], the range of risks and issues the National List process must take account of is not covered in the EPA assessment process.

While it is the responsibility of accredited certifiers and their subcontractors to determine compliance with NOP regulations, the NOSB and NOP are responsible to see that the regulations meet the spirit and letter of the OFPA. The NOSB Is also required to consider the potential of such substances to trigger detrimental chemical interactions with other materials used in organic farming [7 USC 6518(m)(1)]. By their nature, coformulants are designed to interact with other chemicals and alter the environmental fate of mixtures of chemicals. Some of these interactions are positive or beneficial relative to pest management efficacy and pose no known risks. Examples include many safeners, dust suppressants, and stabilizers. Others may enhance efficacy, ***but also increase exposure and/or risk levels***. These can include synergists that increase toxicity, surfactants that accelerate movement through the epidermis of weeds and human skin, and dispersants that can increase drift (Sharkey et al., 2022).

With coformulants, it is not just the toxicity that matters, but also the mode of action [7 USC 6518(m)(2)]. The functionality of coformulants needs to be taken into consideration. Because coformulants often alter the fate of the active ingredients in the environment and enhance toxicity, the whole formulation can be more toxic to some organisms than the technical active ingredient alone (Defarge et al., 2018; Mesnage et al., 2019; Mesnage & Antoniou, 2018; Tarazona et al., 2017). Many coformulants alter the toxicokinetics of a formulation's **A**bsorption, **D**istribution, **M**etabolism, **E**xcretion (ADME) in ways that amplify adverse health effects (Buist et al., 2017). For example, the POEA surfactants in most glyphosate-based herbicides increase the rate of dermal penetration and accentuate the movement of glyphosate through cell walls, where it can then induce oxidative stress and damage DNA (Mesnage et al., 2019). Differential toxicity has been observed in many other pesticide formulations and no doubt occurs in some pesticide products on the NOP-approved National List.

The sources and manufacturing processes used to make synthetic substances on the National List also require consideration, along with any environmental contamination caused by normal use, as well as misuse and disposal [7 USC 6518(m)]. Some ingredients in a formulation may be relatively stable or non-toxic, but their manufacturing process may involve the use of toxic substances, such as ethylene oxide, nonyl phenol, or formaldehyde.

The environmental impacts of pesticides are underestimated when only active ingredients are considered. One example is the use of organosilicone coformulants and heightened adverse impacts on

honey bees and other pollinators (Fine et al., 2017; Mullin et al., 2016). Another is the enhanced toxicity of formulated fungicides to earthworms, compared to fungicide parent compounds (Jorge-Escudero et al., 2022).

When considering the question of necessity, the OFPA also requires the NOSB to consider alternatives to a given synthetic substance [7 USC 6518(m)(6)]. Such alternatives could encompass practices and/or other available materials. Lastly, the NOSB is supposed to evaluate the compatibility of a given substance within a system of sustainable agriculture [7 USC 6518(m)(7)].

Many synergistic effects of non-active, coformulant ingredients are well documented. One impact is the greater dispersion of the active ingredient over a broader area. While organic farmers are more often the victims of drift than the perpetrators, the use of coformulants that contribute to broader distribution beyond field boundaries opens organic farmers to greater liability for drift damage. Many organic farmers manage land in densely populated areas where there is little tolerance for drift. They and their neighbors need to know all the chemicals involved when drift occurs, whether the chemicals are in organically-approved pesticides or pesticides used on conventional farms.

Responses to Questions

HHRA and the Swette Center would like to address the specific questions in the ANPR.

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 EPA and are obsolete. Innovation and the development of safer alternatives to currently used coformulants has been stymied. New information has come to light on some of the ingredients that were classified on List 4. A prominent example is the capacity of nonylphenol ethoxylate and other alkyl phenol ethoxylates to disrupt endocrine system functions (Acir & Guenther, 2018).

- *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?*

The ANPR does not provide adequate information to answer this question. As stressed previously, full public disclosure of the coformulants, including their concentrations, sources, and functionality, is essential for an informed review and appraisal as called for in OFPA and the NOP rule.

We respectfully ask that the USDA work closely with and support the NOSB in carrying out their statutory authority and mandates contained in the OFPA. The NOSB is charged with recommending to the Secretary what synthetic substances may be used in organic production via the National List process. 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)]. Only coformulants that

have been explicitly recommended for inclusion on the National List by the NOSB may be added to formulated pesticides sold for use on organic farms and ranches.

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

The Organic Materials Review Institute (OMRI) filed a public comment that provides useful data about what ingredients are currently used in products that have been listed as approved for organic production (OMRI, 2022). Specifically, the OMRI and Pennsylvania Certified Organic (PCO) prepared a database of coformulants declared as "inert ingredients" in pesticide formulations that have been reviewed and approved for use in organic production (OMRI, 2022). The list includes approximately 300 substances, a subset of the approximately 829 substances that appear on the 2004 EPA List 4 referenced in the current NOP Rule.

Of these, over half are allowed for use in minimum risk Section 25b pesticides. The EPA has determined that both the active ingredients and coformulants on this list pose such low risk that they are not even required to be registered. Most of the 31 active ingredients that are exempt from the requirement of registration are allowed for organic production. Almost all coformulants allowed for 25b exempt pesticides were historically on List 4A. Pesticides exempt from EPA registration are required by the agency to list all ingredients. Such an enlightened policy should be applied to all pesticides for reasons noted above, as well as to verify compliance with NOP-imposed, pesticide-related requirements.

Many of the substances that are not on the 25b list are non-synthetic or can be obtained from natural sources. These include mineral clays, vegetable oils, and natural gums. Unless they are placed on the prohibited, non-synthetic list at 205.602, these ingredients are allowed coformulants by default.

Another 60-70 appear on the Food Substances database published by the Food and Drug Administration (US FDA, 2022). Some are not permitted for use as a synthetic food additive in organic food on 7 CFR 205.605(b). Others are listed as "not of toxicological concern", yet still may be unacceptable for other reasons.

Assuming that 25b substances are allowed in NOP-listed pesticides, there will remain between 70 and 100 synthetic substances that would require further evaluation. This is a significant number, but not insurmountable. Many of the substances can be grouped into families. EPA has classified around 40 as exempt from the requirement for a tolerance for pre- and post-harvest handling food use at 40 CFR 180.910. About 32 are considered polymers exempt from the requirement of a tolerance 40 CFR 180.960.

Between 20 and 30 synthetic substances not on the 25b list for incorporation in pesticides applied to food crops are exempt from tolerance when used on livestock [40 CFR 180.930]. Given the limited number of external animal parasiticides allowed, there are probably fewer than ten synthetic

coformulants that are not on the 25b list. We urge the NOP to explore options to establish a sunset list composed of List 4 inerts from 7 CFR 205.603(e) before doing so with coformulants listed at 7 CFR 205.601(m).

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

Options A, B, C, and D are neither mutually exclusive nor collectively exhaustive. HHRA and the Swette Center proposes a combination of these four options, with some modification and additional considerations to resolve unique and complex challenges. See our recommendation below under the heading, "The Way Forward". As stressed throughout this comment, consideration of all possible options and informed public comment is possible only with full public disclosure of the substances in question.

Before the USDA proceeds further with the rulemaking process, all substances currently used in organic agriculture—both as active and coformulant ingredients—need to be disclosed prior to any consideration for inclusion on the National List. HHRA and the Swette Center believes that all ingredients in all pesticide formulations—not just those used in organic production—need to be disclosed on the product labels and in Material Safety Data Sheets. Farmers, farmworkers, pest control operators, and others have a right to know the chemicals to which they are being exposed.

When implementing the NOP rule, it is important to keep in mind that it covers operations in other countries that do not have equivalency arrangements with the US but export food ingredients and products labeled as organic to the US. Pesticides in these countries are not subject to US pesticide laws. Determining whether pesticides applied abroad on "organic" farms are NOP-rule compliant will also require full disclosure of formulation ingredients.

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?*

No. The AMS should not delegate responsibility for the review of coformulants to any party other than the EPA, and only then when the EPA has gone through a rulemaking process comparable to what is required in OFPA. Only coformulants that have been reviewed and recommended by the NOSB should be added to the National List at 7 CFR 205.601(m) and 7 CFR 205.603(e). Third-party lists can be considered in a technical review, but final recommendations are the responsibility of the NOSB. ***All final rules are the responsibility of the NOP and should be unambiguously aligned with NOSB recommendations.***

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

Following technical review and consideration by the NOSB, coformulants should be added to or removed from the National List in accord with NOP policy, the requirements of the OFPA, and NOSB recommendations. EPA assessments of the properties, toxicity, and fate of coformulants should be relied on to the extent they provide relevant and reliable technical information.

- *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?*

It makes sense for AMS to track and assess the results of other, data-driven appraisals of coformulant properties and toxicity. But as stressed below, such appraisals, and any resulting lists, should be relied on for information purposes only. It is unlikely that any one list will be developed by a third-party that fully meets the requirements of the NOP rule and OFPA.

- *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.*

Such an approach would be unwise and subject to challenges from the start. The NOSB should be able to consider third-party lists along with other sources of information but cannot delegate their essential role and authority in the assessment of pesticides allowed for use on organic farms and ranches.

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?*

Substances that are both currently allowed and currently used should be listed individually at sunset. The primary responsibility for the evaluation of coformulants rests with the EPA. Our recommended approach would provide the NOSB and the NOP a straightforward, practical, transparent, and data-driven path to update the list of allowed coformulants.

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

Necessary regulatory changes should take place in an orderly, stepwise fashion that allows for manufacturers of currently allowed products to reformulate, petition the EPA, or petition the NOP for additions, deletions, or modifications to the list of allowed coformulants. The NOSB may want to recommend accelerated phase outs for certain coformulants, such as endocrine disruptors, but otherwise the sunset period 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?*

A list of approved coformulants will almost certainly be necessary to move forward, as well a list of coformulants that will not be considered for incorporation in formulations of pesticide products approved for use in organic production. In the final sections of our comments, we suggest how the initial content of such lists should be established, and describe the processes for adding or removing coformulants from either list. Pesticide registrants and/or coformulant manufacturers will be responsible for covering the cost and providing needed data when they seek NOP approval of a change in either list. The OFPA does not give the USDA statutory authority to regulate pesticide manufacturers directly. Any regulation of pesticide manufacturers would be indirect through requirements imposed to qualify for inclusion on the National List.

- *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?*

List 3 inerts currently on the National List are easily migrated by the incorporation of a reference to 40 CFR 180.1122. Given their use in passive pheromone dispensers, these coformulants pose low risk of release into the environment and *de minimis* worker and consumer exposure. Please see the proposal below for a stepwise procedure for the migration of Lists 3 and 4 to dynamic and transparent lists that are collaboratively managed by the USDA and EPA.

- *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?*

No. The ANPR did not include the names of the petitions, and there are apparent discrepancies between the petitioned-substances database and compounds cited in the footnote. The proper USDA management of petitioned substances is a separate question not limited to the category and use of the petitioned coformulant substances. Before USDA proceeds with further rulemaking on this subject, we respectfully request that the USDA: 1) provide a list of those substances petitioned for inclusion on the USDA's National List of Allowed Synthetic Substances, 2) identify the active ingredients with which they were petitioned for use, and 3) provide the reasons given for those coformulants to be regarded as necessary to sustain organic production.

Moving forward, we suggest that the NOSB tailor a petition process to evaluate coformulants to be added to 7 CFR 205.601(m) and 7 CFR 603(e). The suggested procedure should meet the spirit and letter of OFPA and take advantage of guidance from the EPA Administrator. One resulting list would establish which ingredients were of toxicological concern and thus are not eligible for use in pesticide formulations marketed to organic farmers and ranchers. The guidance would also establish the criteria the NOSB/NOP should use in evaluating substances to be added or removed without a technical review, and which ones would require a technical review, and the scope and depth of such a review.

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))?*

"Inerts of toxicological concern" was the official title of the old List 1 created in 1987, which is now obsolete, as is List 4. HHRA and the Swette Center believe the only coformulants that presumptively meet the criteria governing identification as "not of toxicological concern" are those that are classified as "minimum risk" by 40 CFR 152.25(f)(2) and are exempt from the requirement of a tolerance at 40 CFR 180.950. All other coformulants—including food substances recognized by FDA—may pose some ecological or toxicological risks that require additional scrutiny, and possibly limitations on use in NOP-listed pesticide formulations. Ideally, those that are not considered "commonly consumed food commodities" and are used as indirect food additives would be petitioned and, if qualified, added to 40 CFR 152.25(f)(2) and 40 CFR 180.950 of the pesticide regulations as well.

- *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?*

No. While the EPA is the primary government agency responsible for implementing pesticide regulations, their evaluation and registration criteria is based on a different set of goals and criteria than those set forth in the OFPA. Again, being allowed by EPA should be a *necessary* but not a *sufficient* condition for use within pesticide formulations marketed for use in organic production.

- *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?*

All coformulants that are ***not classified as minimum risk*** will need to be reviewed and deemed safe and necessary in organic production to remain on the list. Food substances recognized by FDA may also be added on an interim basis, pending review by either the EPA or NOSB. However, their environmental impacts as a pesticide ingredient should be evaluated. Ingredients that fall within the following categories should not be added to the National List:

- Petroleum distillates with high levels of volatile aromatic hydrocarbons such as benzene, toluene, and xylene;
- Amines and other substances that initiate or promote cancer, or degrade into carcinogens;
- Neurotoxins and substances that synergistically increase neurotoxicity, impair neurodevelopment, or trigger or advance decline in cognitive ability;
- Endocrine disruptors, including various alkyl phenol ethoxylates such as NPE-9 and bisphenol A;
- Substances identified as highly toxic to beneficial organisms, such as honey bees, pollinators, and earthworms;
- All per- and poly-fluoroalkyl substances (PFAS) (e.g. 1,1 difluoroethane, which is a propellant that was petitioned for inclusion on the National List).

Some specific coformulants/inerts now in NOP-listed pesticide products may need to be delisted, or limited to specific uses—e.g. for use in pheromone dispensers or traps that are not in contact with food when used according to the label.

- *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?*

The EPA has identified inert ingredients permitted in minimum risk pesticides [40 CFR 152.25(f)(2)]. Such coformulants are exempt from the requirement of a tolerance [40 CFR 180.950] because data confirms they likely pose minimal risks. We believe that these inerts meet the OFPA criteria and should be allowed for organic production. All such ingredients on this list are currently allowed for organic production and they should not be subject to sunset provisions. We believe that the 40 CFR 152.25(f)(2) and 40 CFR 180.950 offer a safe harbor, and that adding substances to that list is the preferable avenue for a coformulant to appear on 7 CFR 205.601(m) and 7 CFR 205.603(e).

In addition to a clear and transparent process leading to a coformulant gaining designation as a Minimal Risk inert ingredient, there must also be an equally clear and transparent process for any member of the pubic, government entity, scientist, company, or private organization to submit a petition to the NOP laying out why a given coformulant on the minimal risk list should be removed from the list, or restricted to specific applications in order to mitigate risks and more assuredly comply with OFPA and the NOP rule.

HHRA and the Swette Center also consider it necessary for the NOP to provide the option for interested parties to submit a petition calling for the NOP to add, remove, or modify the conditions under which a given coformulant appears on the minimal risk list, or on the "not eligible for use" list.

The Way Forward

We appreciate the ongoing efforts of the USDA to find a data-driven, pragmatic, and affordable path forward in resolving complex, long-standing concerns over the coformulants allowed in formulated pesticides applied by organic farmers and ranchers.

While the rulemaking process offers an opportunity to add substances that have been reviewed and cleared, it is also likely and important that some substances currently allowed on the historic List 4 are removed from the National List or subjected to additional scrutiny during a sunset period.

The USDA should proceed in a stepwise progression that follows the continuous-improvement spirit and letter of the OFPA, while minimizing disruptions to farmers, producers, handlers, and registrants. It is important for the NOSB and EPA to be engaged throughout the process. HHRA and the Swette Center recommends the following process:

1) As soon as possible but no later than three months after publishing the final or an interim rule in response to this ANPR, the NOSB and NOP should issue guidance to all pesticide manufacturers regarding the information they must supply to the NOP for sharing with the NOSB and the public. This information will include the identify and source of all coformulants, their concentrations in formulated products, their intended function within the formulation, and data gathered suggesting there are no viable natural alternatives. Such information should be submitted to the NOP no later than three months after the issuance of the NOP request for such information.
2) The NOP should retain in effect and eligible for use in NOP-listed pesticide formulations all List 4 coformulants noted on 601(m) and 603(e). These coformulants will constitute the initial Minimal Risk list. The ANPR Federal Register notice notes that the USDA intends to replace the obsolete lists with a process consistent with the recommendations received in response to this ANPR. We are hopeful that this approach will come to fruition.
3) As soon as possible, and no later than six months after publication of an interim or final rule in response to this ANPR, the NOSB and NOP compile and publish for comment a list of coformulants that will not be allowed for use in NON-listed pesticide formulations. Those deemed unacceptable based on the criteria above should be subject to immediate sunset. A 90-day public comment period should follow. The criteria and decision rules that will NOSB/NOP will abide by in adding or removing coformulants from the prohibited list should be described. A final rule setting forth the prohibited list shall be issued by the NOP within a year of the beginning of this process.
4) The NOSB recommends and the USDA proposes 40 CFR 180.1122 to replace List 3 on 601(m)(2) before that sunset period occurs. Again, if there are no objections, that change should be made without removing any semiochemicals currently used by organic farmers.
5) The USDA proposes all individual ingredients that are on both EPA List 4 AND exempt from a tolerance on 910, 920, or 960 to be added to the Minimal Risk list and incorporated in appropriate tables.
6) All coformulants currently in use in an NOP-listed, formulated pesticide that do not appear on the Minimal Risk or prohibited lists shall be subject to an interim three-year sunset period. After this accelerated sunset period, any coformulants remaining on neither list will be moved to the prohibited list. Any members of the public or companies may petition the NOSB/NOP to move such coformulants to the Minimal Risk or prohibited lists at any time. The NOSB/NOP will issue needed guidance on the information that should be submitted to the NOP in support of such petitions.
7) As needed, the NOSB/NOP will request technical assistance from EPA and NIEHS regarding the toxicological concerns arising from coformulants petitioned for addition to the Minimal Risk List. The manufacturers of such coformulants, or pesticide products containing the coformulants, will be provided an opportunity to respond to such petitions and submit additional data and technical information that might be useful during NOSB/NOP review and decision processes. The costs of processing information submitted in response to petitions should be borne by the entity

supplying such information. A fee-for-service schedule aligned with the provisions in pesticide law should be adhered to in this process.

8) If EPA declares that there are no toxicological concerns associated with coformulants not currently on List 4, and further states that such coformulants are equivalent in risk to others on the Minimal Risk list, such coformulants can be petitioned as a group of compounds. The NOSB/NOP can request additional information from NIEHS and other sources, when and as considered necessary.
9) Registrants that hope to see additional coformulants added to the Minimal Risk list may: (a) petition the NOP for addition to the appropriate section of the National List, or (b) petition the EPA to add such coformulants to 40 CFR 180.950.

As the above process unfolds, the NOSB/NOP should seek information and assistance from registrants of impacted pesticide products, the EPA, and the certifying agents and materials review organizations. Before proceeding with any rulemaking, step #1 must be completed (full disclosure of coformulants/inert ingredients). If a manufacturer chooses to not comply with this requirement, they will forfeit access to the market for pesticides approved for use by the NOP on organically managed farms and ranches.

Most of the research conducted on the adverse impacts of non-active coformulants in pesticide formulations have been performed in experiments or with data from pesticides prohibited for organic production. Identifying pesticide formulations that are both *safe* and *effective* must become an NOSB/NOP priority. If research on such formulations is publicly funded, the recipients of that funding have an obligation to share with the public the results of that research, including disclosure of the coformulants used.

The loss of some currently listed pesticide products may cause a temporary hardship for some organic producers. The process outlined above will provide for key options and mechanisms to assure an adequate supply for NOP-compliant pesticides that are both effective and safe. Specifically:

1. *Manufacturers can reformulate and register products containing only Minimal Risk coformulants*.

Such an option would involve removing sunset ingredients from currently approved formulations. This process will require no more than two years to accomplish given current EPA registration procedures and policies that expedite review and approvals of low-risk and reduced risk, and biochemical products.

One possible source of funding to help defray the costs of reformulation and/or reregistration for compliance with organic standards would be the IR-4 program. IR-4 works directly with crop growers, registrants of crop protection products, and other members of the specialty crop community to develop data required by the EPA for the registration of pest management tools for specialty crops. IR-4 also supports the registration of minor or specialty uses on major crops. If Congress concurs that “organic crops” should be considered a specialty pesticide use, reformulated products seeking a place on the NOP list could be eligible for IR-4 support.

2. *Petition the NOP and NOSB to have the substance added to the National List.*

Registrants and other parties currently have the option to petition for approval of added substances for use in formulating pesticides on the National List. The ANPR mentions that the USDA has received petitions for approximately 15 ingredients to be used as coformulants. However, the notice does not include the names of those petitioned substances, or the specific recommendations made by the NOSB. In some cases, the substances are already on EPA List 4 and were being petitioned to be used as active ingredients. This again shows that the lines between active and non-active ingredients are not clear and sometimes warrant reassessment. In two or three cases, these petitions appear to form the basis for allowing List 3 substances in passive pheromone dispensers, and review work is completed. Some were rejected and some are on hold, but it is not clear which substances are still pending review and which are withdrawn or denied. Before proceeding with any rulemaking or accepting any new petitions for coformulants, we suggest that the NOSB and NOP expeditiously finalize action on all substances currently petitioned as pesticide coformulants. ***Insights gained in the process should be drawn upon in crafting global solutions to the challenges giving rise to this ANPR***.

3. *Petition the US EPA to have a substance added to a list referenced in OFPA.*

Prior to the implementation of the NOP rule in the 2000s, there was an expectation that the EPA would continue to review and classify coformulants of toxicological concern, leading to only two lists: (a) a list of inert ingredients of toxicological concern that would be scheduled to be phased out of the manufacture of all pesticides, not just organic, and (b) a list of coformulants/inert ingredients of minimal concern would be compiled and used to expedite the pesticide registration process. If the NOP Rule continues to allow all ingredients currently on List 4, either the EPA needs to recognize it as a living document, or the USDA will need to rely on a petition process to add, remove, and amend the status of substances on the Minimal Risk list.

Pesticides and Organic Food: Further Considerations

Health concerns—specifically reduced dietary risk from exposure to pesticides—is a leading motivating factor for people to purchase organic food (Baranski et al., 2014; Hemmerling et al., 2015; Hughner et al., 2007; Mie et al., 2017). A growing body of scientific literature documents that organic agriculture offers various health benefits, including a way to dramatically reduce exposure and health risks arising to pesticides in food. Our research over many years has documented reductions in the presence of high-risk residues in organic food (Baker et al., 2002; Benbrook, Kegley, et al., 2021; Benbrook & Baker, 2014; Benbrook & Davis, 2020). The results confirm that consumption of organic food significantly and consistently reduces pesticide dietary risks here and abroad (Baranski et al., 2014; Mie et al., 2017).

We ask the USDA to recognize, and openly discuss and share the growing body of scientific evidence that supports the public-health benefits stemming from consumption of organic food, especially among vulnerable segments of the population including pregnant women, children, and the elderly. In addition, biomedical-science advances are rapidly leading to new insights into how even low, ill-timed exposures to pesticides can undermine health via impacts on the microbiome, heritable epigenetic change,

damage to DNA, cancerous cell growth, impaired immune system function, loss of IQ, and more frequent and more serious behavioral and neurological problems.

The NOSB has subjected the relatively small number of pesticides allowed for use by organic farmers to rigorous technical review and public comment. All non-synthetic botanical pesticides registered with the EPA were considered for prohibition before any synthetic substances were added to the National List. The NOSB and NOP reviews go well beyond the inherent toxicity and biochemical properties and impacts of pesticides and include an assessment of the circumstances and situations when a pesticide can be applied on organic farms. The NOSB also considers impacts on soil health and the diversity of soil-microbial communities, as well as possible disruption in the ecological interactions and cycles that lie at the core of all successful organic farms.

For these and other reasons explained above, entire formulations and all ingredients in pesticides are properly subject to NOSB review and NOP regulations. The OFPA and its implementing regulations and policies justifiably restrict the coformulants that can be incorporated in the pesticides approved for use on organic farms. HHRA and the Swette Center urges the USDA to take a practical approach that allows organic farmers to protect their crops in a safe and healthy manner, but also recognizes and responds to those coformulants that heighten existing, or may lead to new risks. New coformulants shown to pose no significant risks need a clear path onto the minimal risk list. For the same reason, excessive hurdles should not be imposed by the NOP in specifying the data required and process to move risky coformulants onto the prohibited list (or a specific, high-risk application of an otherwise minimal-risk coformulant).

We support USDA efforts to further reduce the dietary risks of organic food relative to conventionally grown food. Comparisons of the residues and risks in the conventionally grown versus organically grown samples of foods tested by the USDA AMS's Pesticide Data Program (PDP) are accessible on the HHRA website at https://hhra-tools.vercel.app/dri/by_commodity. The interactive tables in the "Conventional vs Organic" module within the Dietary Risk Index (DRI) system show clearly that organically grown foods, and especially fruits and vegetables, largely eliminate high-risk residues, and have done so consistently for many years.

In partnership with USDA accredited organic certifying agents, HHRA is developing additional tools within the DRI to assess the levels, distribution, and changes in pesticide residues and risk in organic food drawing on the residue testing required by the NOP and carried out by certifiers. A new "Org Tracker" module within the DRI will launch in the first quarter of 2023 and provide certifiers, the NOP, growers, and the food industry a powerful new tool to target certifier-conducted residue testing toward those organic foods, grown in a specific region, that sometimes do not comply with the pesticide provisions in NOP rules.

As scientists use the data generated by Org Tracker and the enhanced organic module within the DRI, consumers are likely to gain a better understanding of the expected health benefits of eating organic foods. Certifying agents will have access better tools to detect and investigate fraud. The USDA "Certified Organic" seal will gain further value in the marketplace.

As a result, and for years to come, the pesticide-related consumer health benefits of organic food and farming are bound to grow and remain one of the major reasons why consumers choose certified organic brands. The availability of nutrient-dense, flavorful, ***and essentially pesticide-risk free food*** will continue to drive growth in demand for organic foods. Growth in demand is necessary to sustain and expand the economic incentives and value-added rewards that make possible the continued conversion of cropland to organic farming systems.

We call upon USDA to devote the resources needed to build the capacity of the organic sector to control pests via heightened reliance on management and lessened use of chemicals, e.g. by building soil health and above and below-ground biodiversity. Regulations and market incentives are important, but not enough. New investments in research, development, technical support, and infrastructure designed to specifically serve the needs of organic enterprises are also needed. We ask that the Grow Organic Report, and the Critical To Do List for Organic Agriculture be entered into the record (Merrigan et al., 2022; Merrigan et al., 2021).

Conclusion

The NOP is a voluntary program. Pesticide registrants have the option to make products that are allowed only for use on land and livestock that are, or are not certified organic. For reasons discussed above, upholding the standards of safety and alignment with core organic principles must remain the top priority as the NOSB/NOP carries out its statutory duties. We ask the USDA to acknowledge the large and growing body of scientific evidence that confirms that organic food, farming, and ranching dramatically reduces pesticide use and risks, both via the diet and through other routes of exposure.

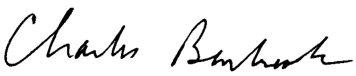
The USDA is well aware that reducing pesticide risk is an important factor motivating consumers who choose to purchase organic food. This recognition is among the key reasons why the USDA and NOP need to move forward with a new system and practical strategies governing the coformulants approved for incorporation in pesticide products used in organic production, both here and around the world.

We appreciate the opportunity to comment on this ANPR and hope that the NOSB and USDA take up our suggestions as this process unfolds.

Kathleen Merrigan

Brian Baker

Mark Lipson



Charles Benbrook

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Appendix 1

Suggested Revisions to the National Organic Program Rule

§ 205.601 Synthetic substances allowed for use in organic crop production.

. . .

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use as coformulants with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) ~~EPA List 4 – Inerts of Minimal Concern.~~ Ingredients classified as Minimum Risk by EPA at 40 CFR 152.25(f)(2) and exempt from the requirement of a tolerance at 40 CFR 180.950.

(2) Ingredients approved for use as food additives allowed for human consumption by FDA regulations at 21 CFR §73, 74, 172, 173, 182, and 184.

(3) ~~EPA List 3 – Inerts~~ Ingredients used in semiochemical dispensers that conform with the specifications in 40 CFR 180.1122. ~~of unknown toxicity – for use only in passive pheromone dispensers.~~

(4) The following ingredients previously classified by EPA as Inerts of Minimal Concern and are exempted from the requirement of a tolerance when used pre- and post-harvest at 40 CFR 180.910 or when used pre-harvest and exempt from tolerance at 40 CFR 180.920 or 40 CFR 180.960:

Itemized list of ingredients identified by accredited certifying agents and materials review organizations as currently used in organic production recommended by the NOSB.

. . .

§ 205.603 Synthetic substances allowed for use in organic livestock production.

. . .

As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use as coformulants with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) ~~EPA List 4 –~~ Inerts ~~of Minimal Concern.~~ classified as Minimum Risk by EPA at 40 CFR 152.25(f)(2) and exempt from the requirement of a tolerance at 40 CFR 180.950.

(2) Ingredients approved for use as food additives allowed for human consumption by the Food and Drug Administration (FDA) regulations at 21 CFR §§73, 74, 172, 173, 182, and 184, and animal feed regulations at 21 CFR §§582 and 584.

(3) The following ingredients previously classified by EPA as Inerts of Minimal Concern and are exempted from the requirement of a tolerance for use on animals at 40 CFR 180.930:

Itemized list of ingredients identified by accredited certifying agents and materials review organizations as currently used in organic production recommended by the NOSB.

(4) The following inerts previously classified by EPA as of Minimal Concern and are exempted from the requirement of a tolerance at 40 CFR 180.960:

Itemized list of ingredients identified by accredited certifying agents and materials review organizations as currently used in organic production recommended by the NOSB.